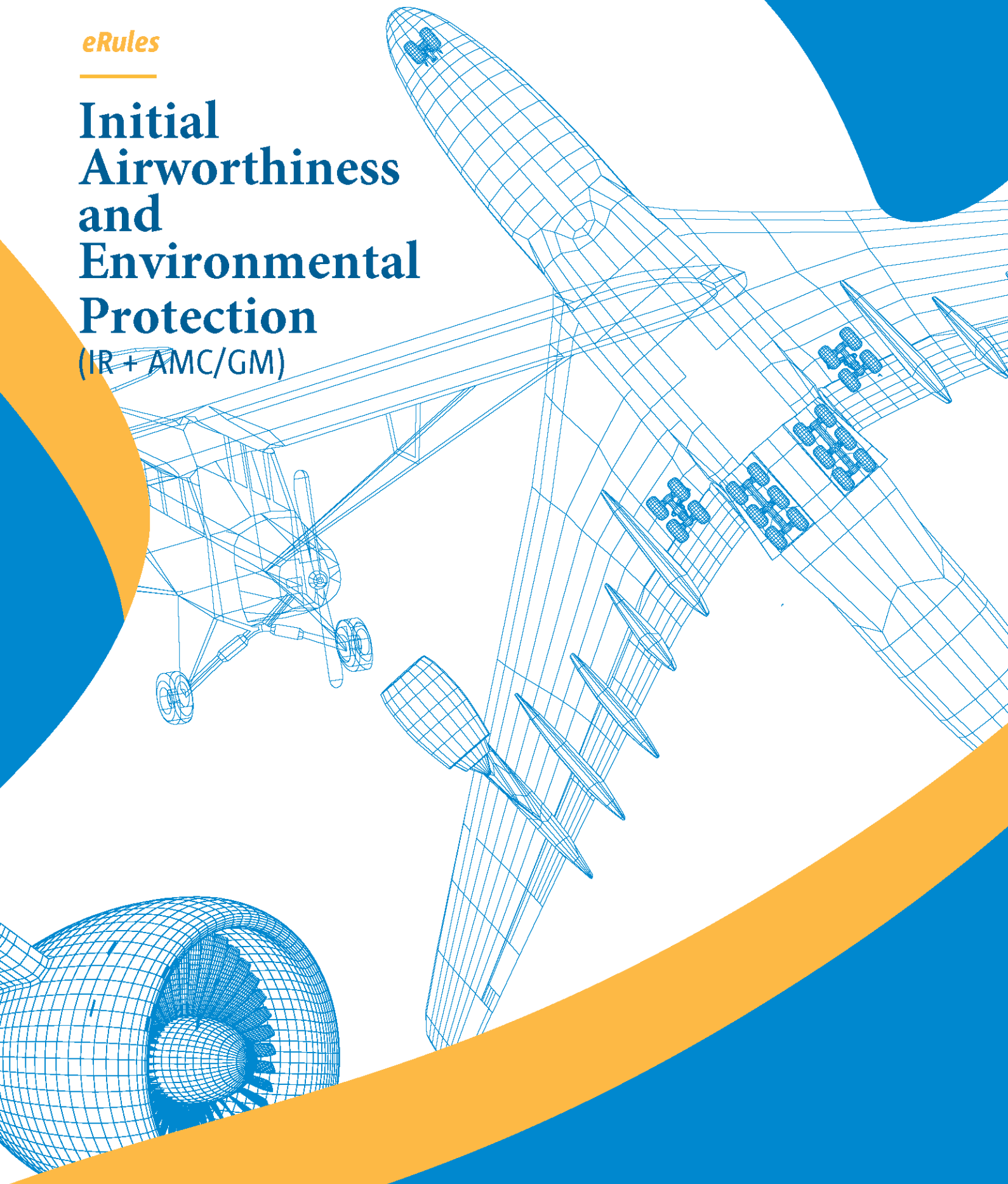
EASA
European Union Aviation Safety Agency

eRules

Initial Airworthiness and Environmental Protection

(IR + AMC/GM)



Easy Access Rules for Initial Airworthiness and Environmental Protection (Regulation (EU) No 748/2012)

EASA eRULES

EASA eRules: aviation rules for the 21st century

Rules are the core of the EU civil aviation system. The aim of the EASA eRules project is to make them accessible to stakeholders in an efficient and reliable way.

EASA eRules is a comprehensive, single system for structuring, sharing, and storing of rules. It is the single, easy-access online database for all aviation safety rules applicable to persons and organisations subject to Basic Regulation (Regulation (EU) 2018/1139).

The Easy Access Rules (EAR) are the output of the eRules project. The EAR books are consolidated versions of those rules, combining EU regulations with the related EASA Executive Director (ED) decisions in an easy-to-read format with advanced navigation features through links and bookmarks. The EAR books are regularly updated, following the adoption of an official publication.

The EAR books are available:

— in PDF format;

— as dynamic online publications (online format) with a wide range of functionalities, such as filters to obtain regulatory material tailored to one's needs, a search function through the table of contents to quickly access the relevant sections, and easy navigation for computers, tablets, and mobiles; and

— in XML (machine-readable) format that can be easily processed and automated by recipients, producing output that is compatible and can be synchronised with local applications, search databases, etc.

The EASA eRules system is developed and implemented in close cooperation with the Member States and aviation industry to ensure that all its capabilities are relevant and effective.

Published July 2024[1]

[1] The published date represents the date when the consolidated version of the EAR book was generated.

[2] Euro-Lex, Important Legal Notice: http://eur-lex.europa.eu/content/legal-notice/legal-notice.html.

DISCLAIMER

This version of Regulation (EU) No 748/2012 Easy Access Rules (EAR) book is issued by the European Union Aviation Safety Agency (EASA) to provide its stakeholders with an updated, consolidated, and easy-to-read publication. It has been prepared by putting together the officially published Commission Regulations and EASA Executive Director (ED) decisions. However, this is not an official publication and EASA accepts no liability for damage of any kind resulting from the risks inherent in the use of this document.

LIST OF REVISIONS

Published	Reason for revision
February 2018	First Easy Access Rules document powered by eRules.
December 2019	To incorporate ED Decision 2019/003/R introducing AMC/GM to Annex I (Part-21) to Regulation (EU) No 748/2012 for proportionality and simplification of airworthiness and environmental certification regulations for small aircraft.
	To incorporate Commission Delegated Regulation (EU) 2019/897 of 12 March 2019 amending Regulation (EU) No 748/2012 as regards the inclusion of risk-based compliance verification in Annex I (Part 21) thereto and the implementation of requirements for environmental protection, and the associated ED Decision 2019/018/R amending the AMC and GM to Part 21 — Issue 2, Amendment 9.
June 2020	To incorporate Commission Delegated Regulation (EU) 2020/570 of 28 January 2020 amending and correcting Regulation (EU) No 748/2012 as regards the alignment of rules for continuing airworthiness of aircraft and aeronautical products, parts and appliances with Regulation (EU) No 1321/2014.
November 2020	To incorporate ED Decision 2020/006/R amending the AMC and GM to Part 21 — Issue 2, Amendment 10, as regards 'Aircraft cybersecurity'.
March 2021	To incorporate ED Decision 2021/001/R amending the AMC and GM to Annex I (Part 21) — Issue 2, Amendment 11.
September 2021	To incorporate the following: — Commission Delegated Regulation (EU) 2021/699 of 21 December 2020 amending and correcting Regulation (EU) No 748/2012 as regards the instructions for continued airworthiness, the production of parts to be used during maintenance and the consideration of ageing aircraft aspects during certification, as well as ED Decision 2021/007/R issuing Amendment 12 to Issue 2 of the AMC and GM to Part 21 to support the implementation of the amendments introduced in Part 21 through Regulation (EU) 2021/699; — Commission Delegated Regulation (EU) 2021/1088 of 7 April 2021 amending Regulation (EU) No 748/2012 as regards updating the references to the environmental protection requirements, as well as ED Decision 2021/011/R issuing Amendment 13 to Issue 2 of the AMC and GM to Part 21 to support the application of Regulation (EU) 2021/1087 amending Article 9(2) of Regulation (EU) 2018/1139 and the application of Regulation (EU) 2021/1088; and — the Corrigendum to Decision 2021/011/R to correct errors in references and listings and change the order of some text in the AMC and GM to Part 21.
May 2022	To incorporate the following: — Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation; — Commission Implementing Regulation (EU) 2022/203 of 14 February 2022 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by competent authorities, and

	correcting Regulation (EU) No 748/2012 as regards the issuance of airworthiness review certificates.
October 2022	To incorporate Commission Implementing Regulation (EU) 2022/1253 of 19 July 2022 correcting Regulation (EU) No 748/2012 as regards derogations from certain requirements introduced by Delegated Regulation (EU) 2022/201.
March 2023	To incorporate ED Decision 2022/021/R amending the AMC and GM to Annex I (Part 21) — Issue 2, Amendment 14.
July 2024	To incorporate the following: — Commission Delegated Regulation (EU) 2022/1358 of 12 June 2022 amending Regulation (EU) No 748/2012 as regards the implementation of more proportionate requirements for aircraft used for sport and recreational aviation; — Commission Implementing Regulation (EU) 2022/1361 of 28 July 2022 amending Regulation (EU) No 748/2012 as regards the certification, oversight and enforcement tasks of the competent authorities in the implementation of the rules concerning the organisations involved in the design and production of aircraft used for sport and recreational aviation; — Commission Delegated Regulation (EU) 2022/1645 of 14 July 2022 laying down rules for the application of Regulation (EU) 2018/1139 of the European Parliament and of the Council, as regards requirements for the management of information security risks with a potential impact on aviation safety for organisations covered by Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 and amending Commission Regulations (EU) No 748/2012 and (EU) No 139/2014; — Commission Implementing Regulation (EU) 2023/203 of 27 October 2022 laying down rules for the application of Regulation (EU) 2018/1139 of the European Parliament and of the Council, as regards requirements for the management of information security risks with a potential impact on aviation safety for organisations covered by Commission Regulations (EU) No 1321/2014, (EU) No 965/2012, (EU) No 1178/2011, (EU) 2015/340, Commission Implementing Regulations (EU) 2017/373 and (EU) 2021/664, and for competent authorities covered by Commission Regulations (EU) No 748/2012, (EU) No 1321/2014, (EU) No 965/2012, (EU) No 1178/2011, (EU) 2015/340 and (EU) No 139/2014, Commission Implementing Regulations (EU) 2017/373 and (EU) 2021/664 and amending Commission Regulations (EU) No 1178/2011, (EU) No 748/2012, (EU) No 965/2012, (EU) No 139/2014, (EU) No 1321/2014, (EU) 2015/340, and Commission Implementing Regulations (EU) 2017/373 and (EU) 2021/664; — Commission Delegated Regulation (EU) 2023/1028 of 20 March 2023 amending Regulation (EU) No 748/2012 as regards the definition of complex motor-powered aircraft and correcting that Regulation; — ED Decision 2023/010/R amending the AMC and GM to Annex I (Part 21) — Issue 2, Amendment 15; — ED Decision 2023/014/R amending the AMC and GM to Annex I (Part 21) — Issue 2, Amendment 16; — ED Decision 2023/013/R issuing the AMC and GM to Annex Ib (Part 21 Light) — Issue 1.

NOTE FROM THE EDITOR

The Regulation (EU) No 748/2012 EAR book is divided into two main sections.

The introductory section provides general information on the EAR book (e.g. EAR revisions, the tables of the incorporated amendments). The table of contents reflects the content of the EAR book. It is not the officially published table of contents.

The consolidated regulatory material section contains:

— the cover of Regulation (EU) No 748/2012 with the articles;

— the transitional provisions from regulations amending Regulation (EU) No 748/2012;

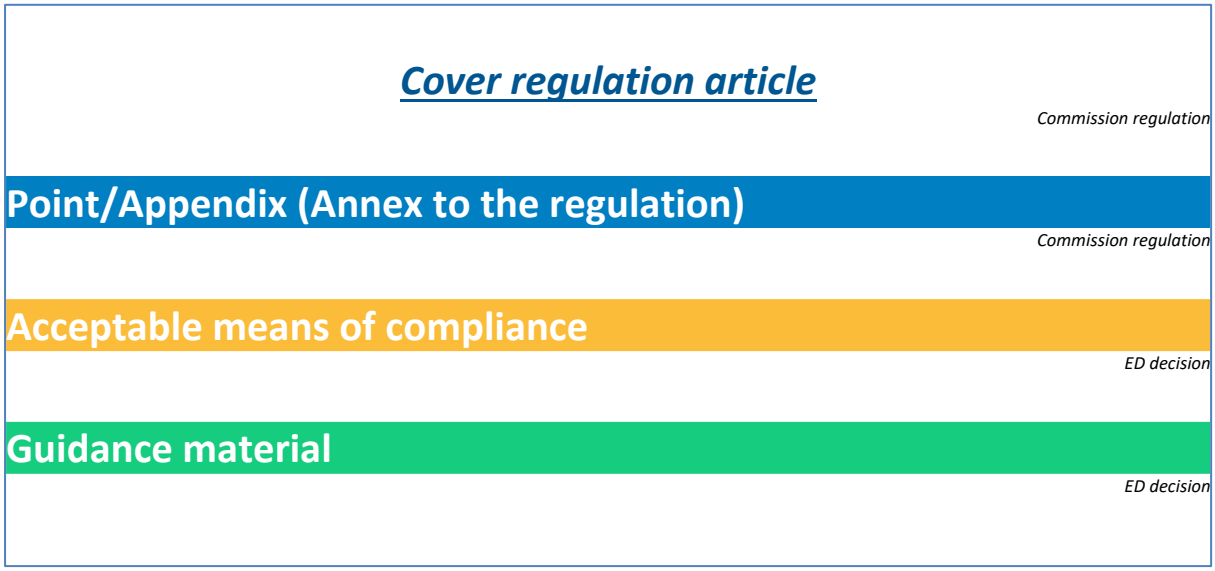
— the points of and appendices to Annex I (Part 21) of Regulation (EU) No 748/2012, and the related acceptable means of compliance (AMC) and guidance material (GM);

— the points of and appendices to Annex Ib (Part 21 Light) of Regulation (EU) No 748/2012, and the related AMC and GM;

— Annex II and Annex III from the first issue of Regulation (EU) No 748/2012 providing information on Regulation (EC) No 1702/2003 (repealed).

All elements of the regulatory material are colour-coded and can be identified according to the illustration below. The Commission regulation or EASA Executive Director (ED) decision through which the element was introduced or last amended is indicated below the element title(s) *in italics*.

Note: Regulatory material that becomes applicable after the publication of the EAR book is marked with a different colour and with the respective applicability date.



This EAR book will be updated regularly to incorporate further amendments.

The format of this EAR book has been adjusted to make it user-friendly and for reference purposes. Any comments should be sent to erules@easa.europa.eu.

INCORPORATED AMENDMENTS

COMMISSION REGULATIONS

Incorporated Commission Regulation	Applicability date[1]
Regulation (EU) No 748/2012	10/09/2012
Regulation (EU) No 7/2013	29/01/2013
Regulation (EU) No 69/2014	17/02/2014
Regulation (EU) 2015/1039	21/07/2015
Regulation (EU) 2016/5	26/01/2016
Regulation (EU) 2019/897	23/06/2019 23/03/2020
Regulation (EU) 2020/570	24/03/2020
Regulation (EU) 2021/699	18/05/2021 18/05/2022
Regulation (EU) 2021/1088	25/07/2021
Regulation (EU) 2022/201	07/03/2022 07/03/2023
Regulation (EU) 2022/203	07/03/2022 07/03/2023
Regulation (EU) 2022/1253	07/03/2023
Regulation (EU) 2022/1358	25/08/2023
Regulation (EU) 2022/1361	25/08/2023
Regulation (EU) 2022/1645	16/10/2025
Regulation (EU) 2023/203	22/02/2026
Regulation (EU) 2023/1028	25/08/2023

[1] This is the date of application (i.e. the date from which an act or a provision in an act produces its full legal effects) as defined in the relevant cover regulation article.

ED DECISIONS (AMC AND GM)

To Annex I (Part 21)

Incorporated ED Decision	AMC and GM Issue No, Amendment No	Applicability date
ED Decision 2012/020/R	Recast	06/11/2012
ED Decision 2013/001/R	AMC and GM to Part-21 — Issue 2, Amendment 1	29/01/2013
ED Decision 2014/007/R	AMC and GM to Part-21 — Issue 2, Amendment 2	31/01/2014
ED Decision 2015/016/R	AMC and GM to Part-21 — Issue 2, Amendment 3	10/07/2015
ED Decision 2015/026/R	AMC and GM to Part-21 — Issue 2, Amendment 4	11/11/2015
ED Decision 2016/003/R	AMC and GM to Part-21 — Issue 2, Amendment 5	26/01/2016
ED Decision 2016/007/R	AMC and GM to Part-21 — Issue 2, Amendment 6	19/12/2016
ED Decision 2017/024/R	AMC and GM to Part-21 — Issue 2, Amendment 7	15/12/2017
ED Decision 2019/003/R	AMC and GM to Part-21 — Issue 2, Amendment 8	14/02/2019
ED Decision 2019/018/R	AMC and GM to Part-21 — Issue 2, Amendment 9	30/08/2019
ED Decision 2020/006/R	AMC and GM to Part-21 — Issue 2, Amendment 10	01/01/2021
ED Decision 2021/001/R	AMC and GM to Part 21 — Issue 2, Amendment 11	03/03/2021
ED Decision 2021/007/R	AMC and GM to Part 21 — Issue 2, Amendment 12	29/05/2021 18/05/2022
ED Decision 2021/011/R	AMC and GM to Part 21 — Issue 2, Amendment 13	25/07/2021
ED Decision 2022/021/R	AMC and GM to Part 21 — Issue 2, Amendment 14	07/03/2023
ED Decision 2023/010/R	AMC and GM to Part 21 — Issue 2, Amendment 15	22/02/2026
ED Decision 2023/014/R	AMC and GM to Part 21 — Issue 2, Amendment 16	21/10/2023

To Annex Ib (Part 21 Light)

Incorporated ED Decision	AMC and GM Issue No, Amendment No	Applicability date
ED Decision 2023/013/R	AMC and GM to Part 21 Light — Issue 1	21/10/2023

Note: To access the official versions, please click on the hyperlinks provided above.

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COVER REGULATION

COMMISSION REGULATION (EU) No 748/2012

of 3 August 2012

laying down implementing rules for the airworthiness and environmental certification or declaration of compliance of aircraft and related products, parts and appliances, as well as for the capability requirements of design and production organisations

(recast)

Article 1 Scope and definitions

Regulation (EU) 2023/1028

1. This Regulation lays down, in accordance with Articles 19 and 62 of Regulation (EU) 2018/1139, common technical requirements and administrative procedures for the airworthiness and environmental certification of products, parts and appliances specifying:

   (a) the issue of type certificates, restricted type certificates, supplemental type certificates and changes to those certificates;

   (b) the issue of certificates of airworthiness, restricted certificates of airworthiness, permits to fly and authorised release certificates;

   (c) the issue of repair design approvals;

   (d) the showing of compliance with environmental protection requirements;

   (e) the issue of noise certificates and restricted noise certificates;

   (f) the identification of products, parts and appliances;

   (g) the certification of certain parts and appliances;

   (h) the certification of design and production organisations;

   (i) the issue of airworthiness directives;

   (j) the making of declarations of design compliance and changes to those declarations;

   (k) the making of declarations of design and production capability.

2. For the purpose of this Regulation, the following definitions shall apply:

   (a) "JAA" means the "Joint Aviation Authorities";

   (b) "JAR" means "Joint Aviation Requirements";

   (c) "Part 21" means the requirements and procedures for the certification of aircraft and related products, parts and appliances, and of design and production organisations laid down in Annex I (Part 21) to this Regulation;

   (d) "Part 21 Light" means the requirements and procedures for the certification or declaration of design compliance of aircraft intended primarily for sports and recreational use and related products and parts, and declaration of design and production capability of organisations laid down in Annex Ib (Part 21 Light) to this Regulation;

   (e) "principal place of business" means the head office or registered office of the undertaking within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised;

(f) "article" means any part and appliance to be used on civil aircraft;

(g) "ETSO" means European Technical Standard Order. The European Technical Standard Order is a detailed airworthiness specification issued by the European Union Aviation Safety Agency (the "Agency") to ensure compliance with the requirements of this Regulation as a minimum performance standard for specified articles;

(h) "EPA" means European Part Approval. European Part Approval of an article means that the article has been produced in accordance with approved design data not belonging to the type-certificate holder of the related product, except for ETSO articles;

(ha) "complex motor-powered aircraft" means:

(i) an aeroplane

— with a maximum certificated take-off mass exceeding 5 700 kg, or

— certificated for a maximum passenger seating configuration of more than nineteen, or

— certificated for operation with a minimum crew of at least two pilots, or

— equipped with (a) turbojet engine(s) or more than one turboprop engine, or

(ii) a helicopter certificated:

— for a maximum take-off mass exceeding 3 175 kg, or

— for a maximum passenger seating configuration of more than nine, or

— for operation with a minimum crew of at least two pilots, or

(iii) a tilt rotor aircraft.

(i) "ELA1 aircraft" means the following manned European Light Aircraft:

(i) an aeroplane with a maximum take-off mass (MTOM) of 1 200 kg or less that is not classified as complex motor-powered aircraft;

(ii) a sailplane or powered sailplane of 1 200 kg MTOM or less;

(iii) a balloon with a maximum design lifting gas or hot air volume of not more than 3 400 m3 for hot air balloons, 1 050 m3 for gas balloons, 300 m3 for tethered gas balloons;

(iv) an airship designed for not more than four occupants and a maximum design lifting gas or hot air volume of not more than 3 400 m3 for hot air airships and 1 000 m3 for gas airships;

(j) "ELA2 aircraft" means the following manned European Light Aircraft:

(i) an aeroplane with a maximum take-off mass (MTOM) of 2 000 kg or less that is not classified as complex motor-powered aircraft;

(ii) a sailplane or powered sailplane of 2 000 kg MTOM or less;

(iii) a balloon;

(iv) a hot air airship;

(v) a gas airship complying with all of the following characteristics:

— 3 % maximum static heaviness,

— non-vectored thrust (except reverse thrust),

— conventional and simple design of structure, control system and ballonet system,

— non-power assisted controls;

(vi) a rotorcraft with an MTOM not exceeding 600 kg which is of a simple design, designed to carry not more than two occupants, not powered by turbine and/or rocket engines; restricted to VFR day operations;

(k) "operational suitability data (OSD)" means data, which is part of an aircraft type certificate, restricted type certificate or supplemental type certificate, consisting of all of the following:

(i) the minimum syllabus of pilot type rating training, including determination of type rating;

(ii) the definition of scope of the aircraft validation source data to support the objective qualification of simulators or the provisional data to support their interim qualification;

(iii) the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;

(iv) determination of type or variant for cabin crew and type-specific data for cabin crew;

(v) the master minimum equipment list.

Article 2 Certification of products, parts and appliances

Regulation (EU) 2022/1358

1. Products, parts and appliances shall be issued certificates as specified in Annex I (Part 21)

2. By way of derogation from paragraph 1 of this Article, certificates may be alternatively issued as specified in Annex Ib (Part 21 Light) for the following products:

(a) an aeroplane with a maximum take-off mass (MTOM) of 2 000 kg or less and a maximum operational seating configuration of four persons;

(b) a sailplane or powered sailplane of 2 000 kg MTOM or less;

(c) a balloon;

(d) a hot air airship;

(e) a passenger gas airship designed for not more than four persons;

(f) a rotorcraft of 1 200 kg MTOM or less and a maximum operational seating configuration of four persons;

(g) a piston engine or fixed pitch propeller that is intended to be installed on an aircraft referred to in points (a) to (f); or

(h) a gyroplane.

3. By way of derogation from paragraphs 1 and 2 of this Article, a declaration of design compliance may alternatively be made, as specified in Annex Ib (Part 21 Light), for the following products:

(a) an aeroplane of 1 200 kg MTOM or less that is not jet-powered and with a maximum operational seating configuration of two persons;

(b) a sailplane or a powered sailplane of 1 200 kg MTOM or less;

(c) a balloon designed for not more than four persons;

(d) a hot air airship designed for not more than four persons.

4. By way of derogation from paragraphs 1 to 3 of this Article, aircraft, including any installed product, part and appliance, which are not registered in a Member State shall be exempted from the provisions of Subparts H and I of Section A of Annex I (Part 21) and Subparts H and I of Section A of Annex Ib (Part 21 Light). They shall also be exempted from the provisions of Subpart P of Section A of Annex I (Part 21) and Subpart P of Section A of Annex Ib (Part 21 Light), except where aircraft identification marks are prescribed by a Member State.

Article 2a - Transitional arrangements for certificates previously issued under Annex I (Part 21)

Regulation (EU) 2022/1358

1. A holder of a valid type certificate or a supplemental type certificate issued, or deemed to have been issued, by the Agency under Annex I (Part 21) may, until 25 August 2025 request to the Agency to maintain, from a given date, the type design approved under that certificate in accordance with Annex Ib (Part 21 Light), provided that the product covered by that certificate is within the scope of Article 2(2).

2. Where a request is made pursuant to paragraph 1, that type certificate or supplemental type certificate shall be governed, as of the given date referred to in paragraph 1, by the provisions of Annex Ib (Part 21 Light) regarding the type certificates or supplemental type certificates, as applicable. The Agency shall amend the type certificate data sheet or supplemental type certificate data sheet accordingly.

Article 3 Continued validity of type-certificates and related certificates of airworthiness

Regulation (EU) 2023/1028

1. With regard to products which had a type-certificate, or a document allowing the issuing of a certificate of airworthiness, issued before 28 September 2003 by a Member State, the following provisions shall apply:

(a) the product shall be deemed to have a type-certificate issued in accordance with this Regulation when:

(i) its type-certification basis was:

— the JAA type-certification basis, for products that have been certificated under JAA procedures, as defined in their JAA data sheet, or

— for other products, the type-certification basis as defined in the type-certificate data sheet of the State of design, if that State of design was:

— a Member State, unless the Agency determines, taking into account, in particular, certification specifications used and service experience, that such type-certification basis does not provide for a level of safety equivalent to that required by Regulation (EU) 2018/1139 and this Regulation, or

— a State with which a Member State had concluded a bilateral airworthiness agreement or similar arrangement under which such products have been certificated on the basis of the certification specifications of that State of design, unless the Agency determines that such certification specifications or service experience or the safety

system of that State of design do not provide for a level of safety equivalent to that required by Regulation (EU) 2018/1139 and this Regulation.

The Agency shall make a first evaluation of the implication of the provisions of the second indent in view of producing an opinion to the Commission including possible amendments to this Regulation;

(ii) the environmental protection requirements were those laid down in Annex 16 to the Chicago Convention, as applicable to the product;

(iii) the applicable airworthiness directives were those of the State of design.

(b) the design of an individual aircraft, which was on the register of a Member State before 28 September 2003, shall be deemed to have been approved in accordance with this Regulation when:

(i) its basic type design was part of a type-certificate referred to in point (a);

(ii) all changes to this basic type design, which were not under the responsibility of the type-certificate holder, had been approved; and

(iii) the airworthiness directives issued or adopted by the Member State of registry before 28 September 2003 were complied with, including any variations to the airworthiness directives of the State of design agreed by the Member State of registry.

2. With regard to products for which a type-certification process was proceeding through the JAA or a Member State on 28 September 2003, the following shall apply:

(a) if a product is under certification by several Member States, the most advanced project shall be used as the reference;

(b) points 21.A.15(a), (b) and (c) of Annex I (Part 21) shall not apply;

(c) by way of derogation from point 21.B.80 of Annex I (Part 21), the type-certification basis shall be that established by the JAA or, where applicable, the Member State at the date of application for the approval;

(d) compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purposes of compliance with points 21.A.20(a) and (d) of Annex I (Part 21).

3. With regard to products that have a national type certificate, or equivalent, and for which the approval process of a change carried out by a Member State was not finalised at the time when the type certificate had to be approved in accordance with this Regulation, the following conditions shall apply:

(a) if an approval process is being carried out by several Member States, the most advanced project shall be used as the reference;

(b) point 21.A.93 of Annex I (Part 21) shall not apply;

(c) the applicable type-certification basis shall be that established by the JAA or, where applicable, the Member State at the date of application for the approval of change;

(d) compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purposes of compliance with point 21.B.107 of Annex I (Part 21).

4. With regard to products that had a national type-certificate, or equivalent, and for which the approval process of a major repair design carried out by a Member State was not finalised at the time when the type-certificate had to be determined in accordance with this Regulation, compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purpose of complying with point 21.A.433(a) of Annex I (Part 21).

5. A certificate of airworthiness issued by a Member State attesting conformity with a type-certificate determined in accordance with paragraph 1 shall be deemed to comply with this Regulation.

Article 4 Continued validity of supplemental type-certificates

Regulation (EU) No 748/2012

1. With regard to supplemental type-certificates issued by a Member State under JAA procedures or applicable national procedures and with regard to changes to products proposed by persons other than the type-certificate holder of the product, which were approved by a Member State under applicable national procedures, if the supplemental type-certificate, or change, was valid on 28 September 2003, the supplemental type-certificate, or change shall be deemed to have been issued under this Regulation.

2. With regard to supplemental type-certificates for which a certification process was being carried out by a Member State on 28 September 2003 under applicable JAA supplemental type-certificate procedures and with regard to major changes to products, proposed by persons other than the type-certificate holder of the product, for which a certification process was being carried out by a Member State on 28 September 2003 under applicable national procedures, the following shall apply:

   (a) if a certification process was being carried out by several Member States, the most advanced project shall be used as the reference;

   (b) point 21.A.113 (a) and (b) of Annex I (Part 21) shall not apply;

   (c) the applicable certification basis shall be that established by the JAA or, where applicable, the Member State at the date of application for the supplemental type-certificate or the major change approval;

   (d) the compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purpose of complying with point 21.A.115(a) of Annex I (Part 21).

Article 5

Regulation (EU) No 69/2014

(deleted by Regulation (EU) No 69/2014, 27.01.2014)

Article 6 Continued validity of parts and appliances certificates

Regulation (EU) No 748/2012

1. Approvals of parts and appliances issued by a Member State and valid on 28 September 2003 shall be deemed to have been issued in accordance with this Regulation.

2. With regard to parts and appliances for which an approval or authorisation process was being carried out by a Member State on 28 September 2003, the following shall apply:

   (a) if an authorisation process was being carried out by several Member States, the most advanced project shall be used as the reference;

   (b) point 21.A.603 of Annex I (Part 21) shall not apply;

   (c) the applicable data requirements laid down in point 21.A.605 of Annex I (Part 21) shall be those established by the relevant Member State, at the date of application for the approval or authorisation;

   (d) compliance findings made by the relevant Member State shall be deemed to have been made by the Agency for the purpose of complying with point 21.A.606(b) of Annex I (Part 21).

Article 7 Permit to fly

Regulation (EU) No 748/2012

The conditions determined before 28 March 2007 by the Member States for permits to fly or other airworthiness certificate issued for aircraft which did not hold a certificate of airworthiness or restricted certificate of airworthiness issued under this Regulation, are deemed to have been determined in accordance with this Regulation, unless the Agency has determined before 28 March 2008 that such conditions do not provide for a level of safety equivalent to that required by Regulation (EC) No 216/2008 or this Regulation.

Article 7a Operational suitability data

Regulation (EU) No 69/2014

1. The holder of an aircraft type-certificate issued before 17 February 2014 intending to deliver a new aircraft to an EU operator on or after 17 February 2014 shall obtain approval in accordance with point 21.A.21(e) of Annex I (Part 21) except for the minimum syllabus of maintenance certifying staff type rating training and except for aircraft validation source data to support the objective qualification of simulator(s). The approval shall be obtained not later than 18 December 2015 or before the aircraft is operated by an EU operator, whichever is the latest. The operational suitability data may be limited to the model which is delivered.

2. The applicant for an aircraft type-certificate for which the application was filed before 17 February 2014 and for which a type-certificate is not issued before 17 February 2014 shall obtain approval in accordance with point 21.A.21(e) of Annex I (Part 21) except for the minimum syllabus of maintenance certifying staff type rating training and for aircraft validation source data to support the objective qualification of simulator(s). The approval shall be obtained not later than 18 December 2015 or before the aircraft is operated by an EU operator, whichever is the latest. Compliance findings made by the authorities in Operational Evaluation Board processes conducted under the responsibility of the JAA or the Agency before the entry into force of this Regulation shall be accepted by the Agency without further verification.

3. Operational Evaluation Board reports and master minimum equipment lists issued in accordance with JAA procedures or by the Agency before the entry into force of this Regulation shall be deemed to constitute the operational suitability data approved in accordance with

point 21.A.21(e) of Annex I (Part 21) and shall be included in the relevant type-certificate. Before 18 June 2014 the relevant type-certificate holders shall propose the Agency a division of the operational suitability data in mandatory data and non-mandatory data.

4. Holders of a type-certificate including operational suitability data shall be required to obtain approval of an extension of the scope of their design organisation approval or procedures alternative to design organisation approval, as applicable, to include operational suitability aspects before 18 December 2015.

Article 8 Design organisations

Regulation (EU) 2023/1028

1. An organisation responsible for the design of products, parts and appliances or for changes or repairs thereto shall demonstrate its capability in accordance with Annex I (Part 21).

2. By way of derogation from paragraph 1 of this Article, a natural or legal person responsible for the design of products whose principal place of business is in a Member State and who applies for or holds a certificate for the design of products, or changes or repairs thereto, in accordance with Article 2(2) may, alternatively, demonstrate their capability in accordance with Annex Ib (Part 21 Light).

3. Natural or legal persons involved in the design of aircraft subject to a declaration of design compliance referred to in Article 2(3) need not demonstrate their capability.

4. By way of derogation from points 21.B.433(d)(1) and (2) of Annex I (Part 21), a design organisation that holds a valid approval certificate issued in accordance with Annex I (Part 21) may correct, until 7 March 2025, any findings of non-compliance related to the Annex I requirements introduced by Commission Delegated Regulation (EU) 2022/201 ([1]).

   Where after 7 March 2025, the organisation has not closed such findings, the approval certificate shall be revoked, limited or suspended in whole or in part.

5. By way of derogation from paragraph 1 of this Article, an organisation whose principal place of business is in a non-Member State may demonstrate its capability by holding a certificate issued by that State for the product, part and appliance for which it applies in accordance with Annex I (Part 21), provided that:

   (a) that State is the State of design;

   (b) the Agency has determined that the system of that State includes the same independent level of checking of compliance as provided by this Regulation, either through an equivalent system of approvals of organisations or through direct involvement of the competent authority of that State.

6. Design organisation approvals issued or recognised by a Member State in accordance with the JAA requirements and procedures and valid before 28 September 2003 shall be deemed to comply with this Regulation.

[1] Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation (OJ L 33, …, p. 7)

Article 9 Production organisations

Regulation (EU) 2023/1028

1. An organisation responsible for the manufacture of products, parts and appliances shall demonstrate its capability in accordance with the provisions of Annex I (Part 21). This demonstration of capability is not required for the parts or appliances that an organisation manufactures which, in accordance with the provisions of Annex I (Part 21), are eligible for installation in a type-certified product without the need to be accompanied by an authorised release certificate (i.e. EASA Form 1).

2. By way of derogation from point 1, a manufacturer whose principal place of business is in a non-member State may demonstrate its capability by holding a certificate issued by that State for the product, part and appliance for which it applies, provided:

   (a) that State is the State of manufacture; and

   (b) the Agency has determined that the system of that State includes the same independent level of checking of compliance as provided by this Regulation, either through an equivalent system of approvals of organisations or through direct involvement of the competent authority of that State.

3. Production organisation approvals issued or recognised by a Member State in accordance with the JAA requirements and procedures and valid before 28 September 2003 shall be deemed to comply with this Regulation.

4. By way of derogation from paragraph 1, the production organisation may apply to the competent authority for exemptions from the environmental protection requirements referred to in the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139.

5. By way of derogation from points 21.B.225(d)(1) and (2) of Annex I (Part 21), a production organisation that holds a valid approval certificate issued in accordance with Annex I (Part 21) may correct, until 7 March 2025, any findings of non-compliance related to the Annex I requirements introduced by Commission Delegated Regulation (EU) 2022/201 ([1]).

   Where after 7 March 2025 the organisation has not closed those findings, the approval certificate shall be revoked, limited or suspended in whole or in part.

6. By way of derogation from point 21.A.125C(a)(1) of Annex I (Part 21), an organisation that produces products, parts or appliances without an approval certificate and that holds a valid letter of agreement issued on or before 7 March 2023 in accordance with Annex I (Part 21) shall not be required to comply with the relevant Annex I requirements introduced by Delegated Regulation (EU) 2022/201.

7. By way of derogation from paragraph 1 of this Article, a natural or legal person whose principal place of business is in a Member State and who is responsible for the manufacture of products and their parts and appliances in accordance with Article 2(2) may alternatively demonstrate their capability in accordance with Annex Ib (Part 21 Light).

8. The demonstration of capability pursuant to paragraphs 1 or 2 shall not be required where the production organisation or natural or legal person are involved in the following manufacturing activities:

[1] Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation (OJ L 33, 15.2.2022, p. 7).

(a) the manufacture of parts or appliances that are eligible, in accordance with Annex I (Part 21), for installation in a type-certified product without the need to be accompanied by an authorised release certificate (that is to say EASA Form 1);

(b) the manufacture of parts that are eligible, in accordance with Annex Ib (Part 21 Light), for installation in an aircraft that has been subject to a declaration of design compliance without the need to be accompanied by an authorised release certificate (that is to say EASA Form 1);

(c) the manufacture of an aircraft that has been subject to a declaration of design compliance referred to in Article 2(3), and of parts that are eligible for installation on such aircraft. In such case, the manufacturing activities shall be conducted in accordance with Subpart R of Section A of Annex Ib (Part 21 Light) by a production organisation or a natural or legal person whose principal place of business is in a Member State.

Article 10 Agency measures

Regulation (EU) 2022/1358

1. The Agency shall develop acceptable means of compliance ("AMC") which competent authorities, organisations and personnel may use to demonstrate compliance with the provisions of Annex I (Part 21) and Annex Ib (Part 21 Light).

2. The AMC issued by the Agency shall neither introduce new requirements nor alleviate the requirements of Annex I (Part 21) and Annex Ib (Part 21 Light).

Article 11 Repeal

Regulation (EU) No 748/2012

Regulation (EC) No 1702/2003 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 12 Entry into force

Regulation (EU) No 748/2012

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

TRANSITIONAL PROVISIONS FROM REGULATIONS AMENDING REGULATION (EU) NO 748/2012

Article 2 Transitional provisions (Regulation (EU) 2015/1039)

Regulation (EU) 2015/1039

1. Member States that at 21 July 2015 issued national licences for flight test crew members other than pilots may continue to do so in accordance with their national law until 31 December 2017. The holders of those licences may continue to exercise their privileges until that date.

2. After 31 December 2017, applicants for or holders of a permit to fly may continue to use the services of pilots engaged in Category Three or Four flight tests referred to in Appendix XII to Annex I to Regulation (EU) No 748/2012 and of flight test engineers that were conducting flight test activities in accordance with the applicable rules of national law before that date. Any such use shall remain limited to the scope of functions of the flight test crew members as established before 31 December 2017.

   The scope of functions of the flight test crew member shall be established by the applicant for or holder of a permit to fly that uses or plans to use their services, based on the flight test crew members' flight test experience and training, and on the relevant records of the applicant for or the holder of a permit to fly. That scope of functions of a flight test crew member shall be made available to the competent authority.

   Any addition or any other amendment to the scope of the functions established for these flight test crew members by the applicant for or holder of a permit to fly that uses or plans to use their services shall comply with the requirements of Appendix XII to Annex I to Regulation (EU) No 748/2012.

3. Until 31 December 2015, the competent authorities may continue to issue the airworthiness review certificate EASA Form 15a, as laid down in Appendix II to Annex I to Regulation (EU) No 748/2012, in force prior to 21 July 2015. Certificates issued before 1 January 2016 remain valid until they are changed, suspended or revoked.

ANNEX I

PART 21

Certification of aircraft and related products, parts and appliances, and of design and production organisations

GM1 Annex I Definitions

ED Decision 2022/021/R

For the purpose of the Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Annex I (Part 21) to Regulation (EU) No 748/2012, the following definitions apply:

Audit	It refers to a systematic, independent, and documented process for obtaining evidence and objectively evaluating it to determine the extent to which the requirements are complied with. *Note: audits may include inspections.*
Assessment	In the context of management system performance monitoring, continuous improvement, and oversight, it refers to a planned and documented activity that is performed by competent personnel to evaluate and analyse the achieved level of performance and maturity in relation to the organisation's policy and objectives. *Note: an assessment focuses on desirable outcomes and the overall performance, looking at the organisation as a whole. The main objective of the assessment is to identify the strengths and weaknesses to drive continual improvement.* *Remark: for 'risk assessment', please refer to the definition below.*
Certificate	It is any certificate, approval, licence, authorisation, attestation or other document that is issued as the outcome of the certification process, which attests compliance with the applicable requirements.
Competency	It is a combination of individual skills, practical and theoretical knowledge, attitude, training, and experience.
Correction	It is the action to eliminate detected non-compliance.
Corrective action	It is the action to eliminate or mitigate the root cause(s) and prevent the recurrence of existing detected non-compliance, or of any other undesirable condition or situation. Proper determination of the root cause(s) is crucial for defining effective corrective action to prevent reoccurrence.
Error	It is a person's action or inaction that may lead to deviations from the accepted procedures or regulations. *Note: errors are often associated with occasions when a planned sequence of mental or physical activities either fails to achieve its intended outcome, or is not appropriate with regard to the intended outcome, and when results cannot be attributed purely to chance.*
Fatigue	It is a physiological state of reduced mental or physical performance capability, resulting from sleep loss or extended wakefulness, circadian phase, or workload (mental and/or physical activity), which can impair a person's alertness and ability to safely perform their tasks.
Hazard	It is a condition or an object with the potential to cause, or contribute to, an aircraft incident or accident.
Human factors (HF)	It is anything that affects human performance, which means principles that apply to aeronautical activities, and which seek safe interface between the human and other system components by proper consideration of human

	performance (ref. ICAO Doc 10151 — Human Performance (HP) Manual for Regulators[1]).
Human performance (HP)	It refers to human capabilities and limitations that have an impact on the safety and efficiency of aeronautical activities (ref. ICAO Doc 10151 — Human Performance (HP) Manual for Regulators[2]).
Inspection	In the context of compliance monitoring and oversight, it refers to an independent and documented conformity evaluation by observation and judgement, which is accompanied, as appropriate, by measurements, testing or gauging, in order to verify compliance with the applicable requirements. *Note: inspection may be part of an audit (e.g. product audit), but may also be conducted outside the normal audit plan; for example, to verify the closure of a particular finding.*
'Just culture'	Ref. Article 2 of Regulation (EU) No 376/2014[3].
Near miss	It is an event in which an occurrence to be mandatorily reported according to Regulation (EU) No 376/2014 was narrowly averted or avoided. *Example: a staff member, on rechecking their work at the end of a task, realises that one work card step was not properly carried out.*
Organisational factor	It is a condition that affects the effectiveness of safety risk controls, and is related to the culture, policies, processes, resources, and the workplace of an organisation.
Oversight planning cycle	It refers to the time frame within which the areas of the approval and the processes that are identified through a risk assessment should be reviewed by the competent authority by means of audits and inspections.
Oversight programme	It refers to the detailed oversight schedule that defines the number of audits and other activities, including the scope and duration of each activity, as well as the details of product audits and locations, as appropriate, to be performed by the competent authority, and to the tentative time frame for performing each activity.
Preventive action	It is the action to eliminate the cause of potential non-compliance, or any other undesirable potential situation.
Risk assessment	It is an evaluation that is based on engineering and operational judgement and/or analysis methods in order to establish whether the achieved or perceived risk is acceptable or tolerable.
Safety culture	It is an enduring set of values, norms, attitudes, and practices within an organisation, which is concerned with minimising the exposure of the workforce and the general public to dangerous or hazardous conditions. In a positive safety culture, a shared concern for, commitment to, and accountability for, safety is promoted.
Safety risk	It refers to the predicted probability and severity of the consequences or outcomes of a hazard.
Safety training	It refers to dedicated training to support safety management policies and processes, including HF training. *Note 1: the main objective of the safety training programme is to ensure that personnel at all levels of the organisation maintain their competency to fulfil their roles safely. Safety training should, in particular, consider the safety*

1 ICAO Document 10151 'Manual on Human Performance (HP) for Regulators', First Edition, 2021.

2 Ibid.

3 Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0376&qid=1669377456448).

	knowledge that is derived from hazard identification and risk management processes, and forster a positive safety culture. *Note 2: safety management training refers to specific training for the staff that are involved in safety management functions in accordance with points 21.A.139(c) and 21.A.239(c) of Part 21.*
Working days	It refers to days between, and including, Monday and Friday, except public holidays.

GM2 Annex I Abbreviations

ED Decision 2022/021/R

For the purpose of the AMC and GM to Part 21, the following abbreviations apply:

AFM	Aircraft flight manual
AMC	Acceptable means of compliance
APU	Auxiliary power unit
CEO	Chief executive officer
CMR	Certification maintenance requirement
CofA	Certificate of airworthiness
CRI	Certification review item
CS	Certification specification
CS-CCD	Certification Specifications for Cabin Crew Data
CS-FCD	Certification Specifications for Operational Suitability Data (OSD) Flight Crew Data
CS-GEN-MMEL	Certification Specifications for Generic Master Minimum Equipment List
CS-MMEL	Certification Specifications for Master Minimum Equipment List
CS-MCSD	Certification Specifications for Maintenance Certifying Staff Data
CS-SIMD	Certification Specifications for Simulator Data
DAH	Design approval holder
DO	Design organisation
DOA	Design organisation approval
EDTO	Extended diversion time operation
ELOS	Equivalent level of safety
ESF	Equivalent safety finding
ETSO	European technical standard order
FOD	Foreign object damage
HDO	Head of the design organisation
ICAO	International Civil Aviation Organization
ICA	Instructions for continued airworthiness
OP	Other party

OSD	Operational suitability data
PAH	Production approval holder
PO	Production organisation
POA	Production organisation approval
POATL	Production organisation approval team leader
POE	Production organisation exposition
GM	Guidance material
MoC	Means of compliance
RCofA	Restricted certificate of airworthiness
RTC	Restricted type certificate
SC	Special condition
SMS	Safety management system
STC	Supplemental type certificate
TC	Type certificate
TCDS	Type certificate data sheet

21.1. Competent authority

Regulation (EU) 2022/203

For the purpose of this Annex, the 'competent authority' shall be:

(a) for Section A, Subpart A,

1. for design organisations, the Agency;
2. for production organisations that have their principal place of business in a territory for which a Member State is responsible under the Convention on International Civil Aviation, signed in Chicago on 7 December 1944 ('the Chicago Convention'), the authority designated by that Member State or by another Member State in accordance with Article 64 of Regulation (EU) 2018/1139, or the Agency if the responsibility has been reallocated to the Agency in accordance with Article 64 or 65 of Regulation (EU) 2018/1139;
3. for production organisations that have their principal place of business outside a territory for which a Member State is responsible under the Chicago Convention, the Agency;

(b) for Section A, Subparts B, D, E, J, K, M, O and Q, the Agency;

(c) for Section A, Subparts F and G:

1. for natural or legal persons that have their principal place of business in a territory for which a Member State is responsible under the Chicago Convention, the authority designated by that Member State or by another Member State in accordance with Article 64 of Regulation (EU) 2018/1139, or the Agency if the responsibility has been reallocated to the Agency in accordance with Article 64 or, as regards Subpart G, Article 65 of Regulation (EU) 2018/1139;

2. for natural or legal persons that have their principal place of business outside a territory for which a Member State is responsible under the Chicago Convention, the Agency;

(d) for Section A, Subpart H and I, the authority designated by the Member State where the aircraft is registered or will be registered:

(e) for Section A, Subpart P:

1. for aircraft registered in a Member State, the authority designated by the Member State of registry;

2. for unregistered aircraft, the authority designated by the Member State which prescribed the identification marks;

3. for the approval of the flight conditions related to the safety of the design, the Agency.

GM1 21.1 Competent authority

ED Decision 2022/021/R

RESPONSIBILITY FOR THE IMPLEMENTATION OF PART 21

Each certificate or approval in accordance with Part 21, Section A, Subparts F, G, H, I, and P is normally issued and overseen by the competent authority of the Member State in which the applicant or holder is located. Therefore, to ensure consistency between the competent authorities of the Member States in issuing certificates and approvals, the implementation of Part 21 should be based on the following three principles:

(a) the establishment and maintenance of an effective organisation and of the corresponding processes by the competent authorities;

(b) the operation of the competent authorities in accordance with Part 21 and the AMC and GM thereto; and

(c) a standardisation process that is established and applied by EASA to assess the standard(s) achieved, and to provide timely advice and guidance to the competent authorities.

As a result, the responsibility for implementation of Part 21 has two main objectives:

(a) to ensure that certificates and approvals are only granted to applicants that comply with the requirements of Part 21; and

(b) to ensure that there is sufficient visibility of the processes, to give EASA and the Member States the necessary confidence in the certificates or approvals granted.

GM1 21.1(e) Competent authority

ED Decision 2022/021/R

PERMIT TO FLY

An aircraft that is registered in a Member State is under the responsibility of that Member State regarding continuing-airworthiness aspects. Consequently, permits to fly under Part 21 may be issued by that Member State, including for cases in which the aircraft flies in another State. The permit to fly contains all the conditions and restrictions to ensure safe flight, but other airspace and operational rules remain within the competence of the authority of the State where the flight takes place, and may apply. Therefore, the applicant is also required to ensure compliance with the applicable rules of that State.

21.2 Scope

Regulation (EU) 2022/203

Section A of this Annex establishes the provisions that lay down the rights and obligations of the applicant for, and holder of, any certificate issued or to be issued in accordance with this Annex.

Section B of this Annex establishes the conditions for conducting the certification oversight and enforcement tasks as well as the administrative and management system requirements to be complied with by the competent authority that is responsible for the implementation of Section A of this Annex.

SECTION A — TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

21.A.1 Scope

Regulation (EU) 2022/201

This Subpart establishes the general rights and obligations of the applicant for, and holder of, any certificate that has been issued or is to be issued in accordance with this Annex.

21.A.2 Undertaking by another person than the applicant for, or holder of, a certificate

Regulation (EU) No 748/2012

The actions and obligations required to be undertaken by the holder of, or applicant for, a certificate for a product, part or appliance under this Section may be undertaken on its behalf by any other natural or legal person, provided the holder of, or applicant for, that certificate can show that it has made an agreement with the other person such as to ensure that the holder's obligations are and will be properly discharged.

21.A.3A Reporting system

Regulation (EU) 2022/201

(a) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council[1] and its delegated and implementing acts, all natural or legal persons that have applied for or hold a type-certificate, restricted type-certificate, supplemental type-certificate, European Technical Standard Order (ETSO) authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall:

1. establish and maintain a system for collecting, investigating and analysing occurrence reports in order to identify adverse trends or to address deficiencies and to extract occurrences whose reporting is mandatory in accordance with point 3 and those which are reported voluntarily. When the principal place of business is located in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts. The reporting system shall include:

   (i) reports of and information related to failures, malfunctions, defects or other occurrences which cause or might cause adverse effects on the continuing airworthiness of the product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or by any other relevant approval deemed to have been issued under this Regulation;

[1].Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

(ii) errors, near misses and hazards that do not fall under point (i);

2. make available to known operators of the product, part or appliance and, on request, to any person authorised under other implementing or delegated acts the information about the system established in accordance with point 1, and on how to provide reports of and information related to failures, malfunctions, defects or other occurrences referred to in point 1(i);

3. report to the Agency any failure, malfunction, defect or other occurrence of which it is aware and is related to a product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or by any other relevant approval deemed to have been issued under this Regulation, and which has resulted or may result in an unsafe condition.

(b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person that holds or has applied for a production organisation approval certificate under Subpart G of this Section, or that produces a product, part or appliance under Subpart F of this Section, shall:

1. establish and maintain a system for collecting and assessing occurrence reports, including reports on errors, near misses and hazards, in order to identify adverse trends or to address deficiencies and extract occurrences whose reporting is mandatory in accordance with points 2 and 3 and those which are reported voluntarily. For organisations that have their principal place of business in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts;

2. report to the responsible design approval holder all the cases where products, parts or appliances have been released by the production organisation and possible deviations from the applicable design data have been subsequently identified, and investigate with the design approval holder to identify those deviations which could lead to an unsafe condition;

3. report to the competent authority of the Member State responsible in accordance with point 21.1 and the Agency the deviations that have been identified in accordance with point 21.A.3A(b)2 and which could lead to an unsafe condition;

4. if the production organisation acts as a supplier to another production organisation, also report to that other organisation all the cases where it has released products, parts or appliances to that organisation and possible deviations from the applicable design data have been subsequently identified.

(c) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person, when reporting in accordance with points (a)(3), (b)(2), (b)(3) and (b)(4), shall appropriately protect the confidentiality of the person who reports and of the person(s) mentioned in the report.

(d) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person shall make the reports referred to in points (a)(3) and (b)(3) in a form and manner established by the Agency or the competent authority, respectively, and dispatch them as soon as practicable and in any case not later than 72 hours after the natural or legal person has identified that the occurrence may lead to a possible unsafe condition, unless exceptional circumstances prevent this.

(e) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, if an occurrence reported under point (a)(3) or under point (b)(3) results from a deficiency in the design or a production deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall investigate the reason for the deficiency and report to the competent authority of the Member State responsible in accordance with point 21.1 and to the Agency the results of its investigation and any action it intends to take or proposes to be taken to correct that deficiency.

(f) If the competent authority finds that action is required to correct the deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall submit the relevant data to the competent authority upon its request.

GM1 21.A.3A Reporting system

ED Decision 2022/021/R

LINK BETWEEN POINT 21.A.3A AND REGULATION (EU) No 376/2014

Regulation (EU) No 376/2014 of the European Parliament and of the Council lays down requirements on the reporting, analysis and follow-up of occurrences in civil aviation. Compliance with point 21.A.3A of Part 21 does not exempt organisations from compliance with Regulation (EU) No 376/2014. For each category of reporter, Regulation (EU) 2015/1018[1] defines the nature of items to be mandatorily reported. Regulation EU) No 376/2014 also considers voluntary reporting of other items that are perceived by the reporter as a threat to aviation safety.

Point 21.A.3A lays down requirements for the mandatory reporting of events to the competent authority, in view of performing the necessary activities linked to the continued airworthiness of aircraft, parts, and appliances.

For Part 21 design organisations (DOs) and production organisations (POs), the reportability criteria (i.e. a potential unsafe condition) are the same as the ones laid down by Regulation (EU) No 376/2014.

Furthermore, compliance with Regulation (EU) No 376/2014 does not exempt organisations from compliance with point 21.A.3A. However, this should not give rise to two parallel reporting systems, and point 21.A.3A and Regulation (EU) No 376/2014 should be seen as complementary in that respect.

In practice, this means that reporting obligations under point 21.A.3A on one hand and reporting obligations under Regulation (EU) No 376/2014 on the other hand are compatible. These reporting obligations may be discharged using one reporting channel.

In addition, any natural or legal person that has more than one role subject to the obligation to report may discharge all those obligations through a single report. Organisations are encouraged to properly describe this in their organisation manual, to address cases in which the responsibilities are discharged on behalf of the organisation.

[1] Commission Implementing Regulation (EU) 2015/1018 of 29 June 2015 laying down a list classifying occurrences in civil aviation to be mandatorily reported according to Regulation (EU) No 376/2014 of the European Parliament and of the Council (OJ L 163, 30.6.2015, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1018&qid=1669631925416).

AMC1 21.A.3A(a) Reporting system

ED Decision 2022/021/R

COLLECTION, INVESTIGATION, AND ANALYSIS OF EVENTS

In the context of the following AMC and GM to point 21.A.3A, the term 'event' refers to any failure, malfunction, defect, error, near miss, hazard identification, incident, accident, or other occurrence that is subject to a reporting system.

The 'collection', 'investigation', and 'analysis' functions of the system should include means:

— to analyse events and related available information;

— to identify adverse trends;

— to investigate the associated root cause(s); and

— to determine any necessary corrective action.

It should also allow the determination of reportable occurrences as required by point 21.A.3A(a)(3) or 21.A.3A(b)(3), as applicable.

In addition, for parts whose failure could lead to an unsafe condition, the 'analysis' function of the system should ensure that reports and information sent, or available, to the design approval holder (DAH) are fully investigated so that the exact nature of any event and its effect on continuing airworthiness is understood. This may then result in changes to the design and/or to the instructions for continued airworthiness (ICA), and/or in establishing a mitigation plan to prevent or minimise the possibility of such occurrences in the future, as necessary. The 'analysis' is not limited to those occurrences that require the involvement of EASA under point 21.A.3A(e).

AMC2 21.A.3A(a) Reporting system

ED Decision 2022/021/R

COLLECTION, INVESTIGATION, AND ANALYSIS OF DATA RELATED TO FLAMMABILITY REDUCTION MEANS (FRM) RELIABILITY

Holders of a TC, an RTC, an STC, or any other relevant approval that is deemed to have been issued under Part 21, which have included an FRM in their design, should continuously assess the effects of aeroplane component failures on FRM reliability. This should be part of the system for the collection, investigation, and analysis of data, which is required by point 21.A.3A(a). The applicant/holder should therefore:

(a) demonstrate effective means to collect FRM reliability data; those means should provide data that affect FRM reliability, such as component failures;

(b) unless alternative reporting procedures are approved by EASA, submit a report to EASA every 6 months for the first 5 years after service introduction; after that period, continued reporting every 6 months may be:

- replaced with other FRM reliability tracking methods that are deemed acceptable by EASA; or
- eliminated if it is established that the FRM reliability meets, and will continue to meet, the exposure specifications in paragraph M25.1 of Appendix M to the Certification Specifications for Large Aeroplanes (CS-25); and

(c) develop service instructions or revise the applicable aeroplane manual, according to a schedule that is approved by EASA, to correct any failures of the FRM that occur in service, which could

increase any fuel tank's fleet average flammability exposure to more than what is specified in paragraph M25.1 of Appendix M to CS-25.

AMC3 21.A.3A(a) Reporting system

ED Decision 2022/021/R

COLLECTION, INVESTIGATION, AND ANALYSIS OF DATA RELATED TO EDTO-SIGNIFICANT OCCURRENCES

(a) Holders of a TC, an RTC, an STC, or any other relevant approval that is deemed to have been issued under Part 21 and includes extended diversion time operation (EDTO) capability should implement a specific tracking, reporting, and resolution system for EDTO-significant occurrences. That system should be suitable to ensure the initial and continued fleet compliance with the applicable EDTO reliability objectives, and be part of the system for the collection, investigation, and analysis of data, which is required by point 21.A.3A(a).

Appropriate coordination should exist between the engine TC holder, the propeller TC holder, the auxiliary power unit (APU) ETSO authorisation holder, and the aircraft TC holder, to ensure compliance with the EDTO reliability objectives.

(b) For the tracking, reporting, and resolution of EDTO-significant occurrences, refer to the latest edition of AMC 20-6 of the 'General Acceptable Means of Compliance for Airworthiness of Products, Parts and Appliances' (AMC-20).

GM1 21.A.3A(a) and 21.A.3A(b) Reporting system

ED Decision 2022/021/R

GENERAL — COLLECTING SYSTEM

The term 'collection' means the setting up of systems and procedures that will enable relevant failures, malfunctions, and defects, or other occurrences, to be properly collected when they occur.

As the collection system needs to accept reports that originate outside the organisation (from operators, maintenance organisations, suppliers, etc.), it is necessary to inform possible reporters of the existence of the system and of the appropriate means to introduce reports into it. This does not presume that direct access to the system is to be granted if other mechanisms are more appropriate.

The collection system should also ensure the collection, through an internal reporting scheme, of internal errors, near misses, and hazards that are perceived by the reporter as an actual or potential aviation safety risk.

Considerations for the collection of information related to events should include the following:

— the analysis of failure rates;

— the early rejection of parts from service; and

— comparison with the certification assumptions.

GM1 21.A.3A(a), 21.A.3A(e), and 21.A.3A(f) Reporting system

ED Decision 2022/021/R

GENERAL

In the context of points 21.A.3A(a), 21.A.3A(e), and 21.A.3A(f), the phrase '[…] or any other relevant approval deemed […]' refers to 'grandfathered' design approvals under Part 21, as defined in Article 3 of Regulation (EU) No 748/2012.

Design approval holders (DAHs) of minor changes and minor repairs do not have to comply with the requirements in point 21.A.3A(a), as according to the classification criteria for design changes and repairs (see points 21.A.91 and 21.A.435), minor changes and minor repairs have no appreciable effect on the characteristics that affect the airworthiness of the product. However, it should be noted that the obligations under Regulation (EU) No 376/2014 and its implementing acts still apply.

GM1 21.A.3A(a)(1) and (b)(1) Reporting system

ED Decision 2022/021/R

EVENTS REPORTED VOLUNTARILY TO THE ORGANISATION

A natural or a legal person (including organisations that are not approved by a Member State) may voluntarily report to an organisation any event that is perceived by that person as posing an actual or potential hazard to aviation safety.

Voluntary reports may be originated by:

(a) persons that are not listed in Article 4(6) of Regulation (EU) No 376/2014; or

(b) persons that are listed in Article 4(6) of Regulation (EU) No 376/2014, even though such events are not included in Regulation (EU) 2015/1018; or

(c) an organisation, if such organisation cannot determine whether the event should be mandatorily reported.

Example

A maintenance staff member in a maintenance organisation is reporting to their maintenance organisation a perceived design issue that is not covered by Regulation (EU) 2015/1018. The maintenance organisation should make a final assessment of the voluntary report and if it assesses that the reported event 'may involve an actual or potential aviation safety risk', then it should mandatorily report it to the TC holder, the competent authority, etc., as per point 145.A.60 'Occurrence reporting' of Annex II (Part-145) to Regulation (EU) No 1321/2014[1]. If the maintenance organisation cannot determine whether a safety risk exists (due to lack of competence, lack of data, etc.), it could voluntarily report the event to the TC holder for further assessment.

[1] Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R1321&qid=1669641196734).

GM2 21.A.3A(a)(1) and (b)(1) Reporting system

ED Decision 2022/021/R

INTERNAL SAFETY REPORTING SCHEME

The internal safety reporting scheme is part of the overall collection system. The objective of this GM is to provide specific guidance on the internal safety reporting scheme only.

(a) The overall objectives of the internal safety reporting scheme are:

— to collect information that is reported by the organisation staff; and

— to use that reported information to improve the safety of operations,

in conjunction with the safety management elements that are defined in points 21.A.139 and 21.A.239. Each internal safety reporting scheme should include provisions for confidentiality and enable and encourage free and frank reporting of events, as those listed in points 21.A.3A(a)(1)(i) and (ii). This is facilitated by establishing a 'just culture'.

(b) The specific objectives of the scheme are to:

(1) enable an assessment of the safety implications of each relevant event that is reported, including previous similar events, so that any necessary action can be initiated; and

(2) ensure that lessons from relevant events are shared so that other persons and parts of the organisation may learn from them.

(c) The scheme is an essential part of the overall management system and should be complementary to routine procedures and 'control' systems; it is not intended to duplicate or supersede any of them. The scheme is a tool to identify those instances in which routine procedures have failed or may fail.

(d) All safety-related reports should be retained as the significance of such reports may only become obvious later.

(e) The collection and analysis of timely, appropriate, and accurate data will allow the organisation to react to the information that it receives and to take necessary action.

AMC1 21.A.3A(a)(3), 21.A.3A(b)(3), 21.A.3A(d) Reporting system

ED Decision 2022/021/R

REPORTING TO THE COMPETENT AUTHORITY

Within the overall limit of 72 hours, the degree of urgency for submitting a report should be determined by the level of risk that is judged to have resulted from the occurrence.

If an occurrence is judged by the organisation that identified the possible unsafe condition to have resulted in an immediate and particularly significant hazard, EASA (or the competent authority of the Member State, as required) should be advised immediately and by the fastest possible means (telephone, fax, email, telex, etc.) of whatever details are available at that time. This initial report must be followed up with a full written report within 72 hours. An example would be an uncontained engine failure that results in damage to the aircraft primary structure.

In all other cases, the submission of the report may be delayed up to a maximum of 72 hours after determining the possible unsafe condition, in order to provide more details.

GM1 21.A.3A(a)(3), 21.A.3A(b)(3) and 21.A.3A(d) Reporting system

ED Decision 2022/021/R

REPORTING TO THE COMPETENT AUTHORITY — GENERAL

(a) The reference to 'is aware of an occurrence' implies that the organisation identifies the event as one that falls into the category of occurrences to be reported — usually when the organisation determines that the event is reportable. The 72-hour period starts when the possible unsafe condition is identified.

(b) For organisations that have their principal place of business in a Member State, Regulation (EU) 2015/1018 lays down a generic 'list classifying occurrence in civil aviation to be mandatorily reported'. This list should not be understood as being an exhaustive collection of all the issues that may pose a significant risk to aviation safety and, therefore, reporting should not be limited to the items that are listed in that Regulation.

(c) AMC-20 provides further details on occurrence reporting (AMC 20-8) and also applies to organisations that are approved under Part 21 and do not have their principal place of business in a Member State.

(d) Point 21.A.3A(a)(3) requires the reporting of occurrences that may result in an unsafe condition. GM1 21.A.3B(b) 'Failures, malfunctions and defects — Determination of an unsafe condition' could be used to assist in that determination.

AMC1 21.A.3A(e) Reporting system

ED Decision 2022/021/R

FOLLOW-UP TO, AND CLOSURE OF, REPORTED OCCURRENCES

(a) The organisation should transmit the following information to the competent authority within 30 days from the date of notification of the occurrence to the competent authority:

(1) the latest position of the design organisation (DO) as to whether an unsafe condition is confirmed;

(2) the results of the analysis and of the first investigation — including the cause(s) of the occurrence, if known; and

(3) the measures it has taken, intends to take, or proposes to be taken, including:

(i) containment measures that have already been defined by the reporting organisation and put in place (if any) ; and

(ii) in the case of reports made by the DO, for unsafe conditions, a risk assessment supporting that the product can be operated safely (see GM 21.A.3B(d)(4)) until the corrective action is defined and implemented, or that immediate mitigation measures need to be implemented until a more refined risk assessment can be provided.

Organisations are encouraged to provide a complete analysis and follow-up as soon as available and, in principle, no later than 3 months after the occurrence notification. It is recognised that analysing an occurrence may take longer than 3 months, especially if the investigation is complex or where the services of a special investigator are required.

The requirements for follow-up are not intended to jeopardise the quality and thoroughness of an occurrence analysis. It may be detrimental to safety if the analysis is completed in a rush

within the encouraged 3-month period without properly establishing the root cause(s), making a risk assessment, and determining whether remedial action is required.

The design approval holder (DAH) and the production approval holder (PAH) should cooperate, as necessary, to ensure that any corrective action can be implemented. In addition, affected organisations are expected to cooperate under their respective regulatory framework from the reporting of an occurrence until its closure, to ensure complete results.

The final (close-out) report should include:

— the final DAH position as to whether an unsafe condition exists;

— the results of the occurrence analysis and of the final investigation, including the cause(s) of the occurrence;

— any corrective and preventive action by the reporting organisation; and

— in the case of reports made by the DO, a risk assessment supporting that those corrective and preventive measures allow the product to be operated safely (see GM 21.A.3B(d)(4)).

(b) Notwithstanding point (a), when the organisation identifies that no unsafe condition exists as a result of its analysis of a voluntarily reported occurrence, it can delay further communication to the competent authority up to the issuance of the final report and report the occurrence as closed upon issue (data exchange). In such cases, no follow-up report should be submitted. The final report to EASA should include confirmation and justification that no unsafe condition exists. The organisation is requested to provide information on the cause(s) of the occurrence and on any corrective or preventive action that was taken by the organisation.

This way of reporting should not be understood as an accepted deviation from the requirements of Part 21. If at any stage during the investigation, the organisation identifies that a possible unsafe condition exists, this should be communicated to EASA via a mandatory report within 72 hours.

21.A.3B Airworthiness directives

Regulation (EU) No 748/2012

(a) An airworthiness directive means a document issued or adopted by the Agency which mandates actions to be performed on an aircraft to restore an acceptable level of safety, when evidence shows that the safety level of this aircraft may otherwise be compromised.

(b) The Agency shall issue an airworthiness directive when:

1. an unsafe condition has been determined by the Agency to exist in an aircraft, as a result of a deficiency in the aircraft, or an engine, propeller, part or appliance installed on this aircraft; and

2. that condition is likely to exist or develop in other aircraft.

(c) When an airworthiness directive has to be issued by the agency to correct the unsafe condition referred to in point (b), or to require the performance of an inspection, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, shall:

1. propose the appropriate corrective action or required inspections, or both, and submit details of these proposals to the Agency for approval;

2. following the approval by the Agency of the proposals referred to under point (1), make available to all known operators or owners of the product, part or appliance and, on request, to any person required to comply with the airworthiness directive, appropriate descriptive data and accomplishment instructions.

(d) An airworthiness directive shall contain at least the following information:

1. an identification of the unsafe condition;
2. an identification of the affected aircraft;
3. the action(s) required;
4. the compliance time for the required action(s);
5. the date of entry into force.

AMC1 21.A.3B(b) Failures, malfunctions and defects

ED Decision 2021/001/R

UNSAFE CONDITION

An unsafe condition exists if there is factual evidence (from service experience, analysis or tests) that:

(a) An event may occur that would result in fatalities, usually with the loss of the aircraft, or reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be:

(i) A large reduction in safety margins or functional capabilities, or

(ii) Physical distress or excessive workload such that the flight crew cannot be relied upon to perform their tasks accurately or completely, or

(iii) Serious or fatal injury to one or more occupants

unless it is shown that the probability of such an event is within the limit defined by the applicable certification specifications, or

(b) There is an unacceptable risk of serious or fatal injury to persons other than occupants, or

(c) Design features intended to minimise the effects of survivable accidents are not performing their intended function.

Note 1: Non-compliance with applicable certification specifications is generally considered as an unsafe condition, unless it is shown that possible events resulting from this non-compliance do not constitute an unsafe condition as defined under paragraphs (a), (b) and (c).

Note 2: An unsafe condition may exist even though applicable airworthiness requirements are complied with.

Note 3: The above definition covers the majority of cases where the Agency considers there is an unsafe condition. There may be other cases where overriding safety considerations may lead the Agency to issue an airworthiness directive.

Note 4: There may be cases where events can be considered as an unsafe condition if they occur too frequently (significantly beyond the applicable safety objectives) and could eventually lead to consequences listed in paragraph (a) in specific operating environments. Although having less severe immediate consequences than those listed in paragraph (a), the referenced events may reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be, for example, a significant reduction in safety margins or functional capabilities, a significant increase in crew workload, or in conditions impairing crew efficiency, or discomfort to occupants, possibly including injuries.

GM1 21.A.3B(b) Failures, malfunctions and defects

ED Decision 2021/001/R

DETERMINATION OF AN UNSAFE CONDITION

It is important to note that these guidelines are not exhaustive. However, this material is intended to provide guidelines and examples that will cover most cases, taking into account the applicable certification requirements.

1. INTRODUCTION

Certification or approval of a product, part or appliance is a demonstration of compliance with requirements which are intended to ensure an acceptable level of safety. This demonstration, however, includes certain accepted assumptions and predicted behaviours, such as:

— fatigue behaviour is based on analysis supported by test,

— modelling techniques are used for Aircraft Flight Manual performances calculations,

— the systems safety analyses give predictions of what the systems failure modes, effects and probabilities may be,

— the system components' reliability figures are predicted values derived from general experience, tests or analysis,

— the crew is expected to have the skills to apply the procedures correctly, and

— the aircraft is assumed to be maintained in accordance with the prescribed instructions for continued airworthiness (ICAs) (or maintenance programme).

In service experience, additional testing, further analysis, etc., may show that certain initially accepted assumptions are not correct. Thus, certain conditions initially demonstrated as safe, are revealed by experience as unsafe. In this case, it is necessary to mandate corrective actions in order to restore a level of safety consistent with the applicable certification requirements.

To support the determination of an unsafe condition, the investigation may need to include examinations of worn, damaged and time-expired parts / analysis / certification demonstration / tests / statistical analysis, and comparison with the certification assumptions.

See AMC1 21.A.3B(b) for the definition of 'unsafe condition' used in 21.A.3A(b).

2. GUIDELINES FOR ESTABLISHING IF A CONDITION IS UNSAFE

The following paragraphs give general guidelines for analysing the reported events and determining if an unsafe condition exists, and are provided for each type of product, part or appliance subject to a specific airworthiness approval: type-certificates (TC) or supplemental type-certificates (STC) for aircraft, engines or propellers, or European Technical Standard Orders (ETSO).

This analysis may be qualitative or quantitative, i.e. formal and quantitative safety analyses may not be available for older or small aircraft. In such cases, the level of analysis should be consistent with that required by the certification specifications and may be based on engineering judgement supported by service experience data.

2.1 Analysis method for aircraft

2.1.1 Accidents or incidents without any aircraft, engines, system, propeller or part or appliance malfunction or failure

When an accident/incident does not involve any component malfunction or failure but when a crew human factor has been a contributing factor, this should be assessed from a man-machine interface standpoint to determine whether the design is adequate or not. Paragraph 2.5 gives further details on this aspect.

2.1.2 Events involving an aircraft, engines, system, propeller or part or appliance failure, malfunction or defect

The general approach for analysis of in-service events caused by malfunctions, failures or defects will be to analyse the actual failure effects, taking into account previously unforeseen failure modes or improper or unforeseen operating conditions revealed by service experience.

These events may have occurred in service, or have been identified during maintenance, or been identified as a result of subsequent tests, analyses, or quality control.

These may result from a design deficiency or a production deficiency (non-conformity with the type design), or from improper maintenance. In this case, it should be determined if improper maintenance is limited to one aircraft, in which case an airworthiness directive may not be issued, or if it is likely to be a general problem due to improper design and/or maintenance procedures, as detailed in paragraph 2.5.

2.1.2.1 Flight

An unsafe condition exists if:

— There is a significant shortfall of the actual performance compared to the approved performance (taking into account the accuracy of the performance calculation method), or

— The handling qualities, although having been found to comply with the applicable certification specifications at the time of initial approval, are subsequently shown by service experience not to comply.

2.1.2.2 Structural or mechanical systems

An unsafe condition exists if the deficiency may lead to a structural or mechanical failure which:

— Could exist in a Principal Structural Element that has not been qualified as damage tolerant. Principal Structural Elements are those which contribute significantly to carrying flight, ground, and pressurisation loads, and whose failure could result in a catastrophic failure of the aircraft.

  Typical examples of such elements are listed for large aeroplanes in AMC 25.571(a) 'Damage tolerance and fatigue evaluation of structure', and in the equivalent material for rotorcraft.

— Could exist in a Principal Structural Element that has been qualified as damage tolerant, but for which the established inspections, or other procedures, have been shown to be, or may be, inadequate to prevent catastrophic failure.

— Could reduce the structural stiffness to such an extent that the required flutter, divergence or control reversal margins are no longer achieved.

— Could result in the loss of a structural piece that could damage vital parts of the aircraft, cause serious or fatal injuries to persons other than occupants.

— Could, under ultimate load conditions, result in the liberation of items of mass that may injure occupants of the aircraft.

— Could jeopardise proper operation of systems and may lead to hazardous or catastrophic consequences, if this effect has not been taken adequately into account in the initial certification safety assessment.

2.1.2.3 Systems

The consequences of reported systems components malfunctions, failures or defects should be analysed.

For this analysis, the certification data may be used as supporting material, in particular systems safety analyses.

The general approach for analysis of in-service events caused by systems malfunctions, failures or defects will be to analyse the actual failure effects.

As a result of this analysis, an unsafe condition will be assumed if it cannot be shown that the safety objectives for hazardous and catastrophic failure conditions are still achieved, taking into account the actual failure modes and rates of the components affected by the reported deficiency.

The failure probability of a system component may be affected by:

— A design deficiency (the design does not meet the specified reliability or performance).

— A production deficiency (non-conformity with the certified type design) that affects either all components, or a certain batch of components.

— Improper installation (for instance, insufficient clearance of pipes to surrounding structure).

— Susceptibility to adverse environment (corrosion, moisture, temperature, vibrations etc.).

— Ageing effects (failure rate increase when the component ages).

— Improper maintenance.

When the failure of a component is not immediately detectable (hidden or latent failures), it is often difficult to have a reasonably accurate estimation of the component failure rate since the only data available are usually results of maintenance or flight crew checks. This failure probability should therefore be conservatively assessed.

As it is difficult to justify that safety objectives for the following systems are still met, a deficiency affecting these types of systems may often lead to a mandatory corrective action:

— back up emergency systems, or

— fire detection and protection systems (including shut off means).

Deficiencies affecting systems used during an emergency evacuation (emergency exits, evacuation assist means, emergency lighting system ...) and to locate the site of a crash (Emergency Locator Transmitter) will also often lead to mandatory corrective action.

2.1.2.4 Others

In addition to the above, the following conditions are considered unsafe:

— There is a deficiency in certain components which are involved in fire protection or which are intended to minimise/retard the effects of fire/smoke in a survivable crash, preventing them to perform their intended function (for instance, deficiency in cargo liners or cabin material leading to non-compliance with the applicable flammability requirements).

— There is a deficiency in the lightning or High Intensity Radiated Fields protection of a system which may lead to hazardous or catastrophic failure conditions.

— There is a deficiency which could lead to a total loss of power or thrust due to common mode failure.

If there is a deficiency in systems used to assist in the enquiry following an accident or serious incident (e.g., Cockpit Voice Recorder, Flight Data Recorder), preventing them to perform their intended function, the Agency may take mandatory action.

2.2 Engines

The consequences and probabilities of engine failures have to be assessed at the aircraft level in accordance with paragraph 2.1, and also at the engine level for those failures considered as Hazardous in CS E-510.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.3 Propellers

The consequences and probabilities of propeller failures have to be assessed at the aircraft level in accordance with paragraph 2.1, and also at the propeller level for those failures considered as hazardous in CS P-70.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.4 Parts and appliances

The consequences and probabilities of equipment failures have to be assessed at the aircraft level in accordance with paragraph 2.1.

2.5 Human factors aspects in establishing and correcting unsafe conditions

This paragraph provides guidance on the way to treat an unsafe condition resulting from a maintenance or crew error observed in service.

It is recognised that human factors techniques are under development. However, the following is a preliminary guidance on the subject.

Systematic review should be used to assess whether the crew or maintenance error raises issues that require regulatory action (whether in design or other areas), or should be noted as an isolated event without intervention. This may need the establishment of a multidisciplinary team (designers, crews, human factors experts, maintenance experts, operators etc.)

The assessment should include at least the following:

— Characteristics of the design intended to prevent or discourage incorrect assembly or operation;

— Characteristics of the design that allow or facilitate incorrect operation,

— Unique characteristics of a design feature differing from established design practices;

— The presence of indications or feedback that alerts the operator to an erroneous condition;

— The existence of similar previous events, and whether or not they resulted (on those occasions) in unsafe conditions;

— Complexity of the system, associated procedures and training (has the crew a good understanding of the system and its logic after a standard crew qualification programme?);

— Clarity/accuracy/availability/currency and practical applicability of manuals and procedures;

— Any issues arising from interactions between personnel, such as shift changeover, dual inspections, team operations, supervision (or lack of it), or fatigue.

Apart from a design change, the corrective actions, if found necessary, may consist of modifications of the manuals, inspections, training programmes, and/or information to the operators about particular design features. The Agency may decide to make mandatory such corrective action if necessary.

GM 21.A.3B(d)(4) Defect correction – Sufficiency of proposed corrective action

ED Decision 2012/020/R

This GM provides guidelines to assist in establishing rectification campaigns to remedy discovered defects.

1. STATUS

This document contains GM of a general nature for use in conjunction with engineering judgement, to aid airworthiness engineers in reaching decisions in the state of technology at the material time.

While the main principles of this GM could be applied to small private aeroplanes, helicopters, etc. the numerical values chosen for illustration are appropriate to large aeroplanes for public transport.

2. INTRODUCTION

2.1 Over the years, target airworthiness risk levels underlying airworthiness requirements have developed on the basis of traditional qualitative airworthiness approaches; they have been given more precision in recent years by being compared with achieved airworthiness levels (judged from accident statistics) and by the general deliberations and discussions which accompanied the introduction of rational performance requirements, and more recently, the Safety Assessment approach in requirements. Although the target airworthiness risk level tends to be discussed as a single figure (a fatal accident rate for airworthiness reasons of not more than 1 in 10 000 000 flights/flying hours for large aeroplanes) it has to be recognised that the requirements when applied to particular aircraft types will result in achieved airworthiness levels at certification lying within a band around the target level and that thereafter, for particular aircraft types and for particular aircraft, the achieved level will vary within that band from time to time.

2.2 The achieved airworthiness risk levels can vary so as to be below the target levels, because it is difficult if not impossible to design to the minimum requirements without being in excess of requirements in many areas; also because aircraft are not always operated at the critical conditions (e.g., aircraft weight, CG position and operational speeds; environmental conditions - temperature, humidity, degree of turbulence). The achieved level may vary so as to be above the target level because of undetected variations in material standards or build standards, because of design deficiencies, because of encountering unforeseen combinations of failures and/or combinations of events, and because of unanticipated operating conditions or environmental conditions.

2.3 There is now a recognition of the need to attempt to monitor the conditions which tend to increase the level and to take appropriate corrective action when the monitoring indicates the need to do so in order to prevent the level rising above a predetermined ‘ceiling’.

2.4 The Agency also has a duty in terms of providing the public with aviation services and therefore should consider the penalties associated with curtailment or even removal (by 'grounding') of aviation services when establishing the acceptability of any potential variation in airworthiness level.

2.5 Thus, the purpose of this GM is:

(a) To postulate basic principles which should be used to guide the course of actions to be followed so as to maintain an adequate level of airworthiness risk after a defect has occurred which, if uncorrected, would involve a potential significant increase of the level of risk for an aircraft type.

(b) For those cases where it is not possible fully and immediately to restore an adequate level of airworthiness risk by any possible alleviating action such as an inspection or limitation, to state the criteria which should be used in order to assess the residual increase in risk and to limit it to an appropriate small fraction of the mean airworthiness through life risk.

3. DISCUSSION

3.1 Several parameters are involved in decisions on safety matters. In the past the cost of proposed action has often been compared with the notional 'risk cost', i.e. the cost of a catastrophe multiplied by its probability of occurrence.

3.2 This can be a useful exercise, but it should be held within the constraint of acceptable airworthiness risk levels, i.e., within airworthiness risk targets which represent the maximum levels of risk with which an aircraft design must comply, i.e., in the upper part of the 'band'. Currently for large aeroplanes the mean airworthiness risk level is set at a catastrophe rate for airworthiness reasons of not more than one in every ten- million flights/flying hours. The constraint is overriding in that any option, which could be permitted on risk cost considerations, or other grounds, is unacceptable if it leads to significant long-term violation of this safety requirement.

3.3 While it should clearly be the objective of all to react to and eliminate emergency situations, i.e., those involving a potentially significant increase of airworthiness risk levels, without unreasonable delay, the Agency should be able finally to rule on what is a minimum acceptable campaign programme. It has therefore seemed desirable to devise guidelines to be used in judging whether a proposed campaign of corrective actions is sufficient in airworthiness terms, and clearly this ought to be based on determining the summation of the achieved airworthiness risk levels for the aircraft and passengers during any periods of corrective action and comparing them with some agreed target.

3.4 As the period of corrective action will not be instantaneous (unless by grounding), there is potentially an increase in the achieved airworthiness risk level possibly to and, without controls, even above the higher part of the 'band', and the amount by which the level is above the mean target figure, and the period for which it should be allowed to continue, has been a matter of some arbitrary judgement.

3.5 It would appear desirable to try to rationalise this judgement. For example, if an aircraft were to spend 10 % of its life at a level such that the risk of catastrophe was increased by an order of magnitude, the average rate over its whole life would be doubled which may not be in the public interest. A more suitable criterion is perhaps one which would allow an average increase in risk of, say one third on top of the basic design risk when spread over the whole life of the aircraft an amount which would probably be acceptable within the concept (See Figure 1). It would then be possible to regard the 'through life' risk to an

aircraft - e.g., a mean airworthiness target of not more than one airworthiness catastrophe per 10 million ( ) hours, as made up of two parts, the first being 3/4 of the total and catering for the basic design risk and the other being 1/4 of the total, forming an allowance to be used during the individual aircraft's whole life for unforeseen campaign situations such as described above.

3.6 Investigation has shown that a total of ten such occasions might arise during the life of an individual aircraft.

3.7 Using these criteria, there could then be during each of these emergency periods (assumed to be ten in number) a risk allowance contributed by the campaign alone of:

1×10^{-7} for 2.5% of the aircraft's life; or

5×10^{-7} for 0.5% of the aircraft's life; or

1×10^{-6} for 0.25% of the aircraft's life; or

1×10^{-5} for 0.025% of the aircraft's life, etc.

without exceeding the agreed 'allowance' set aside for this purpose.

3.8 Thus a 'reaction table' can be created as indicated in Table 1 (the last two columns assuming a typical aircraft design life of 60,000 hours and an annual utilisation of 3 000 hours per annum) showing the flying or calendar time within which a defect should be corrected if the suggested targets are to be met.

Estimated catastrophe rate to aircraft due to the defect under consideration (per a/c hour)	Average reaction time for aircraft at risk (hours)	On a calendar basis
4 x 10-8	3 750	15 months
5 x 10-8	3 000	12 months
1 x 10-7	1 500	6 months
2 x 10-7	750	3 months
5 x 10-7	300	6 weeks
1 x 10-6	150	3 weeks
1 x 10-5	15	Return to base

Table 1

3.9 These principles may be applied to a single aircraft or a number of aircraft of a fleet but in calculating risk, all the risk should be attributed to those aircraft which may carry it, and should not be diluted by including other aircraft in the fleet which are known to be free of risk. (It is permissible to spread the risk over the whole fleet when a source is known to exist without knowing where). Where a fleet of aircraft is involved Column 2 may be interpreted as the mean time to rectification and not the time to the last one.

3.10 There is one further constraint. However little effect a situation may have on the 'whole life' risk of an aircraft, the risk should not be allowed to reach too high a level for any given flight. Thus while a very high risk could be tolerated for a very short period without unacceptable degradation of the overall airworthiness target, the few flights involved would be exposed to a quite unacceptable level of risk. It is therefore proposed that the Table 1 should have a cut-off at the 2×10^{-6} level so that no flight carries a risk greater than 20 times the target. At this level the defect is beginning to contribute to a greater likelihood of catastrophe than that from all other causes, including non-airworthiness causes, put together. If the situation is worse than this, grounding appears to be the only alternative with possibly specially authorised high-risk ferry flights to allow the aircraft to

return to base empty. Figures 2 and 3 show a visualisation chart equivalent to Table 1, giving average rectification time (either in flight hours or months) based on probability of defect that must be corrected.

3.11 It will be seen that the above suggestions imply a probability of catastrophe from the campaign alone of 1.5/10 000 per aircraft during each separate campaign period (i.e., p = 0.015 per 100 aircraft fleet).

3.12 In addition, in order to take into account large fleet size effect, the expected probability of the catastrophic event during the rectification period on the affected fleet shall not exceed 0.1. See Figure 4.

3.13 It should also be noted that in assessing campaign risks against 'design risk', an element of conservatism is introduced, since the passenger knows only 'total risk' (i.e. airworthiness plus operations risks) and the fatal accident rate for all reasons is an order of magnitude greater than that for airworthiness reasons only (i.e., 10^{-6} as against 10^{-7}). The summated campaign risk allowance proposed by this GM is therefore quite a small proportion of the total risk to which a passenger is subject. When operating for short periods at the limit of risk proposed (2 x 10^{-6} per hour) the defect is however contributing 100 % more risk than all other causes added together.

3.14 A similar approach is proposed to cover the case of defects associated to hazardous failure conditions for which the safety objectives defined by the applicable certification specifications are not met. According to CS 25.1309, the allowable probability for each hazardous failure condition is set at 10^{-7} per flight hour compared to 10^{-9} per flight hour for a catastrophic failure condition. Figure 5 is showing a visualisation chart giving average rectification time based on probability of defect that should be corrected. This is similar to Figure 2 but with lower and upper boundaries adapted to cover the case of hazardous failure conditions (probabilities of 10^{-7} and $2x10^{-4}$ respectively).

3.15 In addition, in order to take into account large fleet size effect, the expected probability of the hazardous event during the rectification period on the affected fleet shall not exceed 0.5. See Figure 6.

4. GUIDELINES

4.1 The above would lead to the following guidelines for a rectification campaign to remedy a discovered defect associated to a catastrophic failure condition without grounding the aircraft:

(i) Establish all possible alleviating action such as inspections, crew drills, route restrictions, and other limitations.

(ii) Identify that part of the fleet, which is exposed to the residual risk, after compliance has been established with paragraph (i).

(iii) Using reasonably cautious assumptions, calculate the likely catastrophic rate for each aircraft carrying the risk in the affected fleet.

(iv) Compare the speed with which any suggested campaign will correct the deficiency with the time suggested in Figure 2. The figure should not be used beyond the $2x10^{-6}$ level, except for specially authorised flights.

(v) Also ensure that the expected probability of the catastrophic event during the rectification period on the affected fleet is in accordance with Figure 4.

4.2 Similarly, the following guidelines would be applicable for a rectification campaign to remedy a discovered defect associated to a hazardous failure condition without grounding the aircraft:

(i) Establish all possible alleviating action such as inspections, crew drills, route restrictions, and other limitations.

(ii) Identify that part of the fleet, which is exposed to the residual risk, after compliance has been established with paragraph (i).

(iii) Using reasonably cautious assumptions, calculate the likely hazardous rate for each aircraft carrying the risk in the affected fleet.

(iv) Compare the speed with which any suggested campaign will correct the deficiency with the time suggested in Figure 5.

(v) Also ensure that the expected probability of the hazardous event during the rectification period on the affected fleet is in accordance with Figure 6.

4.3 It must be stressed that the benefit of these guidelines will be to form a datum for what is considered to be the theoretically maximum reaction time. A considerable amount of judgement will still be necessary in establishing many of the input factors and the final decision may still need to be tempered by non-numerical considerations, but the method proposed will at least provide a rational 'departure point' for any exercise of such judgement.

4.4 It is not intended that the method should be used to avoid quicker reaction times where these can be accommodated without high expense or disruption of services.

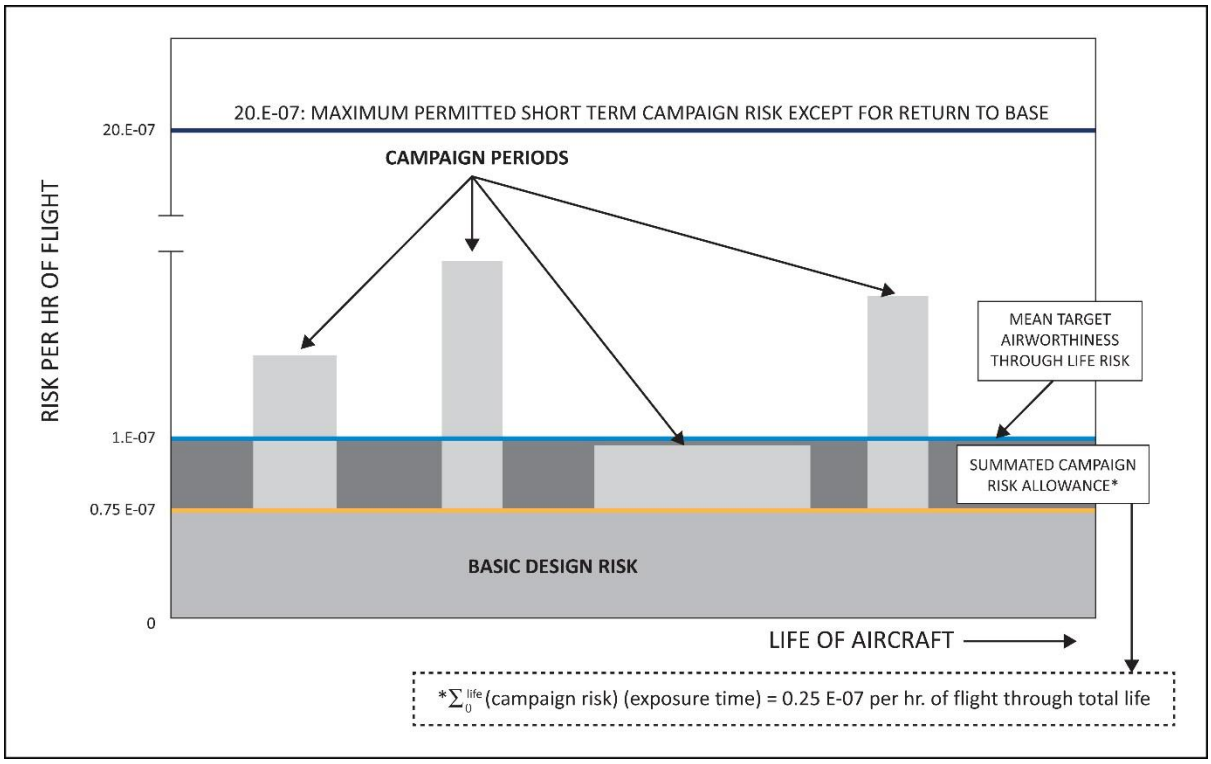


Figure 1 - Visualisation Chart for CS-25

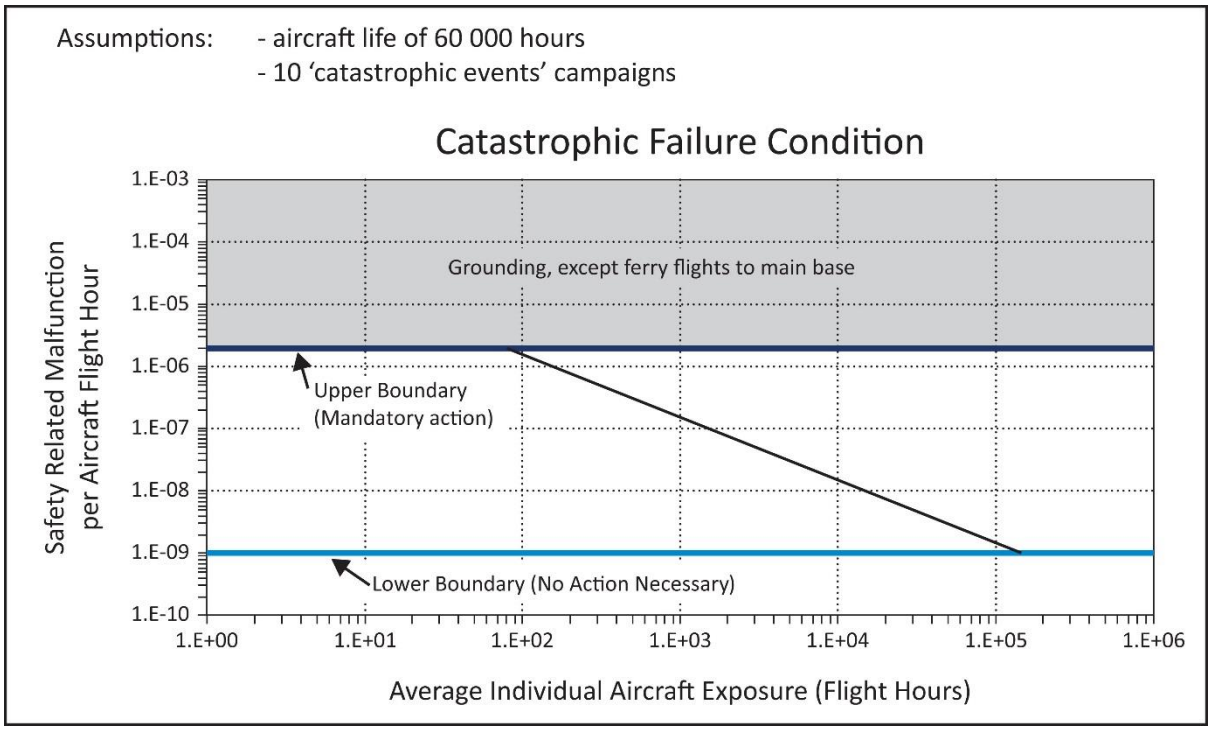


Figure 2 - Visualisation Chart for CS-25 (Flight hours)

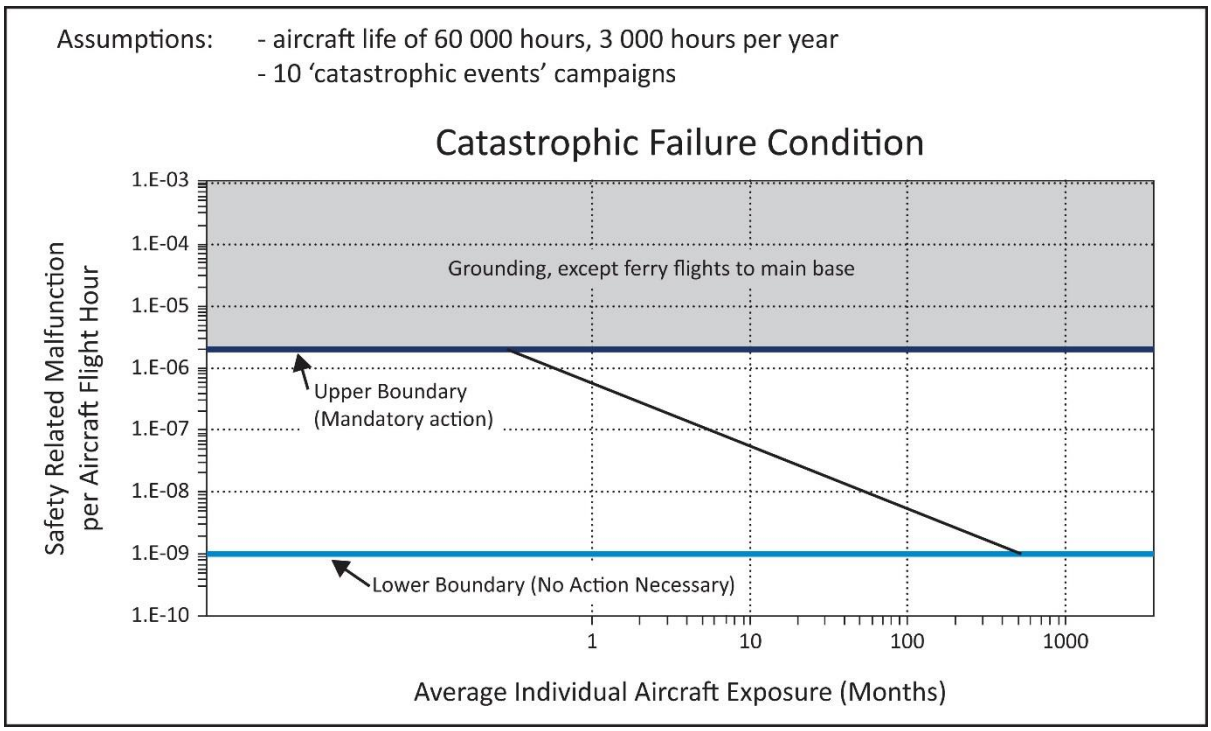


Figure 3 - Visualisation Chart for CS-25 (Calendar basis)

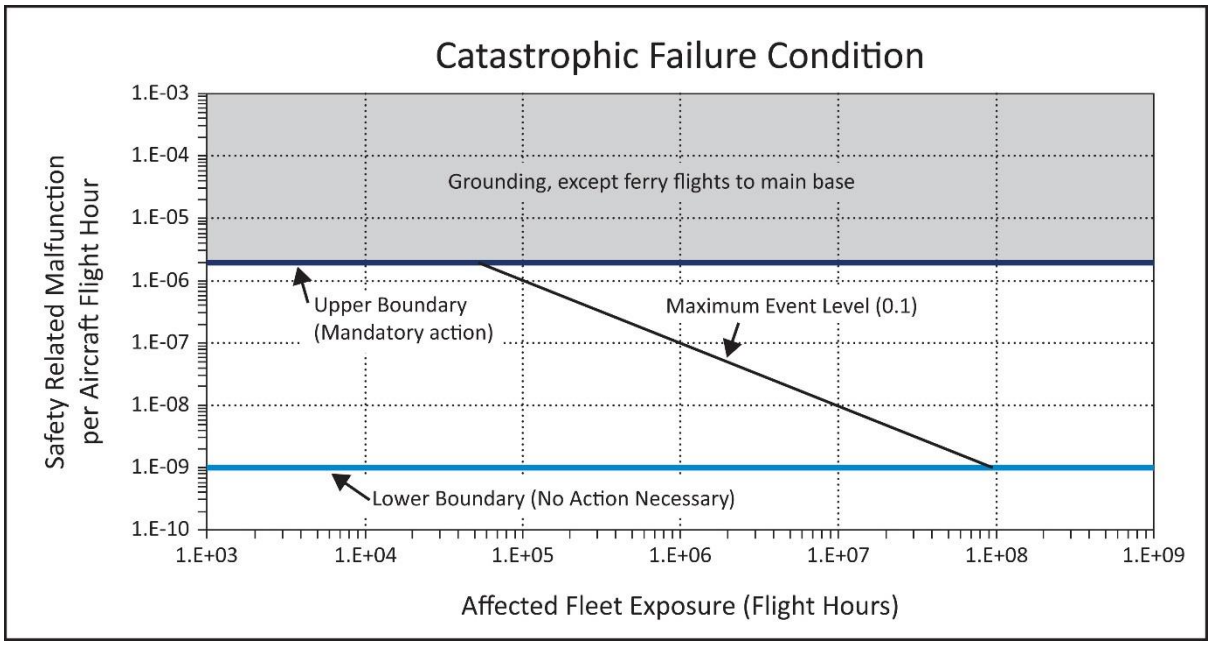


Figure 4 - Visualisation Chart for CS-25 (Flight Hours)

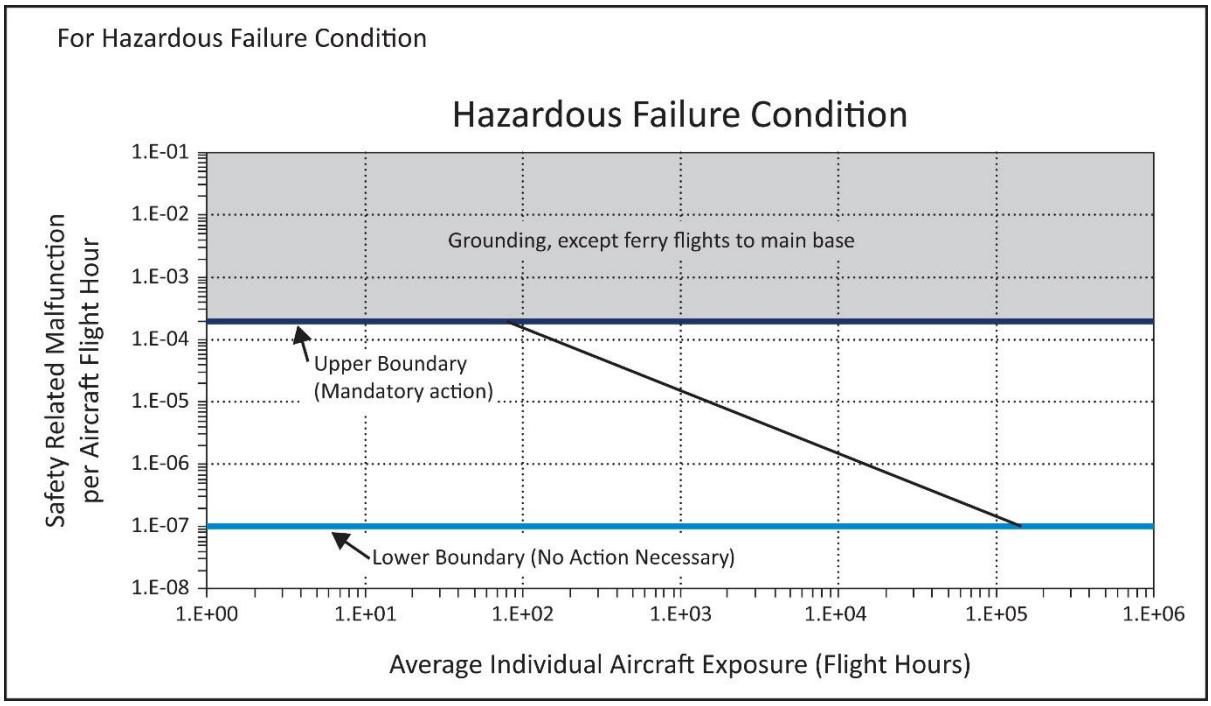


Figure 5 - Visualisation Chart for CS-25 (Flight hours)

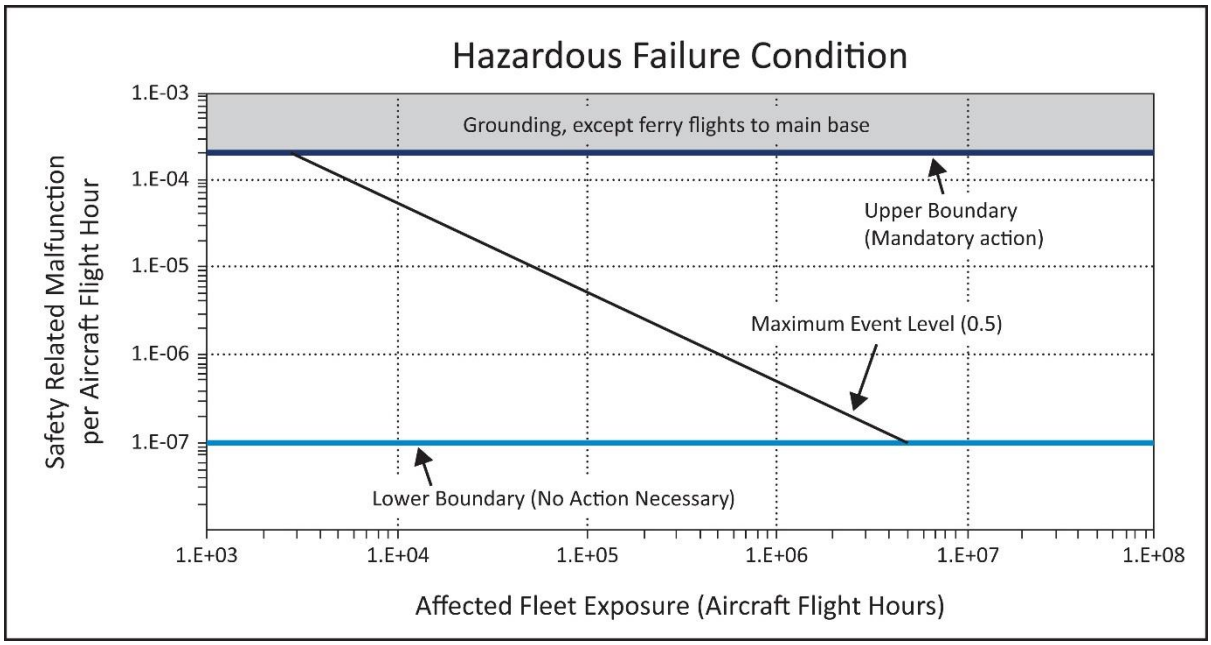


Figure 6 - Visualisation Chart for CS-25 (Flight hours)

21.A.4 Coordination between design and production

Regulation (EU) No 69/2014

Each holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, approval of a change to type-certificate or approval of a repair design, shall collaborate with the production organisation as necessary to ensure:

(a) the satisfactory coordination of design and production required by 21.A.122, 21.A.130(b)(3) and (4), 21.A.133 and 21.A.165(c)(2) and (3) as appropriate; and

(b) the proper support of the continued airworthiness of the product, part or appliance.

AMC 21.A.4 Transferring of information on eligibility and approval status from the design holder to production organisations

ED Decision 2014/007/R

Where there is a need to provide (normally outside the design organisation) a visible statement of approved design data or airworthiness, operational suitability or environmental protection data associated with the approved design data, the following minimum information must be provided. The need for a visible statement may be in relation to Company holding a production organisation approval (POA) in relation to 21.A.163(c).

The procedures related to the use of forms or other electronic means to provide this information must be agreed with the Agency.

Information to be provided:

Company Name: the name of the responsible design organisation (TC, STC, approval of repair or minor change design, ETSO authorisation holder) issuing the information.

Date: the date at which the information is released.

Eligibility: indicate the specific products or articles, in case of ETSO authorisation, for which data have been approved.

Identification: the part number of the part or appliance. Preference should be given to the use of the Illustrated Parts Catalogue (IPC) designation. Alternatively the reference to the instruction for continued airworthiness (e.g., SB, AMM, etc.) could be stated. Marking requirements of Part 21 Section A Subpart Q should be taken into account.

Description: the name or description of the part or document should be given. In the case of a part or appliance preference should be given to use of IPC designation. The description is to include reference to any applicable ETSO authorisation or EPA marking, or previous national approvals still valid.

Purpose of data: the reason for the provision of the information should be stated by the design approval holder.

Examples:

a) Provision of approved design data to a production organisation to permit manufacture (AMC No 1 to 21.A.133(b) and (c))

b) Information regarding eligibility for installation (replacement parts, repair, modification, etc.)

c) Direct Delivery Authorisation (AMC No 1 to 21.A.133(b) and (c))

If the data is in support of a change or repair, then reference to the aircraft level approval should be given (make reference to the approved STC, change or repair).

Limitations/Remarks: state any information, either directly or by reference to supporting documentation that identifies any particular data or limitations (including specific importing requirements) needed by a production organisation to complete Block 12 of the EASA Form 1.

Approval: provide reference information related to the approval of the data (Agency document or DOA privilege).

Authorised signature: name and hand-written normal or electronic signature of a person who has written authority from the design organisation, as indicated in the procedures agreed with the Agency.

21.A.5 Record-keeping

Regulation (EU) 2022/201

All natural or legal persons that hold or have applied for a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, design or repair approval, permit to fly, production organisation approval certificate or letter of agreement under this Regulation shall:

(a) when they design a product, part or appliance or changes or repairs thereto, establish a record-keeping system and maintain the relevant design information/data; that information/data shall be made available to the Agency in order to provide the information/data that is necessary to ensure the continued airworthiness of the product, part or appliance, the continued validity of the operational suitability data, and compliance with the applicable environmental protection requirements;

(b) when they produce a product, part or appliance, record the details of the production process relevant to the conformity of the product, part or appliances with the applicable design data, and the requirements imposed on their partners and suppliers, and make that data available to their competent authority in order to provide the information that is necessary to ensure the continuing airworthiness of the product, part or appliance;

(c) with regard to permits to fly:

1. maintain the documents that are produced to establish and justify the flight conditions, and make them available to the Agency and to their competent authority of the Member State in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

2. when they issue a permit to fly under the privilege of approved organisations, maintain the documents associated with it, including inspection records and documents that support the approval of the flight conditions and the issuance of the permit to fly itself, and make them available to the Agency and to their competent authority of the Member State responsible for the oversight of the organisation in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

(d) retain records of the competence and qualifications, referred to in points 21.A.139(c), 21.A.145(b), 21.A.145(c), 21.A.239(c), 21.A.245(a) or 21.A.245(e)(1), of the personnel that are involved in the following functions:

1. design or production;

2. independent monitoring of the compliance of the organisation with the relevant requirements;

3. safety management;

(e) retain records of the authorisation of personnel, when they employ personnel that:

1. exercise the privileges of the approved organisation pursuant to points 21.A.163 and/or 21.A.263, as appropriate;

2. carry out the independent function to monitor the compliance of the organisation with the relevant requirements pursuant to points 21.A.139(e) and/or 21.A.239(e), as appropriate;

3. carry out the independent verification function of the demonstration of compliance pursuant to point 21. A.239(d)(2).

AMC1 21.A.5 Record-keeping

ED Decision 2023/014/R

GENERAL

(a) The record-keeping system should ensure that all the records that are required by point 21.A.5 are accessible within a reasonable time. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.

(b) The records should remain legible throughout the required retention period and be protected against damage, alteration, and tampering.

(c) The format of the records should be specified in the organisation's procedures.

(d) The organisation should ensure that copies of all the documents and supporting information that are developed:

(1) under the privileges that are defined under points 21.A.163 and 21.A.263; or

(2) for type certificates (TCs), restricted type certificates (RTCs), supplemental type certificates (STCs), major changes, and major repairs that are not issued under the privileges that are defined under point 21.A.263,

are retained throughout the operational life of the product or part.

(e) The retention period starts when the record is created or when it is last amended.

If the organisation transfers a certificate or a letter of agreement to another natural or legal person, the records related to the certificate or to the letter of agreement should be transferred to the new holder.

GM1 21.A.5 Record-keeping

ED Decision 2023/014/R

GENERAL

For organisations that hold or have applied for a type certificate (TC), restricted type certificate (RTC), supplemental type certificate (STC), a European technical standard order (ETSO) authorisation, a change to the TC approval, a repair design approval, a permit to fly, a production organisation approval (POA), or a letter of agreement under Part 21, the relevant design information/data includes at least the following, as applicable:

— design data such as type design data, as defined in point 21.A.31, and changes to that data, ETSO design data, and repair design data;

— drawings and test reports, including inspection records for the product tested;

— the certification programme, including related certification basis data (certification review items (CRIs), special conditions (SCs), equivalent safety findings (ESFs)); and

— compliance demonstration data.

For repair designs, the record-keeping requirement of point 21.A.5 applies to the data described in AMC1 21.A.433(b).

For production organisations (POs), the relevant records include at least:

— conformity justification data; and

— conformity attestation data (e.g. EASA Form 1 or EASA Form 52).

GM1 21.A.5(a) and (b) Record-keeping

ED Decision 2022/021/R

RECORDING AND ARCHIVING SYSTEM

The main objective of record-keeping in design organisations (DOs) and production organisations (POs) is to ensure the retrievability of data that is required for the continued airworthiness of in-service products.

In addition, records within the design environment are essential to ensure proper control of the configuration of the type design and of its compliance with the certification basis.

In the production environment, records are also required, to ensure that products or parts are in conformity with the applicable data throughout the manufacturing cycle. In addition, certain records of milestones are needed, to subsequently provide objective evidence that all the prescribed stages of the production process have been satisfactorily completed.

Therefore, the approved DO or PO (or a natural or legal person that is demonstrating their design capability through an agreement on alternative procedures or through the acceptance of the organisation's certification programme, or a natural or legal person that produces products and parts under Part 21, Subpart F) are required to implement a system for the compilation and retention of

records during all stages of design or production, which covers short-term and long-term records as appropriate to the nature of the product and its processes.

The management of such information is subject to the appropriately documented procedures in the management system that is required by points 21.A.139 and 21.A.239 or to the manual/procedures that are required by points 21.A.14(b), 21.A.125A(b), or 21.A.602B(b)(2), as appropriate. This also applies in case of demonstrating the design capability through the acceptance of the certification programme under point 21.A.14(c).

All forms of recording media are acceptable (paper, film, magnetic, etc.), including the use of electronic records*, provided that they can meet the required duration for archiving under the given conditions and that the continued readability of the records is ensured.

The related procedures are required to:

— identify the records to be kept;

— describe the organisation of, and responsibility for, the archiving system (its location, compilation, format) and the conditions for access to the information (e.g. by product, subject, etc.);

— control access to the data and provide effective protection from deterioration or accidental damage, alteration, and tamperering;

— ensure the continued readability of the records;

— demonstrate to the competent authority the proper functioning of the record system; and

— define an archiving period for each type of data as follows:

    — production data that supports the conformity of a product, part, or appliance is kept for not less than 3 years from the issue date of the related statement of conformity or authorised release certificate; and

    — design data, including data that supports the compliance of a product, part, or appliance with the certification basis (see GM1 21.A.5), as well as data that is considered essential for continuing airworthiness, is kept throughout the operational life of the product, part, or appliance; such continued airworthiness data may include, but are not limited to, in-service occurrence reports and mandatory continuing-airworthiness information;

— for organisations that are approved according to Part 21, Subparts G and J and organisations that demonstrate their design capability through an agreement on alternative procedures or acceptance of their certification programme by EASA, ensure that the recording and record-keeping systems that are used by the partners, suppliers, and subcontractors meet the record-keeping objectives with the same level of confidence as they do for their own system;. in each case, it should be defined who should retain the data record (organisation, partner, supplier, or subcontractor), as well as the method of surveillance of the recording/record-keeping system of the partners, suppliers, or subcontractors; and

— for natural or legal persons that produce items under Part 21, Section A, Subpart F, the data on supplied parts may be retained by the supplier if the supplier has a system that is agreed by the competent authority under Part 21, Section A, Subpart F; in each case, the PO is required to define the archiving period and satisfy itself and the competent authority that the recording media are acceptable.

*Related to electronic records, the following definitions apply:

— electronic record: electronic or digital data that is created, generated, sent, communicated, received, or stored by electronic means;

— electronic data: it is typically in the form of documentation that is statically stored in a computer file that is not modifiable (e.g. pdf of a scanned document with wet ink signatures); and

— digital data: it is typically in the form of computer-generated bytes of information that is stored in a computer workable file (e.g. MS Word file, MS Excel file, 3D CAD file).

AMC1 21.A.5 (d) & (e) Record-keeping

ED Decision 2022/021/R

RECORD OF STAFF INVOLVED IN DESIGN OR PRODUCTION

(a) The following should be the minimum information to be recorded for each person that exercises the privileges of an organisation that is approved according to Part 21, Subparts G and J, or according to points 21.A.163 or 21.A.263, or that carries out the independent monitoring of compliance and adequacy according to points 21.A.139(e) and 21.A.239(e), or that carries out the independent verification function of demonstration of compliance pursuant to point 21.A.239(d)(2):

(a) name;

(b) date of birth;

(c) basic training received and standard attained;

(d) specific training received and standard attained;

(e) continuation training received (if appropriate);

(f) experience gained;

(g) scope of the authorisation;

(h) date of first issue of the authorisation;

(i) expiry date of the authorisation (if appropriate;

(j) identification number of the authorisation (or equivalent means to identify the link between the authorisation and the staff member that holds the authorisation); and

(k) changes to the data.

(b) The record may be kept in any format and should be controlled through an internal procedure of the organisation. That procedure is part of the management system.

(c) The staff member should be given reasonable access, on request, to their own records as per Regulation (EU) 2016/679.

(d) A design organisation (DO) or production organisation (PO) should keep the record for at least 3 years after the staff member is no longer employed by the organisation or has changed their position in the organisation, or after the withdrawal of the authorisation, whichever occurs sooner.

(e) Records of authorisation of the production staff are to be archived for at least 3 years after the staff member is no longer employed by the organisation or as soon as the authorisation is withdrawn. This staff member is any person that has an activity that is essential for ensuring:

— the conformity to applicable design data, or

— a condition for the safe operation of a product, part, or appliance.

21.A.6 Manuals

Regulation (EU) 2021/699

The holder of a type-certificate, restricted type-certificate, or supplemental type-certificate shall produce, maintain and update master copies of all manuals or variations in the manuals required by the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements for the product or article, and provide copies, on request, to the Agency.

21.A.7 Instructions for continued airworthiness

Regulation (EU) 2021/699

(a) The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, design change or repair design approval shall develop or reference the instructions which are necessary for ensuring that the airworthiness standard related to the aircraft type and any associated part is maintained throughout the operational life of the aircraft, when demonstrating compliance with the applicable type-certification basis established and notified by the Agency in accordance with point 21.B.80.

(b) At least one set of complete instructions for continued airworthiness shall be provided by the holder of:

1. a type-certificate or restricted type-certificate to each known owner of one or more products upon its delivery or upon the issuance of the first certificate of airworthiness or restricted certificate of airworthiness for the affected aircraft, whichever occurs later,

2. a supplemental type-certificate or design change approval to all known operators of the product affected by the change upon the release to service of the modified product,

3. a repair design approval to all known operators of the product affected by the repair upon the release to service of the product in which the repair design is embodied. The repaired product, part or appliance may be released into service before the related instructions for continued airworthiness have been completed, but this shall be for a limited service period, and in agreement with the Agency.

Thereafter, those design approval holders shall make those instructions available on request to any other person required to comply with those instructions.

(c) By way of derogation from point (b), the type-certificate holder or restricted type-certificate holder may delay the availability of a part of the instructions for continued airworthiness, dealing with long lead accomplishment instructions of a scheduled nature, until after the product or modified product has entered into service, but shall make those instructions available before the use of this data is required for the product or modified product.

(d) The design approval holder, who is required to provide instructions for continued airworthiness in accordance with point (b), shall also make available changes to those instructions to all known operators of the product affected by the change and, on request, to any other person required to comply with those changes. That design approval holder shall demonstrate to the Agency, on request, the adequacy of the process of making changes to the instructions for continued airworthiness available in accordance with this point.

AMC1 21.A.7(a) ICA contents

ED Decision 2021/007/R

(a) The instructions for continued airworthiness (ICA) should identify the following, in accordance with the applicable certification specifications:

(1) any limitations that are necessary for the continued airworthiness of the product or article;

(2) the means to determine when the product or article has deteriorated to the extent that it is no longer airworthy;

(3) the minimum actions required to restore the airworthiness of the product or article before the limitations (as per point (1)) have been exceeded or before their deterioration (as per point (2)), as an alternative to the withdrawal of the product or article from service.

(b) The ICA should, therefore, include, in accordance with the applicable certification specifications:

(1) any limitations determined through the certification of the product or article, and instructions on how to determine that the limitations have been exceeded;

(2) any inspection, servicing or maintenance actions determined to be necessary by the certification process;

(3) any inspection or troubleshooting actions determined to be necessary to establish the nature of faults and the necessary remedial actions;

(4) sufficient general information on the operation of the product or article to enable the understanding of the instructions in (a)(1) to (a)(3) above.

AMC2 21.A.7(a) Identification of ICA

ED Decision 2021/007/R

The instructions for continued airworthiness (ICA) may be provided together with other, additional or optional, maintenance information, as described in point 21.A.6, or in another acceptable format as per GM1 21.A.7(a), with the following conditions:

(a) The information that is necessary for the continued airworthiness is clearly identified (refer to AMC1 21.A.7(b)).

(b) The ICA may reference additional instructions for continued airworthiness in separate publications, where necessary (for example, those produced by suppliers).

If the product ICA reference the use of supplier's data (e.g. component maintenance manual (CMM) or section of it) as the appropriate location for the ICA, those applicable instructions are incorporated by reference and become part of the complete set of the ICA for the product.

(c) Additional or optional maintenance information not considered as ICA but referenced by the design approval holder (DAH) together with the ICA should be evaluated appropriately by the DAH in order to ensure that its use will not compromise the continued airworthiness of the product or article.

(d) If the maintenance data made available by a DAH includes data from an operator (i.e. in order to customise the data for the operator, and created under the authority of the operator), the operator's data should be identified as such, and the DAH is not required to additionally evaluate it.

AMC3 21.A.7(a) DAH responsibility to check the supplier data which is part of the ICA or referenced with the ICA

ED Decision 2021/007/R

The DAH may carry out a complete check of the supplier data, or may choose to rely, in whole or in part, on the supplier's process. In the latter case, the DAH will propose a means to validate the supplier's process. Supplier data may also be issued by the supplier to the DAH under a contract or an arrangement, addressing the following:

(a) the accuracy and the adequacy of the technical documentation, which should be checked through a verification processes (e.g. component workshop verification);

(b) evidence showing that workshop verification was performed should be kept by the supplier and a clear statement should be given in the introduction to the supplier data as a confirmation that component verification is complete;

(c) evidence that the supplier has taken into account all justified feedback and changes to data requested by any person required to use the ICA; typical examples would be the correction of reported errors, or mistakes.

In addition, some validation activities may be decided by the DAH, depending on the articles and the capability level of the supplier.

For articles subject to an ETSO authorisation, the validation of the supplier's process is not needed. This is also valid for other national TSO authorisations (e.g. FAA TSOs) accepted by EASA as stipulated in related bilateral agreements.

GM1 21.A.7(a) Scope of ICA, their publication format and typical ICA data

ED Decision 2021/007/R

(a) ICA can be published in documents or in a manner other than the traditional understanding of a document — for example, as a series of web pages, or Information Technology (IT) tools, or in a publishing format linked to tasks or data modules rather than pages.

(b) The design approval holder (DAH) can decide — within the framework provided by point 21.A.7 and its acceptable means of compliance and guidance material — to publish the ICA in the most suitable location as part of all the information published to support the airworthiness of an aircraft. Publications typically produced by DAHs (e.g. for the demonstration of compliance with a certification basis established on the basis of CS-25), and which may therefore include ICA, consist of:

- aircraft maintenance manuals (AMMs);
- scheduled maintenance requirements (e.g. MRBRs);
- off-wing component maintenance or overhaul manuals;
- parts catalogues;
- tooling manuals;
- wiring diagram manuals;
- weight and balance manuals;
- electrical loads analyses;

— extended range operations (ETOPS) configuration maintenance programs/plans;

— supplemental structural inspection documentation;

— certification maintenance requirements;

— Airworthiness Limitations items;

— ageing aircraft maintenance requirements;

— fuel tank safety related limitations (e.g. critical design configuration control limitation (CDCCL));

— electrical wiring interconnection system instructions;

— corrosion prevention and control programmes;

— troubleshooting manuals.

Note: The above is only an example of the publications that may contain ICA according to CS-25; the list is not exhaustive, nor does it represent a minimum list of ICA.

(c) The requirement for ICA is not intended to ensure that all products or articles may be restored to an airworthy condition. A certain level of deterioration may require a product or an article to be permanently withdrawn from service, and restoration may not be reasonably achievable. Notwithstanding the above, the existence of an MRBR task other than 'Discard (DS or DIS)' should be a clear indication of the necessity/obligation to produce a corresponding ICA.

Certain deteriorations or levels of deterioration may require specific instructions (e.g. inspection or restoration) that will only be developed and provided on a case-by-case basis, as needed, for a given product or article, and as such, will not be included in the ICA.

In some exceptional cases, product ICA may ultimately instruct the user to contact the DAH in order to define the specific instructions on a case-by-case basis. This typically happens when the definition of generic instructions covering all possible cases is not possible. For example, following an aircraft hard landing, a detailed analysis may have to be carried out by the DAH to determine the specific instructions to be followed, which depends on the touchdown loads, recalculated postflight, based on recorded flight data.

GM2 21.A.7(a) Determination of which supplier data is part of the ICA

ED Decision 2021/007/R

Note 1: For the purpose of this GM, the term 'supplier data' also applies to similar types of data when issued directly by the DAH (e.g. component maintenance manuals issued by the DAH).

Note 2: For the purpose of this GM, the term 'supplier data' has to be understood as data coming from the supplier and related to either a full CMM or to part of a CMM.

Note 3: The link between the aircraft ICA and the engine/propeller CMM, as detailed below, is similar to the link between engine/propeller ICA and the CMM of equipment fitted to the engine/propeller.

Note 4: If the supplier is also the DAH (for instance, an engine or propeller manufacturer), then the ICA for these items will be made available by virtue of the DAH obligations as type-certificate holder (TCH) and need not be included in the aircraft ICA.

(a) When determining whether a supplier data is part of the ICA, the following should be considered:

(1) Supplier data related to the Airworthiness Limitations Section (ALS) of the ICA is part of the ICA. A typical CS-25 example is critical design configuration control limitation (CDCCL) items that are included in CMMs.

(2) Supplier data related to instructions on how to accomplish the scheduled maintenance part of the aircraft ICA (such as MRBR) are part of the aircraft ICA. A typical case is the periodical removal of a component to perform a workshop task.

Example: Escape slide removal for restoration in accordance with the supplier data instructions.

(3) Supplier data related to scheduled maintenance on the component should be endorsed by the DAH before becoming part of the aircraft ICA, to define and confirm that the supplier data is applicable and effective.

(4) If the ICA are defined at aircraft level, the following principles apply to the other supplier data that is not related to the ALS nor to scheduled maintenance:

(i) If the supplier data includes a maintenance instruction for an action identified in the aircraft-level ICA, including an engine or propeller, this supplier data should be referenced in the aircraft-level ICA and should be made available like any other ICA.

As an alternative to linking such supplier data to the aircraft-level ICA (e.g. with cross references), it is possible to include the relevant data directly into the aircraft ICA. In such a case, the supplier data is not part of the aircraft ICA since the aircraft ICA already contain all the required information.

(ii) If an aircraft ICA task only requires a replacement task for an engine, propeller, part or appliance (i.e. ‘remove and replace’ or ‘discard’) and does not refer to the supplier data for further maintenance of the removed engine, propeller, part or appliance, this means that the aircraft airworthiness may only be maintained by replacement action, and that the supplier data is not part of the ICA for the aircraft. In such cases, the supplier data does not need to be referenced in the aircraft ICA.

Example: If supplier data provides off-aircraft maintenance instructions for an engine, propeller, or other article (i.e. workshop maintenance), then this data may not be considered as part of the complete set of ICA for the aircraft, but may be considered as part of the complete set of ICA for the engine or propeller. However, the procedure for removal from / installation on the aircraft is necessarily part of the aircraft ICA.

(b) However, for the above cases, aircraft-level ICA can provide, as additional or optional maintenance information, the references to the supplier data even if it is not considered part of the ICA. In such cases, it should be made clear that the supplier data references are provided as additional or optional maintenance information and is not part of the product ICA. Besides, it should be ensured that the use of additional or optional maintenance information not considered as ICA but referenced together with the ICA will not compromise the continued airworthiness of the product or article.

(b) For the supplier data identified as part of the ICA, the DAH should:

(1) identify the supplier data that is part of the ICA; this can be achieved either by creating a listing or by any other acceptable means that allow to identify which data is part of the ICA and which data is not part of the ICA (refer to AMC1 21.A.7(b));

(2) just as for any other ICA, ensure the publication of the supplier data;

(3) ensure the accuracy and the adequacy of the technical content of the supplier data (refer to GM No. 1 to 21.A.239(a), point 3.1.5)

GM3 21.A.7(a) Non-ICA supplier data (e.g. component maintenance manuals (CMMs))

ED Decision 2021/007/R

(a) Non-ICA supplier data referenced together with the ICA

Supplier data, or parts of the supplier data, which is not considered to be part of the ICA but is additional or optional maintenance information referenced together with the product-level ICA, may be issued by the supplier to the DAH under a contract or an arrangement, using the methodology proposed in AMC3 21.A.7(a).

(b) Other non-ICA supplier data

Non-ICA supplier data, which is not referenced together with the ICA, but which can be used for the maintenance of components approved for installation by the DAH, should be acceptable to the DAH. This non-ICA supplier data may be documented in a list.

AMC1 21.A.7(b) Identification of a complete set of instructions for continued airworthiness (ICA)

ED Decision 2021/007/R

The design approval holder (DAH) should identify the complete set of ICA according to point 21.A.7(b) in such a way that the complete set can be:

(a) directly listed in the product TCDS; or

(b) indirectly referenced in the TCDS through other means, which allow the complete list of the ICA to be obtained (e.g. a complete listing of ICA contained in a 'principal manual' or a reference to a DAH's website); or

(c) directly listed in the product STC; or

(d) indirectly referenced in the STC through other means, which allow the obtainment of the complete list of the ICA; or

(e) if direct reference is made to the ICA in the TCDS or the STC, no reference to the revision level of the ICA should be made; in this case, the revision level should be available elsewhere (e.g. on the DAH's website).

For changes to type certificates and repairs, the identification of 'a complete set of the changes to the instructions for continued airworthiness' should be performed by the DAH by a statement to provide this information, or by confirmation that there are no changes to the ICA. This statement can also be made in the accomplishment document (e.g. embodiment instructions).

For products and articles for which the DAH holds a design organisation approval (DOA), the ICA are considered to be issued under the authority of the DOA and, therefore, the approval of the ICA should be made explicit to the reader in accordance with point 21.A.265(h), unless otherwise agreed with EASA.

GM1 21.A.7(b) Other persons required to comply

ED Decision 2021/007/R

For the purpose of this GM, 'any other person required to comply' means:

— any independent certifying staff who performs maintenance on a product or article, in accordance with Regulation (EU) No 1321/2014, in the framework of a contract (or work order) with the person or organisation responsible for the aircraft continuing airworthiness;

— any maintenance organisation approved to maintain a product or article, in accordance with Regulation (EU) No 1321/2014, in the framework of a contract (or work order) with the owner of the engine or article, or the person or organisation responsible for the aircraft continuing airworthiness;

— any organisation approved to manage the aircraft continuing airworthiness in accordance with Regulation (EU) No 1321/2014, in the framework of a contract with the aircraft owner or aircraft operator.

GM2 21.A.7(b) ICA — format

ED Decision 2021/007/R

ICA can be furnished or made available by various means (including paper copies, electronic documents, or web-based access). Regardless of the format, the design approval holder (DAH) is expected to furnish or make ICA available in a means that is readily accessible for and useable by the owner and any person required to comply with the ICA. Service documents, such as service information letters, may be used for transmitting ICA information and updates.

(a) Formatting standards

Applicants may use the latest ATA, AECMA/ASD or GAMA formatting standards such as:

(1) AeroSpace and Defence Industries Association of Europe (ASD), ASD-S1000D, *International Specification for Technical Publications Utilizing a Common Source Data Base*, version 4 or higher;

(2) the Air Transport Association's (ATA) iSpec 2200, *Information Standards for Aviation Maintenance*, latest edition (ATA is now known as Airlines for America (A4A) but the standard is still listed as ATA); or

(3) General Aviation Manufacturers Association (GAMA) Specification No. 2, *Specification for Manufacturers Maintenance Data*, latest edition.

In regard to scheduled maintenance, applicants may also refer to the glossary of the ATA MSG-3 standard, latest revision, for standardised task definitions and designations.

(b) General considerations

ICA should be easy to read and to follow. All ICA should include a means to identify their applicability (model, type, etc.), and the associated revision status. Refer to sample formats in the Air Transport Association's iSpec 2200, *Information Standards for Aviation Maintenance*, latest edition, or AECMA/ASD standards. There is no requirement for any specific format or arrangement of the ICA in document or documents. However, the specific format selected by the applicant should be used and applied in a uniform manner. Empty pages in a document should contain a statement like 'Intentionally left blank' or similar.

At the beginning of each procedure, the ICA should contain cautions and warnings regarding possible mistakes that can be made when following the instructions.

Abbreviations, acronyms and symbolisation should be either avoided or explained as part of the ICA documentation.

ICA contain units of measurement. Measurements could be, for instance, instrument readings, temperatures, pressures, torque values with tolerances, limits, and ranges when applicable. If the ICA contain units of measurement of a system other than the metric, the ICA should include a conversion to the metric system for each measurement, tolerance, or torque value. A general conversion table alone should not be provided, as it may introduce an additional source of error.

The DAH should use a means to indicate changes to the ICA directly in relation to each item of the information/data of the ICA, e.g. using a vertical change bar in the margin next to the line.

(c) Publication of ICA in multiple documents

DAHs may prepare ICA as a document, or several documents, depending on how much data is necessary to provide a complete set of ICA.

If there are multiple documents, there should be a principal document that describes the general scope of all other documents, in order to provide an overview of the multiple document structure.

According to different standards, the Airworthiness Limitations Section (ALS) needs to be included in the principal document as a dedicated section. However, EASA may also accept a separate Airworthiness Limitations document, when it is at least referenced as such in the principal document.

DAHs who decide to segregate information dedicated to a specific subject from a principal document into a separate document, e.g. 'Fuel Pipe Repair Manual', 'Cable Fabrication Manual', 'Duct Repair Manual' or 'Instrument Display Manual', should declare these documents to be ICA.

DAHs may decide to integrate certain information in a principal document (as, for example, troubleshooting information as part of the aircraft maintenance manual (AMM) instead of a separate troubleshooting manual (TSM)).

(d) Language

ICA should be provided in any of the official language(s) of the European Union which is (are) acceptable to the competent authority.

Note: In certain countries, such as the USA, English is required for ICA. EASA, therefore, recommends that DAHs include a version of the ICA in simplified technical English (e.g. in accordance with ASD Specification STE100).

(e) Electronic media

ICA may be provided in an electronic format (e.g. CDs, via the internet, etc.) instead of paper copies or microfilms (refer to AMC1 21.A.7(b)).

When an electronic format is used, the DAH should consider aspects such as the traceability of updates, keeping previous versions (record keeping), data security and the obligations of the person(s) or organisation(s) responsible for the aircraft continuing airworthiness, considering that the ICA form the basis of the data used for continuing airworthiness activities.

GM3 21.A.7(b) Approval status of the manual for a component or article

ED Decision 2021/007/R

When the ICA refer to a document for a specific component or article, it is possible that this document is used for products from more than one DAH. In such cases, instead of placing approval statements from each DAH in the same manual, it may be more practical to identify the approved status of the relevant document through its inclusion in lists managed by the DAH in accordance with the AMC1 21.A.7(b).

GM4 21.A.7(b) Integration of ICA between products (aircraft, engines, propellers)

ED Decision 2021/007/R

The aircraft/engine/propeller type-certificate holder (TCH) should ensure the availability of ICA to allow maintenance of the aircraft, including engines/propellers when installed on the aircraft.

When referring to engine/propeller ICA directly in the aircraft ICA, the aircraft TCH should not perform additional verification and validation. However, the integration and interface aspects between the aircraft and the engine/propeller are still under the responsibility of the aircraft TCH.

If the ICA published by the aircraft TCH include some engine/propeller ICA developed by the engine/propeller TCH, the engine/propeller TCH should make an arrangement with the aircraft TCH setting out engine/propeller TCH and aircraft TCH shared responsibilities with respect to the ICA under point 21.A.7.

This arrangement should:

— define the part of the engine/propeller ICA which is published in the aircraft ICA; and

— address the development, publication and update processes of these ICA, including completeness and timely availability aspects.

The incorporated engine/propeller data content remains under the responsibility of the engine/propeller TCH, and the publication is under the responsibility of the aircraft TCH. Therefore, the aircraft TCH must coordinate with the engine/propeller TCH regarding any modification or alteration of the incorporated data.

AMC1 21.A.7(c) Completeness and timely availability of the ICA

ED Decision 2021/007/R

COMPLETENESS AND TIMELY AVAILABILITY OF THE ICA FOR TYPE-CERTIFICATE (TC) AND RESTRICTED TYPE-CERTIFICATE (RTC) APPLICANTS

(a) An applicant may wish to choose among the three options described below. Once the certification programme starts, it may be necessary to modify the initially selected option to accommodate programme changes. All such changes should be coordinated with EASA.

(1) Option 1: Complete ICA are available at the time of the design approval (TC/RTC)

(i) The ICA will be made available at the time of the design approval. This option minimises the risk of incomplete ICA, especially for changes.

(ii) With all ICA available at the time of the design approval, they should also be furnished / made available to the aircraft operator / aircraft owner and made available to any other person required to comply with any of those instructions in accordance with points 21.A.21(c)(4), 21.A.44 and 21.A.7, without using the provision to delay certain parts of the ICA after the entry into service.

(iii) Frequently, there is only a short period of time between the design approval and the entry into service. Nevertheless, applicants/holders may still wish to apply Option 2 or 3 for a part of their ICA as stated below.

(2) Option 2: Complete ICA are available at entry into service (TC/RTC)

If an applicant plans to make part of the ICA available to EASA at entry into service, the following approach is acceptable:

(i) For the ALS, as part of the type design, notwithstanding the selection of Option 2: the applicant submits the ALS for approval prior to the design approval. Any ALS content that is incomplete, not yet demonstrated for compliance, or delayed beyond the design approval, requires to be compensated through an interim limitation to establish compliance within this limitation. The interim limitation is notified to the aircraft operator(s) concerned as a temporary operational limitation in a manner agreed with EASA.

In this context, ALS content is understood as the task method (e.g. a detailed inspection), including its reference, title and applicability, and the associated threshold / interval / life-limit. The accomplishment procedure itself, i.e. how to carry out the task, is usually described in other parts of the ICA (e.g. in the AMM or NDT manual). However, the feasibility study of the accomplishment procedure is required for compliance with specific requirements (e.g. CS 25.611).

(A) This may typically apply when the aircraft structural full-scale fatigue testing required for compliance with the fatigue- and damage-tolerance requirements, considering the expected operational life, will not be completed prior to the type certificate being issued. In this case, a temporary operational limitation is assigned and stated in the ALS, dependent on the aircraft full-scale fatigue testing progress. The ALS is effectively incomplete beyond this temporary operational limitation, as the required justification and the resulting ICA are not yet available to support the safe operation of the aircraft beyond this limitation.

(B) A TCDS notation is not necessary, since the product is provided with complete ALS content up to the established temporary operational limitation.

(ii) A compliance plan identifying those parts of the ICA that are only to be made available at entry into service is produced, submitted to EASA and agreed between the applicant and EASA prior to the design approval (refer also to (iv) for ICA considered to be necessary at the time of the design approval.

(iii) A commitment is provided to produce, verify and submit (when requested) to EASA the relevant ICA prior to entry into service. This commitment should be provided in a certification document (e.g. the compliance plan) and should also be addressed in a more general manner in a DOA procedure for EU holders/applicants in accordance with points 21.A.239 and 21.A.263. If the respective DOA holder has not previously exercised the practice of delaying the ICA beyond the design approval in order for the DOA to demonstrate this capability in its design assurance system (DAS), the required procedural changes need to be addressed via a significant change to the DAS in accordance with point 21.A.247.

(iv) ICA considered to be necessary at the time of design approval are provided or made available in a format that adequately defines the data. Furthermore, the way the data is presented at the time of the design approval offers the same understanding of the data as in the final published format.

The applicant should agree with the Agency, in a compliance plan, on all ICA necessary at the time of design approval. The Agency investigation may vary from no involvement or evaluating a limited sample of the ICA to performing a thorough review of specific parts of the ICA.

(v) In cases where the AgencyEASA has doubts as to whether the applicant/holder can fulfil the applicable requirements of point 21.A.44 to control and support delaying the ICA beyond the design approval, or TC/RTC, and until entry into service, EASA can decide to assign a condition for entry into service for non-ALS ICA.

As a condition for the entry into service, a note should be included in the type certificate data sheet (TCDS) as a result of these pending issues under the ICA paragraph as follows:

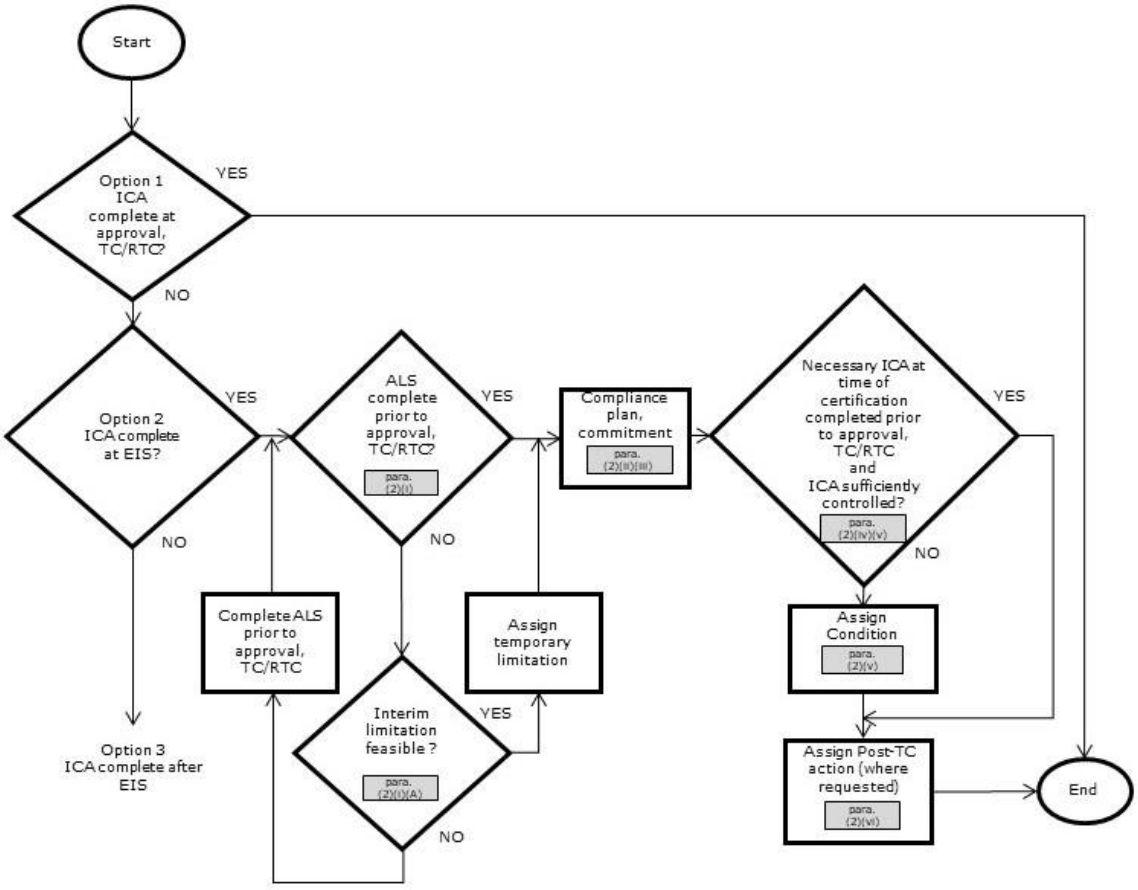
'Note: The ICA are not complete. As per point 21.A.7 of Commission Regulation (EU) No 748/2012, they must be completed before the entry into service of the aircraft. Contact EASA for information on the status.'

The decision to assign a condition may be based on the applicant's performance, e.g. if the applicant has already demonstrated in previous projects that it provided the complete set of ICA before the entry into service, if the applicant has already experienced difficulties in providing the ICA considered necessary at the time of the design approval, or has previously failed on a different project to meet its commitment to complete the ICA prior to entry into service, or if the applicant/holder has no previous experience with the practice of delaying the ICA beyond the design approval.

(vi) Post-TC action is established together with EASA (if EASA requests such a review) to review the ICA status at entry into service.

(vii) If all ICA are made available to EASA at the time of entry into service, they should also be furnished at this time to the aircraft operator / aircraft owner and made available to any other person(s) required to comply with any of those instructions in accordance with points 21.A.21(c)(4), 21.A.44 and 21.A.7, without using the provision to delay certain parts of the ICA beyond the entry into service. For an EU holder/applicant, this should be supported as part of the DOA/ADOA procedure.

Flow chart A — 'Completeness of ICA', Option 1 and 2



(3) Option 3: Complete ICA are available after the entry into service (TC/RTC)

As per point 21.A.7(c), certain ICA dealing with the 'overhaul or other forms of heavy maintenance' may be delayed until after the aircraft entry into service. Although there is no definition of what is meant by 'overhaul or other forms of heavy maintenance', the intention of the rule is to provide flexibility to applicants/holders for long-lead ICA of a scheduled nature.

If an applicant plans to make part of the ICA available only after the entry into service, the following is acceptable for the complete set of ICA:

(i) for the ALS, as it cannot be delayed until after the entry into service, point (i) of Option 2 applies;

(ii) for ICA considered to be necessary at the time of the design approval, point (iv) of Option 2 applies.

(iii) a detailed compliance plan identifying those parts of the ICA that are to be provided prior to and after the entry into service. For ICA made available after the entry into service, the plan should account for when the ICA are needed so that they can be complied with. This approach may only be used for scheduled maintenance accomplishment procedures, where threshold / interval / life-limit requirements of the related scheduled tasks are established. In that respect, the following aspects should be considered:

(A) The majority of the ICA are of an unscheduled nature; therefore, these items should be available at entry into service at the latest.

(B) Consideration should be given to the fact that a number of tasks are used for both scheduled and unscheduled maintenance (e.g. an operational check of a system is planned as a scheduled task at a certain point in time, but is also required as part of the installation procedure to determine the operational status of the system).

(C) For ICA to be made available after entry into service, the detailed plan should contain threshold(s) controlled by the applicant/holder, stating the maximum value in flight hours (FH) / flight cycles (FC) or calendar time (CT), or a combination of them as applicable, by which point in time the delayed ICA should be made available.

(D) This detailed plan should be available prior to the time of the design approval and should be either directly integrated or cross-referenced in a compliance plan.

(E) Information on the format in which the ICA delayed until after entry into service will be made available in time (e.g. regular revisions or temporary revisions (TRs) or service information (SBs, SIL, etc.).

(iv) A procedure/programme that ensures a detailed plan is produced and implemented in the applicant's organisation in order to ensure the timely availability (to the aircraft operator / aircraft owner and to any other person required to comply with any of those instructions and to the Agency, if involved and when requested). For an EU holder/applicant, this should be part of the design organisation approval (DOA) procedure in accordance with points 21.A.239 and 21.A.263.

(v) A commitment is made to produce, verify and provide the relevant ICA in accordance with the detailed plan. This commitment should be provided in a certification document (e.g. a compliance plan) and should also be addressed in a more general manner in a DOA procedure for EU holders/applicants in accordance with points 21.A.239 and 21.A.263. If the respective DOA holder has not previously exercised the practice of delaying the ICA beyond the design approval in order for the DOA to demonstrate this capability in its design assurance system (DAS), the required procedural changes need to be addressed via a significant change to the DAS in accordance with point 21.A.247.

(vi) In order to ensure that the applicant/holder can meet their obligations as set out in point 21.A.44 to control and support delaying the ICA, EASA may decide:

(A) for ICA delayed until entry into service, to assign a condition/notation for the entry into service to be included in the TCDS as a result of these pending issues under the ICA paragraph, as per point (v) of Option 2;

(B) for ICA delayed until after entry into service, to assign an interim limitation to be published and included in the ALS as a temporary operational limitation, also for non-ALS ICA, to compensate for the delayed ICA; this approach may only be used for scheduled maintenance accomplishment procedures, where task and interval requirements are available.

The decision to assign a condition/limitation may be based on the applicant's performance, e.g. if the applicant has already demonstrated in previous projects that it provided the complete set of ICA before the entry into service, if the applicant had already difficulties in providing the ICA considered necessary at the time of the design approval, or has failed before in a different project to control and support delaying the ICA, or if the applicant/holder has not previously exercised the practice of delaying the ICA beyond the design approval.

(vii) Post-TC action should be established with EASA to regularly review the ICA status, if EASA requests such a review, taking into account the DOA oversight activities.

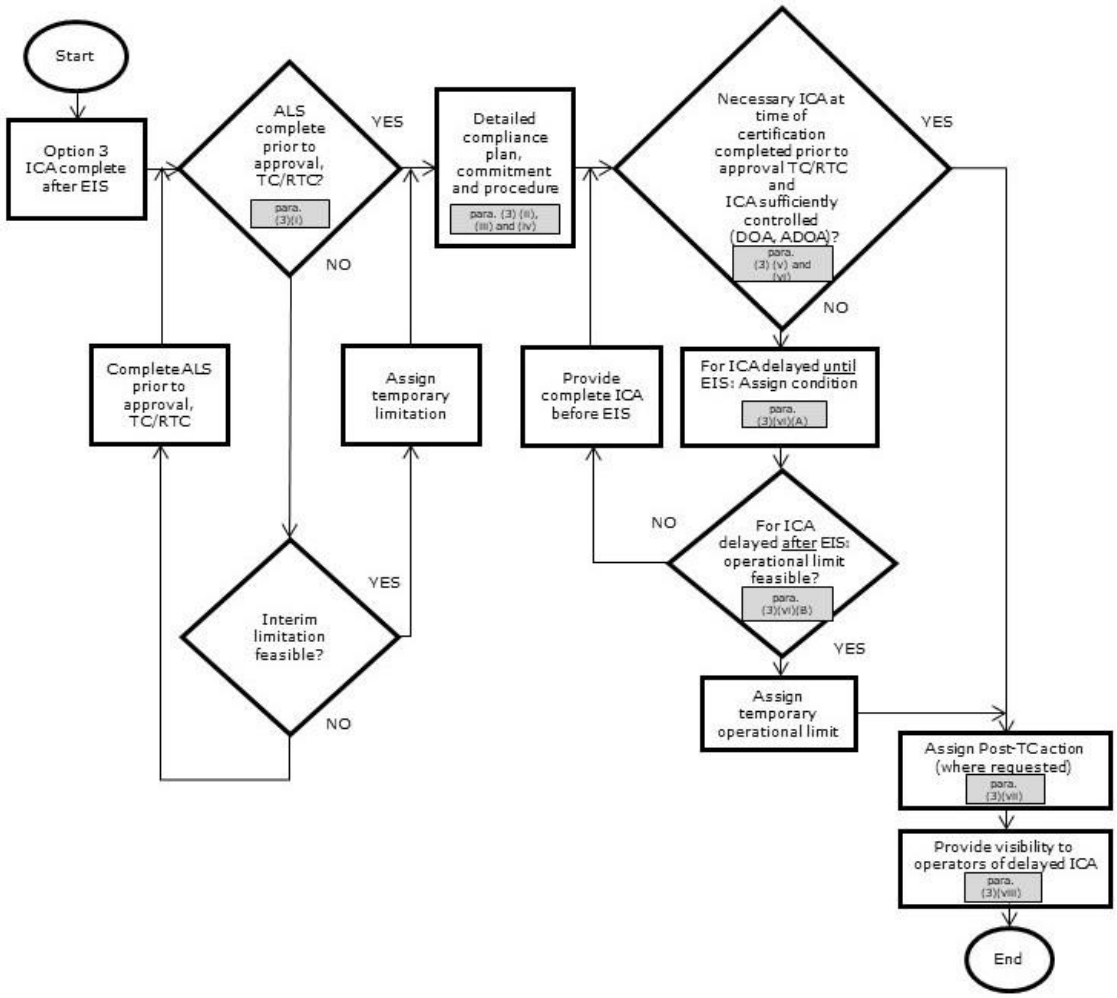
(viii) An applicant/holder should provide visibility, regarding the ICA that are delayed beyond entry into service, to the aircraft operator / aircraft owner and to any other person(s) required to comply with any of those instructions. This can be achieved by providing this information, for example, on a website or in a document, such as an MPD or AMM, preferably in the principal ICA manual. This visibility information is then itself considered to be ICA information.

(ix) It is assumed that for those ICA that are made available to EASA at the time of entry into service, they are also at the same time furnished to the aircraft operator / aircraft owner and made available to any other person(s) required to comply with any of those instructions in accordance with points 21.A.21(c)(4), 21.A.44 and 21.A.7.

This is to satisfy EASA that such a delayed publication will not have an adverse effect on the continuing airworthiness of any individual aircraft.

To allow the timely review and incorporation of a delayed part of the ICA into continuing airworthiness activities and processes (e.g. amendment of the aircraft Maintenance Programme) by the person or organisation responsible for the aircraft continuing airworthiness or for performing maintenance, the Agency considers that the delayed ICA should typically be made available two years before the actual ICA has to be used, when using normal revisions as a format. However, shorter time margins may be acceptable, provided that the format used ensures the prompt notification of the availability of the delayed ICA or the ICA itself, but they should not be less than 1 year before the ICA has to be used.

Flow chart B — 'Completeness of ICA', Option 3



(b) Completeness and timely availability of changes to the ICA (TC/RTC)

Point 21.A.7(d) regulates the distribution of changes to the ICA required from the TC/RTC holder. Those changes to the ICA could result from the design change process (minor and major changes), in-service experience, corrections, and others.

For an EU TC/RTC holder/applicant, a programme showing how changes to the ICA are distributed is part of the respective procedures (e.g. design organisation procedures, or alternative procedures used to demonstrate capabilities). For changes to the ICA triggered by design changes, typically these procedures follow the same principles as those available for TC/RTC, Options 1 to 3, while taking into account the relevant privileges, e.g. that a DOA may approve minor changes in accordance with point 21.A.263(c)(2).

21.A.9 Access and investigation

Regulation (EU) 2022/201

Any natural or legal person that holds or has applied for a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, design change or repair approval, certificate of airworthiness, noise certificate, permit to fly, design organisation approval, production organisation approval certificate or letter of agreement under this Regulation, shall:

(a) grant the competent authority access to any facility, product, part and appliance, document, record, data, process, procedure or to any other material in order to review any report, make any inspection, or perform or witness any flight and ground test, as necessary, in order to verify the initial and continued compliance of the organisation with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;

(b) make arrangements to ensure the competent authority has access, as provided for in point (a), also in respect of the natural or legal person's partners, suppliers and subcontractors.

GM1 21.A.9 Access and investigations

ED Decision 2022/021/R

ARRANGEMENTS

The arrangements made by the applicant for, or holder of, a type certificate (TC), restricted type certificate (RTC), supplemental type certificate (STC), a European technical standard order (ETSO) authorisation, a major repair design approval, a permit to fly, a design organisation approval (DOA), a production organisation approval (POA), or a letter of agreement under Part 21 are required to allow the competent authority to make investigations that include the complete organisation, including its partners, subcontractors, and suppliers, whether they are in the State of the applicant or not.

The investigations may include audits, enquiries, questions, discussions, and explanations, monitoring, witnessing, inspections, checks, as well as flight and ground tests and inspections of completed products, parts, or appliances that are either designed or produced.

In order to maintain its confidence in the standards that are achieved by the organisation, the competent authority may make an investigation into a sample product, part, or appliance and of its associated records, reports, and certifications.

The arrangements are required to enable the organisation to assist the competent authority and cooperate with it in conducting the investigation during the initial assessment and the subsequent surveillance.

'Cooperation in conducting the investigation' means that the competent authority has been granted full and free access to the facilities and to any information relevant to demonstrating compliance with the Part 21 requirements, and has been provided assistance, as necessary.

'Assistance to the competent authority' includes all the appropriate means regarding the facilities of the organisation, to allow the competent authority to conduct the investigation, such as meeting rooms, offices, personnel support, records, documentation, computer data, and communication facilities, all properly and promptly made available, as necessary.

The competent authority seeks to have an open relationship with the organisation, and suitable liaison staff are required to be nominated to facilitate this, including one or more suitable representatives to accompany competent authority staff during visits, not only at the organisation's own facilities, but also at subcontractors, partners, or suppliers.

SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.A.11 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure for issuing type-certificates for products and restricted type-certificates for aircraft, and establishes the rights and obligations of the applicants for, and holders of, those certificates.

21.A.13 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with point 21.A.14 shall be eligible as an applicant for a type-certificate or a restricted type-certificate under the conditions laid down in this Subpart.

21.A.14 Demonstration of capability

Regulation (EU) 2019/897

(a) An applicant for a type-certificate or restricted type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek the agreement of the Agency for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Annex I (Part 21), when the product is one of the following:

1. an ELA2 aircraft;
2. an engine or propeller installed in ELA2 aircraft;
3. a piston engine;
4. a fixed or adjustable pitch propeller.

(c) By way of derogation from point (a), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.15(b), where the product to be certified is:

1. an ELA1 aircraft; or
2. an engine or propeller installed in ELA1 aircraft.

AMC1 21.A.14(b) Demonstration of capability

ED Decision 2021/001/R

ALTERNATIVE PROCEDURES FOR THE DEMONSTRATION OF DESIGN CAPABILITY

The availability of procedures that state the specific design practices, resources and sequence of activities is an acceptable means to demonstrate design capability in the cases described in points 21.A.14(b), 21.A.112B(b) or 21.A.432B(b). This concept is that the implementation, in the context of specific projects, of the procedures required for a Subpart J DOA, will ensure that the applicant performs the relevant activities, but without the requirements on the organisation itself.

The setting up of those procedures may be seen as a starting phase for a design organization to develop into a Subpart J DOA by the addition of the missing elements.

1. Scope

1.1 A manual of procedures should be provided that sets out the specific design practices, resources and the sequence of activities that are relevant for the specific projects, taking the Part 21 requirements into account.

1.2 These procedures should be concise and limited to the information that is needed for the quality and proper control of activities by the applicant/holder, and by EASA.

2. Management of the (supplemental) type-certification process

2.1 Certification programme: see AMC 21.A.15(b) for type certification and AMC 21.A.93(b) for supplemental type certification.

2.2 Compliance demonstration: see GM 21.A.20.

2.3 Reporting: see GM 21.A.20(b).

2.4 Compliance documentation: see AMC 21.A.20(c).

2.5 Declaration of compliance: see GM 21.A.20(d).

3. Management of changes to type certificates, repair designs and production deviations

3.1 Management of changes to a type certificate or supplemental type certificate (hereinafter referred to as 'changes'), repair designs and production deviations from the approved design data.

The applicant should provide procedures that are acceptable to EASA for the classification and approval of changes (see paragraphs 3.2 and 3.3), repair designs and production deviations from the approved design data.

3.2 Classification

3.2.1 *Content*

The procedure should address the following points:

— the identification of the product configuration(s) to which the change is to be made,

— the identification of the areas of the product that are changed or affected by the change,

— the identification of any reinvestigations that are necessary (see point 21.A.93(b)(2)), including the identification of the applicable certification specifications or environmental protection requirements and means of compliance,

— changes initiated by subcontractors,

— documents to justify the classification,

— authorised signatories,

— the criteria used for classification must be in compliance with 21.A.91 and the corresponding interpretations.

3.2.2 *Identification of changes*

The procedure should indicate how the following are identified:

— major changes,

— those minor changes where additional work is necessary to demonstrate compliance with the certification specifications,

— other minor changes that require no further demonstration of compliance.

3.2.3 *Considerations of effects of the change*

The procedure should show how the effects on airworthiness, operational suitability or environmental protection are analysed, from the very beginning, by reference to the applicable certification specifications.

If no specific certification specifications are applicable to the change, the above review should be carried out at the level of the part or system where the change is integrated and where specific certification specifications are applicable.

3.2.4 *Control of changes initiated by subcontractors*

The procedure should indicate, directly or by cross reference to written procedures, how changes initiated by subcontractors are controlled.

3.2.5 Documents to justify the classification

All decisions of classification of changes should be documented and approved by EASA. The document may be in the format of meeting notes or a register.

3.2.6 *Authorised signatories*

The procedure should identify the persons authorised to sign the proposed classification before release to EASA for approval.

3.3 Approval of changes

3.3.1 *Content*

The procedure should address the following points:

— compliance documentation,

— the internal approval process,

— authorised signatories.

3.3.2 *Compliance documentation*

For major changes and those minor changes where additional work to demonstrate compliance with the applicable type-certification basis, operational suitability data certification basis, and environmental protection requirements (hereinafter referred to as the 'certification basis') is necessary, compliance documentation should be established in accordance with AMC 21.A.20(c).

3.3.3 *Approval process*

A) For the approval of major changes, a certification programme as defined in AMC 21.A.93(b) must be established.

B) For major changes and those minor changes where additional work to demonstrate compliance with the applicable certification basis is necessary, the procedure should define a document to support the approval process.

This document should include at least:

— identification and a brief description of the change and its classification,

— references to the applicable certification basis,

— reference to the compliance documents,

— effects, if any, on limitations and on the approved design data,

— the name of the authorised signatory.

C) For the other minor changes, the procedure should define a means:

— to identify the change,

— to present the change to EASA for approval.

3.3.4 *Authorised signatories*

The procedure should identify the persons authorised to sign the change before release to EASA for approval.

3.4 Repair designs and production deviations from the approved design data

A procedure following the principles of paragraphs 3.2 and 3.3 should be established for the classification and approval of repair designs and unintentional deviations from the approved design data occurring in production (concessions or non-conformances). For repair designs, the procedure should be established in accordance with Part 21, Section A, Subpart M and the associated acceptable means of compliance (AMC) or guidance material (GM).

4. Issue of data and information (including instructions) to owners, operators or others required to use the data and information

4.1 General

Data and information include the operational suitability data.

4.2 Data related to changes

The data and information (including instructions) issued by the holder of a design approval (a TC, STC, approval of a change, approval of a repair design) are intended to provide the owners of a product with all the necessary data and information to embody a change or a repair on the product, or to inspect it.

The data and information (including instructions) may be issued in a format of a service bulletin as defined in ATA 100 system, or in structural repair manuals, maintenance manuals, engine and propeller manuals, etc.

The preparation of this data involves design, production and inspection. The three aspects should be properly addressed and a procedure should exist.

4.3 Procedure

The procedure should address the following points:

— Preparation;

— verification of technical consistency with corresponding approved change(s), repair design(s) or approved data, including effectivity, description, effects on airworthiness or operational suitability, especially when limitations are changed;

— verification of the feasibility in practical applications; and

— approval for the release of data and information.

The procedure should include the information (including instructions) prepared by subcontractors or vendors, and declared applicable to its products by the holder of the TC, STC, approval of changes or approval of repair designs.

4.4 Statement

The data and information should include a statement:

— confirming that the documentation has been produced by the design approval holder in accordance with the associated procedures accepted by EASA; and

— containing a reference to EASA approvals of related changes or repairs, when applicable[1].

5. Obligations addressed in 21.A.44 (TC holder), 21.A.118A (STC holder) or 21.A.451 (major repair design approval holder)

The applicant for alternative procedures to demonstrate their design capabilities should establish the necessary procedures to show to EASA how it will fulfil the obligations that are required under 21.A.44, 21.A.118A or 21.A.451, as appropriate.

6. Control of design subcontractors

The applicant for alternative procedures to demonstrate their design capabilities should establish the necessary procedures to show to EASA how it will control design subcontractors and ensure the acceptability of the parts or appliances that are designed, or the design tasks that are performed.

GM 21.A.14(b) Eligibility for alternative procedures

ED Decision 2012/020/R

Design organisations approved under Part 21 Section A Subpart J ('Subpart J DOA') should be the normal approach for type certification, supplemental type certification, approval of major changes to type design or approval of major repair design, except when agreed otherwise by the Agency in accordance with 21.A.14, 21.A.112B and 21.A.432B.

The acceptance of alternative procedures, as defined in AMC 21.A.14(b), should be limited where the Agency finds it more appropriate for the conduct of type certification, supplemental type certification, approval of changes to type design, approval of repair design.

[1] EASA does not directly approve information or instructions. These are approved as part of the TC, STC, change approval or repair design approval. When stand-alone changes (i.e. not related to a TC change or repair design) to the issued information or instructions (e.g. to take in-service experience into account) are needed, these should be prepared, verified and approved according to the agreed procedures (see above).

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

   a. Scope: The FTOM covers flight test operations.

   The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

   b. Format

   The FTOM may:

   — be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

   — be a separate manual.

   The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

   c. Use by contractors or sub-contractors:

   When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part 21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

   a. Exposition (not applicable in the case of APDOA):

   If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

   b. Risk and safety management:

   The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

   c. Crew members:

   According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

   All crew members should be listed in the FTOM.

   A flight time limitation policy should be established.

   d. Carriage of persons other than crew members:

   According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

  — for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

  — for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

  — for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

21.A.15 Application

Regulation (EU) 2021/699

(a) An application for a type-certificate or restricted type-certificate shall be made in a form and manner established by the Agency.

(b) An application for a type-certificate or restricted type-certificate shall include, as a minimum, preliminary descriptive data of the product, the intended use of the product and the kind of operations for which certification is requested. In addition, it shall include, or be supplemented after the initial application by, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:

1. a detailed description of the type design, including all the configurations to be certified;
2. the proposed operating characteristics and limitations;
3. the intended use of the product and the kind of operations for which certification is requested;
4. a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in points 21.B.80, 21.B.82 and 21.B.85;
5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;
6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on product

safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1) to (4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and

7. a project schedule including major milestones.

(c) After its initial submission to the Agency, the certification programme shall be updated by the applicant when there are changes to the certification project affecting any of the points 1 to 7 of point (b).

(d) An application for a type-certificate or restricted type-certificate for an aircraft shall include, or be supplemented after the initial application by, an application supplement for approval of the operational suitability data.

(e) An application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft shall be valid for five years and an application for any other type-certificate or restricted type-certificate shall be valid for three years, unless the applicant demonstrates at the time of application that its product requires a longer time period to demonstrate and declare compliance and the Agency agrees to that longer time period.

(f) In the case where a type-certificate or restricted type-certificate has not been issued, or it is evident that it will not be issued, within the time limit provided for in point (e), the applicant may:

1. submit a new application and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for the date of the new application; or

2. apply for an extension of the time period provided for in point (e) and propose a new date for the issuance of the type-certificate or restricted type-certificate. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with point 21.B.80, 21.B.82 and 21.B.85 for a date to be selected by the applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the type-certificate or restricted type-certificate by more than five years for an application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for any other type-certificate or restricted type certificate.

AMC 21.A.15(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application form for a type certificate or restricted type certificate (FO.CERT.00030)[2], which may be downloaded from the EASA website.

The form should be completed in accordance with the instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[3].

AMC 21.A.15(b) Content of the certification programme

ED Decision 2019/018/R

The certification programme is a document that allows the applicant and EASA to manage and control the evolving product type design or OSD, as well as the process of compliance demonstration by the applicant and its verification by EASA when required.

The certification programme may be based on modules that may be updated independently.

The level of detail in the certification programme depends on the complexity of the product and its intended use.

In particular, the following information should typically be expected:

General

— Identification of the relevant personnel who make decisions affecting airworthiness, operational suitability and environmental protection, and who will interface with EASA, unless otherwise identified to EASA (e.g. within the DOA procedures).

— A project schedule including major milestones.

— Subcontracting arrangements for design, operational suitability, environmental protection and/or production as well as design organisation approval (DOA) responsibility sharing.

21.A.15(b)(1) 'a detailed description of the type design, including all the configurations to be certified'

An overview of the:

— architecture, functions, systems;

— dimensions, design weights, payloads, design speeds;

— engines and power/thrust rating;

— materials and technologies;

— maximum passenger seating capacity, minimum flight and cabin crew;

— cabin configuration aspects;

[1] https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

[2] http://www.easa.europa.eu/document-library/application-forms/focert00030 (changes to the link provided may not be reflected in this document).

[3] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

— options (e.g. weight variants, power/thrust rating variants, optional avionics equipment items, auxiliary power unit (APU) choices, brake options, tire options, floats, skids);

— noise/emissions level; and

— other items, if considered to be more appropriate, that address the specific aeronautical product.

21.A.15(b)(2) 'proposed operating characteristics and limitations'

— Operating speed limitations.

— Service ceiling, maximum airfield elevation.

— Cabin pressure.

— Limit load factors.

— Number of passengers, minimum crew, payload, range.

— Weight and centre-of-gravity (CG) envelope and fuel loading.

— Performance.

— Environmental envelope.

— Runway surface conditions.

— Other items, if considered to be more appropriate, that address the specific aeronautical product.

21.A.15(b)(3) 'the intended use of the product and the kind of operations for which certification is requested'

— Category A or B (relevant for CS-27 and CS-29), ditching, take-off and landing on water, emergency floatation equipment.

— Extended overwater operation, high-altitude operation (above 41 000 ft).

— High-airfield operation, steep approach, short take-off and landing, extended-range twin-engine operations (ETOPS), all-weather operations (AWO), visual flight rules (VFR)/instrument flight rules (IFR), reduced vertical separation minimum (RVSM), required navigation performance (RNP) type, increased bank angles, single-pilot operation, flight into known icing conditions.

— Flight in ice crystal icing.

— Engine operations in ice-forming conditions, helicopter hoist operations, operation on unpaved runway, operation on narrow runway.

— Take-off and landing in tailwind.

— Volcanic-ash operation (limitation or operation as per CS 25.1593 and CS-E 1050).

— Design service goal (DSG)/limit of validity targets.

— Fatigue missions (general description of assumptions for flight durations, main phases, and parameters, as appropriate).

— Other items, if considered to be more appropriate, that address the specific aeronautical product.

21.A.15(b)(4) 'a proposal for the initial type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, considering the requirements and options specified in 21.B.80, 21.B.82 and 21.B.85'

The proposed certification basis should include applicable certification specifications, proposed special conditions, proposed equivalent safety findings, as well as a proposed 'elect to comply' and proposed deviations, as applicable.

21.A.15(b)(5) 'a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as "compliance demonstration items" (CDIs), including references to their proposed means of compliance and related compliance documents'

See AMC 21.A.15(b)(5) for the determination of the compliance demonstration items (CDIs).

21.A.15(b)(6) on information relevant for the determination of the level of involvement (LoI)

The applicant should provide sufficient detailed information about the novelty, complexity, and criticality aspects of each proposed CDI.

It is recommended to provide this information at the level of each EASA panel or discipline affected by a proposed CDI. Further interpretative material on the necessary level of details is provided in AMC 21.B.100(a) and 21.A.15(b)(6).

The applicant should provide detailed information about the proposed means of compliance with the applicable requirements identified under 21.A.15(b)(4). The information provided should be sufficient for EASA to determine its (initial) LoI. This should include the following, as far as this information is available at the time of submission to EASA:

— a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC 21.A.15(b) below for the relevant codes), and the related compliance document(s);

— identification of industry standards (Society of Automotive Engineers (SAE), American Society for Testing and Materials (ASTM), European Organisation for Civil Aviation Equipment (EUROCAE), AeroSpace and Defence Industries Association of Europe (ASD), etc.), methodology documents, handbooks, technical procedures, technical documents and specifications specified in the type certificate data sheet, certification memoranda, policy statements, guidance material, etc., that should be followed in the demonstration of compliance;

— when the compliance demonstration involves testing, a description of the ground and flight test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and

— when the compliance demonstration involves analyses/calculations, a description/identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose; furthermore, the validation and verification of such tools and methods should be addressed.

For every aspect mentioned above, the applicant should clearly identify whether the demonstration of compliance involves any method (analysis or test) which is novel or unusual for the applicant. This should include any deviations from the published AMC to the relevant CS.

Appendix A to AMC 21.A.15(b) Means of compliance codes

ED Decision 2019/018/R

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analysis
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	Note: Equipment qualification is a process that may include all previous means of compliance at equipment level.

AMC 21.A.15(b)(5) Breakdown of the certification programme into compliance demonstration items (CDIs)

ED Decision 2019/018/R

1. What is a CDI?

   A CDI is a meaningful group of compliance demonstration activities and data identified in the certification programme which can be considered in isolation for the purpose of performing the risk assessment that allows EASA to determine its level of involvement (LoI) using a risk-based approach.

   The possibility to create this grouping of compliance demonstration activities and data is intended to facilitate the risk assessment. However, there may be cases in which the risk assessment may also be performed at the level of the compliance demonstration activity or data, or at the level of the whole certification project.

   The chosen breakdown into CDIs may affect the resulting risk classes (please refer to AMC 21.B.100(a) and 21.A.15(b)(6)), but should not have any effect on the compliance demonstration itself or on EASA's LoI.

2. The grouping of compliance demonstration activities and data

   The compliance demonstration activities and data grouped in a CDI may demonstrate compliance with a requirement, a group of requirements, or even a part of a requirement. In this context, 'requirement' means any element of the type-certification basis or operational suitability data (OSD) certification basis as specified in 21.B.80 and 21.B.82, or the environmental protection requirements as specified in 21.B.85.

   A CDI may comprise any of the means of compliance listed in Appendix A to AMC 21.A.15(b).

CDIs may be tailored to the scope and size of the project. On simple projects, a CDI may address all the compliance demonstration activities within a given technical area (e.g. avionics, flight, structures, hydromechanical systems, OSD-cabin crew data (CCD), etc.) or of the whole project.

A CDI should not be too large, by combining completely unrelated compliance demonstration activities or data, so that it becomes meaningless, but neither should it be so small that it might not be considered in isolation from some other related compliance demonstration activities or data.

A way of meaningfully grouping compliance demonstration activities and data, for example, is to select some activities and data and group them into a single CDI, as the certification programme must already contain the applicable requirements, the proposed means of compliance for each requirement, as well as the associated compliance documents for each means of compliance.

Another way to meaningfully group the data is to do it at the level of the technically related compliance demonstration activities and data. This may facilitate the assessment of those activities and data against the novelty, complexity, and criticality criteria (see AMC 21.B.100(a) and 21.A.15(b)(6)). The resultant CDI may encompass various means of compliance.

3. Description of CDIs

Each CDI should be sufficiently described in the certification programme, and should detail the following:

— the scope of the CDI; and

— the information on the novelty, complexity, and criticality of the item being certified.

However, in cases where the rationale of the assessment is obvious, it is considered to be sufficient to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

Note: Obvious cases are cases for which the classification is straightforward and does not require additional clarifications. In general, applicant explanations/notes regarding the proposed classification should be provided, since this will also facilitate the acceptance of the LOI proposal. Nevertheless, to avoid unnecessary additional effort, these explanations can be omitted if they are obvious.

Additionally, it is recommended to identify the EASA panel(s)/discipline(s) affected by each CDI, as this will support the determination of the novelty, complexity, and criticality, and finally identify the performance of the design organisation approval (DOA) holder.

AMC 21.B.100(a) and 21.A.15(b)(6) Level of involvement (LoI) in a certification project for a type certificate (TC), a major change to a TC, a supplemental type certificate (STC), a major repair design or European technical standard order (ETSO) authorisation for an auxiliary power unit (APU)

ED Decision 2019/018/R

1. Definitions

Risk: the combination of the likelihood and the potential impact of a non-compliance with part of the certification basis.

Likelihood: a prediction of how likely an occurrence of non-compliance with part of the certification basis is, based on a combination of the novelty and complexity of the proposed design and its related compliance demonstration activities, as well as on the performance of the design organisation.

Criticality: a measure of the potential impact of a non-compliance with part of the certification basis on product safety or on the environment.

Compliance demonstration item (CDI): a meaningful group of compliance demonstration activities and data of the certification programme, which can be considered in isolation for the purpose of performing a risk assessment.

EASA panel: an EASA panel is composed of one or more experts who are responsible for a particular technical area. Each technical area addressed during product certification is covered by an EASA panel.

EASA discipline: an EAS447

A discipline is a technical subarea of an EASA panel.

EASA's level of involvement (LoI): the compliance demonstration activities and data that EASA retains for verification during the certification process, as well as the depth of the verification.

2. Background

The applicant has to submit a certification programme for their compliance demonstrations in accordance with point 21.A.15(b). The applicant has to break down the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as 'CDIs', and provide their proposal for EASA's LoI.

The applicant should also indicate the EASA panel(s) that is (are) affected by each CDI.

This AMC explains:

(a) how to propose EASA's LoI for each CDI as per points 21.A.15(b)(6), 21.A.93(b)(3)(iii), 21.A.432C(b)(6) as well as 21.A.113(b); and

(b) how EASA will determine its LoI on the basis of the criteria established in point 21.B.100.

EASA will review the proposal and determine its LoI. Both parties, in mutual trust, should ensure that the certification project is not delayed through the LoI proposal and determination.

Additionally, in accordance with point 21.A.20, the applicant has the obligation to update the certification programme, as necessary, during the certification process, and report to EASA any

difficulty or event encountered during the compliance demonstration process which may require a change to the LoI that was previously notified to the applicant.

In such a case, or when EASA has other information that affects the assumptions on which the LoI was based, EASA will revisit its LoI determination.

In accordance with points 21.A.33, 21.A.447 and 21.A.615, irrespective of the LoI, EASA has the right to review any data and information related to compliance demonstration.

Note: This AMC should not be considered to be interpretative material for the classification of changes or repairs.

3. Principles and generic criteria for the LoI determination EASA determines its LoI based on the applicant's proposal in view of the risk (the combination of the likelihood of an unidentified non-compliance and its potential impact). This is performed after proper familiarisation with the certification project in three steps:

— Step 1: identification of the likelihood of an unidentified non-compliance,

— Step 2: identification of the risk class, and

— Step 3: determination of EASA's LoI.

This AMC contains criteria, common to all EASA panels, for the determination of:

— any novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;

— the complexity of the design and/or compliance demonstration;

— the performance and experience of the design organisation of the applicant in the domain concerned;

— the criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and

— the data and activities to be retained by EASA.

Note: Additional panel-specific criteria are available in further informative material published by EASA[1]. This material should not be considered to be AMC.

For CS-23 commuter (or CS-23 level 4 airplanes as defined in CS-23 Amdt 5), CS-25, CS-27 and CS-29 aircraft, all the panel-specific additional criteria should be considered. For the other products, the panel-specific criteria should only be considered for CDIs that affect noise, propulsion, development assurance and safety assessment (DASA), operational suitability data (OSD) and software and airborne electronic hardware.

The criteria used to determine the likelihood and the potential impact of an unidentified non-compliance generally allow a proportionate approach to be applied, in particular in order to differentiate between CS-25 and general aviation (GA) aircraft projects.

[1] Such additional criteria are contained as an attachment to the EASA Certification Memorandum (CM) CM-21.A/21.B-001, available at: https://www.easa.europa.eu/document-library/product-certification-consultations/cm-21a21b-001.

3.1. LoI determination at CDI level

The determination of EASA's LoI is performed at the level of the CDI (please refer to AMC 21.A.15(b)(5)).

The applicant should demonstrate that all the affected elements of the type-certification basis as specified in point 21.B.80, of the OSD certification basis as specified in point 21.B.82, and of the environmental protection requirements as specified in 21.B.85, the corresponding means and methods of compliance, as well as the corresponding certification activities and data, are fully covered by the proposed CDIs. If the provided data does not clearly show that this is the case, the applicant should clearly state to EASA that all the above-mentioned elements are fully covered.

Note: There could be different ways to 'clearly show' that all the elements of the certification basis are included in at least one CDI. For instance, this could be achieved by means of a 'CDI reference' column added in the table that lists all the elements of the certification basis.

3.2. Method for determining the likelihood of an unidentified non-compliance

3.2.1. Principle The likelihood of an unidentified non-compliance is assessed on the basis of the following criteria:

— novelty,

— complexity, and

— the performance of the design organisation.

3.2.2. Novelty

For the purpose of risk class determination, the following simplification has been made: a CDI may be either novel or non-novel.

Whether or not a CDI is novel is based on the extent to which the respective elements of the certification project, as well as the related requirement or means of compliance, are new/novel to either the industry as a whole, or to the applicant, including their subcontractors, or from an EASA panel perspective.

The determination that a CDI is novel may be driven by the use of new technology, new operations, new kind of installations, the use of new requirements or the use of new means of compliance.

When an applicant utilises a type of technology for the first time, or when that applicant is relatively unfamiliar with the technology, this technology is considered to be 'novel', even if other applicants may be already familiar with it. This also means that a type of technology may no longer be novel for one applicant, while it may still be novel for other applicants.

The following list includes some examples:

— new materials or combinations of materials;

— a new application of materials or combinations of materials;

— new manufacturing processes;

— a new or unusual aircraft configuration and/or system architecture;

— a novel reconfiguration of systems;

— a new interface or interaction with other parts or systems;

— the unusual location of a part or a system, or an unusual construction;

— a new or unusual use;

— new functions;

— new kinds of operations;

— the potential for new failure modes;

— the introduction of a new threat (e.g. new threats regarding fire, fuel, hydrogen, energy storage devices, etc.) or a new prevention/detection/mitigation method;

— new maintenance techniques;

— novel operating conditions or limitations;

— a new human-machine interface (HMI); or

— new flight or cabin crew tasks.

Another consideration is the extent to which the requirements, means of compliance or guidance have changed or need to be adapted due to particular novel features of the design.

The following list includes some examples:

— recently issued or amended CSs with which the applicant has little or no experience;

— new or adapted special conditions;

— new or adapted equivalent safety findings;

— new or adapted deviations;

— new or adapted guidance or interpretative material;

— new or adapted means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices), e.g. the replacing of tests by simulation, numerical models or analytical methods;

— the use of new or adapted industry standards or in-house methods, as well as EASA's familiarity with these standards and methods;

— a change in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs; or

— novelty in the interpretation of the results of the compliance demonstration, e.g. due to in-service occurrences (compliance demonstration results are interpreted differently from the past).

Additional new guidance/interpretative material in the form of new certification memoranda (CM) may be considered for the determination of novelty if its incorrect application/use may lead to an unidentified non-compliance. In the context of novelty, the time between the last similar project and the current project of the applicant should also be considered.

Regardless of the extent of an organisation's previous experience in similar projects, a CDI may be classified as novel if there are specific discontinuities in the process for transferring information and know-how within the organisation.

3.2.3. Complexity For the purpose of risk class determination, the following simplification has been made: a CDI may be either complex or non-complex. For each CDI, the determination of whether it is complex or not may vary based on factors such as the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), interpretation of the results of the compliance demonstration, interfaces with other technical disciplines/CDIs, and the requirements. The compliance demonstration may be considered to be 'complex' for a complex (or highly integrated) system, which typically requires more effort from the applicant. The following list includes some examples:

— Compliance demonstration in which challenging assessments are required, e.g.:

  — for requirements of a subjective nature, i.e. they require a qualitative assessment, and do not have an explicit description of the means of compliance with that requirement, or the means of compliance are not a common and accepted practice; this is typically the case where the requirement uses terms such as 'subjective', 'qualitative', 'assessment' or 'suitable'/'unsuitable'

  — in contrast, engineering judgement for a very simple compliance demonstration should not be classified as 'complex';

  — a test for which extensive interpretation of the results may be anticipated;

  — an analysis that is sensitive to assumptions and could potentially result in a small margin of safety;

  — the classification of structures, depending on the conservatism of the method;

  — an advanced analysis of dynamic behaviour;

  — a multidisciplinary compliance demonstration in which several panels are involved and interface areas need to be managed (e.g. sustained engine imbalance, extended-range twin-engine operation performance standards (ETOPS), 2X.1309 assessment, flight in known icing conditions, full authority digital engine control (FADEC)-controlled engines, etc.);

  — when the representativeness of a test specimen is questionable, e.g. due to its complexity;

— the introduction of complex work-sharing scheme with system or equipment suppliers.

For major changes, the complexity of the change should be taken into account, rather than the complexity of the original system.

Whether or not a CDI is complex should be determined in a conservative manner if this cannot be determined at an early stage of the certification project. When greater clarity has been achieved, the complexity may be re-evaluated and the LoI adapted accordingly.

3.2.4. Performance of the design organisation

The assessment of the level of performance of the design organisation takes into account the applicant's experience with the applicable certification processes, including their performance on previous projects and their degree of familiarity with the applicable certification requirements.

For approved design organisations, EASA uses relevant data to consider the design organisation's expected performance at an organisational, panel or discipline level, depending on the availability of data[1].

This data stems from design organisation audits, the applicant's measured level of performance on previous projects, and their performance during the familiarisation phase. EASA shares this data with the respective design organisations (in the form of the design organisation approval (DOA) dashboard).

For each CDI proposed by the applicant, the DOA holder's performance associated with the affected disciplines or panels is to be considered.

If one CDI affects more panels or disciplines than the others, a conservative approach should be followed in selecting the lower performance level. As an alternative, that CDI may be assessed separately for each affected EASA panel or discipline.

If, for a well-established organisation, there is no shared performance data available at the panel level, it may be acceptable to propose the overall DOA holder's performance. If the organisation or its scope are fundamentally new, the 'unknown' level of performance should be conservatively proposed by the applicant.

The determination of the performance of the design organisation may also take into consideration information that is more specific or more recent than the information on the DOA holder's dashboard, e.g. experience gained during technical familiarisation with the current certification project, the performance of compliance verification engineers and of the affected technical areas, as well as the performance of the design organisation in overseeing subcontractors and suppliers.

The performance of some applicants' organisations is not known if:

— EASA has agreed in accordance with point 21.A.14(b) that the applicants may use procedures that set out specific design practices, as an alternative means to demonstrate their capability (excluding European technical standard order (ETSO) applicants for other than APU, covered by point 21.B.100(b)); or

— the applicants demonstrate their capability by providing EASA with the certification programme in accordance with point 21.A.14(c).

[1] The ultimate objective is to define the organisation's performance at the discipline level.

In these cases, the assumed level of performance is 'unknown'.

Exceptionally, EASA may consider a higher level of performance for a specific CDI if that is proposed and properly justified by the applicant.

The following list includes some examples:

— a CDI with which EASA is fully familiar and satisfied (from previous similar projects) regarding the demonstration of compliance proposed by the applicant;

— if the applicant fully delegates the demonstration of compliance to a supplier that holds a DOA, the performance level of the supplier may be proposed.

3.2.5. Likelihood of an unidentified non-compliance

Assessing the likelihood of an unidentified non-compliance is the first step that is necessary to determine the risk class.

The likelihood of an unidentified non-compliance should not be confused with the likelihood of occurrence of an unsafe condition as per AMC 21.A.3B(b). In fact, that AMC provides EASA's confidence level that the design organisation addresses all the details of the certification basis for the CDI concerned, and that a non-compliance will not occur.

The likelihood of an unidentified non-compliance is established as being in one of four categories (very low, low, medium, high), depending on the level of performance of the design organisation as assessed by EASA, and on whether the CDI is novel or complex, as follows:

Step 1 — Likelihood of an unidentified non-compliance			
CDI Performance level of the DOAH	No novel aspects, no complex aspects	No novel aspects, but complex ones; Novel aspects, but no complex ones	Novel and complex aspects
High	Very low	Low	Medium
Medium	Low	Medium	High
Low or unknown	Medium	High	High

3.3. Criticality

The second step that is necessary to determine the risk class is the assessment of the potential impact of a non-compliance on part of the certification basis regarding the airworthiness or the environmental protection of the product. For the purpose of risk class determination, the following simplification has been made: the impact of a non-compliance can be either critical or non-critical.

Some of the guidance below has been derived from GM 21.A.91, not due to a major/minor change classification, but because the same considerations may be applied to determine the effect of a non-compliance on the airworthiness or environmental protection at the CDI level. It is therefore normal that some of the CDIs of a major change that consists of several CDIs may be critical, and others may be non-critical.

The potential impact of a non-compliance within a CDI should be classified as critical if, for example:

— a function, component or system is introduced or affected where the failure of that function, component or system may contribute to a failure condition that is classified as hazardous or catastrophic at the aircraft level, for instance for 'equipment, systems and installations', e.g. where applicable as defined in 2X.1309;

— a CDI has an appreciable effect on the human–machine interface (HMI) (displays, approved procedures, controls or alerts);

— airworthiness limitations or operating limitations are established or potentially affected;

— a CDI is affected by an existing airworthiness directive (AD), or affected by an occurrence (or occurrences) potentially subject to an AD, a known in-service issue or by a safety information bulletin (SIB); or

— a CDI affects parts that are classified as critical as per CS 27.602/29.602, CS-E 515, or that have a hazardous or catastrophic failure consequence (e.g. a principal structural element as per CS 25.571).

If the classification of the potential impact of a non-compliance within a CDI as critical is based on the criterion that the CDI is affected by an AD, then the impact of a non-compliance within that CDI may be reclassified by EASA as non-critical due to the involvement of EASA in the continued-airworthiness process.

During the early stages of a project, the criticality in terms of the potential safety consequence of a failure may not always be known, but should be conservatively estimated and the LoI should be subsequently re-evaluated, if appropriate. 3.4. Method for the determination of risk classes The risk is determined as a combination of the potential impact of an unidentified non-compliance with part of the certification basis (vertical axis) and of the likelihood of the unidentified non-compliance (horizontal axis) using the following matrix. As a consequence, four qualitative risk classes are established at the CDI level.

Step 2 — Risk classes				
Likelihood (see Section 3.2.5) Criticality (see Section 3.3)	Very low	Low	Medium	High
Non-critical	Class 1	Class 1	Class 2	Class 3
Critical	Class 1	Class 2	Class 3	Class 4

The various inputs and the resulting risk class determination are of a continuous nature, rather than consisting of discrete steps. The selected risk class provides the order of magnitude of EASA's involvement and is used as a qualitative indicator for the determination of EASA's involvement described in Section 3.5 below.

Under specific circumstances, the risk class that is determined on the basis of the above criteria may be reduced or increased on the basis of justified and recorded arguments. For a reused and well-proven item of compliance demonstration for which:

— the CDI is independent of the affected product type or model; and

— the design, operation, qualification, and installation of the product are basically the same; and

— the certification process is identical to one that was used in a modification already approved by EASA,

the CDI may be accepted as being similar, resulting in reduced LoI, as the likelihood of an unidentified non-compliance is low. Furthermore, when an identical CDI is reused for the compliance demonstration in a new project, there is no involvement in the compliance demonstration verification, as the likelihood of an unidentified non-compliance is very low.

3.5. Determination of EASA's LoI

EASA's LoI in the verification of compliance demonstration is proposed by the applicant and determined by EASA in Step 3 on the basis of the qualitative risk class identified per CDI in Step 2, as well as by applying sound engineering judgement.

EASA's LoI is reflected in a list of activities and data, in which EASA retains the verification of compliance demonstration (e.g. review and acceptance of compliance data, witnessing of tests, etc.), as well as the depth of the verification. The depth of the verification for individual compliance reports, data, test witnessing, etc., may range from spot checks to extensive reviews. EASA always responds to those retained compliance demonstration activities and data with corresponding comments or a 'statement of no objection'.

In addition, some data that is not retained for verification may be requested for information. In this case, no 'statement of no objection' will be provided.

It is recommended that an LoI should be proposed for each of the EASA disciplines involved. Depending on the risk classes determined in Section 3.4 above, EASA's LoI in:

(a) compliance demonstration verification data; and

(b) compliance demonstration activities (witnessing of tests, audits, etc.),

may be as follows:

— risk Class 1: there is no EASA involvement in verifying the compliance data/activities performed by the applicant to demonstrate compliance at the CDI level;

— risk Class 2: EASA's LoI is typically limited to the review of a small portion of the compliance data; there is either no participation in the compliance activities, or EASA participates in a small number of compliance activities (witnessing of tests, audits, etc.);

— risk Class 3: in addition to the LoI defined for Class 2, EASA's LoI typically comprises the review of a large amount of compliance data, as well as the participation in some compliance activities (witnessing of tests, audits, etc.); and

— risk Class 4: in addition to the LoI defined for Class 3, EASA's LoI typically comprises the review of a large amount of compliance data, the detailed interpretation of test results, and the participation in a large number of compliance activities (witnessing of tests, audits, etc.).

By default, the following activities require EASA's involvement in all cases:

— initial issues of, and changes to, a flight manual (for those parts that require EASA approval and that do not fall under the DOA holder's privilege);

— classification of failure cases that affect the handling qualities and performance, when:

— performed through test (in flight or in a simulator); and

— initial issues of, and non-editorial changes to, airworthiness limitations.

If the risk assessment (Steps 1 and 2 above) is made on the level of a compliance demonstration activity or on the level of a document, the risk class provides an indication for the depth of the involvement, i.e. the verification may take place only for certain compliance data within a compliance document.

4. Documentation of the LoI

The LoI proposal in the certification programme should include the applicant's proposal regarding the compliance demonstration verification activities and data that would be retained by EASA, as well as the data on which the LoI proposal has been based. For this purpose, the applicant should appropriately document the analysis per CDI, considering the above criteria. In cases where the rationale for the assessment is obvious, it is considered to be sufficient for the applicant to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

EASA documents the LoI determination by accepting the certification programme or, if it deviates from the proposal, by recording its analysis regarding the deviations from the proposal, and notifies the applicant accordingly.

5. Sampling during surveillance of the DOA holder

It should be noted that all the previously defined risk classes may be complemented by the sampling of project files during surveillance of the DOA holder, independently from the ongoing certification project. This is necessary in order to maintain confidence in the DOA system and to constantly monitor its performance.

GM 21.A.15(c) Updates to the certification programme

ED Decision 2019/018/R

Point 21.A.15(b) recognises that the initial submission of the certification programme may not be fully complete, e.g. due to schedule constraints of the design, analysis and testing activities.

Furthermore, even if the initial submission of the certification programme is complete, it may be necessary to amend it throughout the duration of the project.

The certification programme should be updated and resubmitted to EASA. In particular, updates to the following elements should be provided:

— any complementary information that was not included in the initial submission of the certification programme;

— any change in the intended use or kind of operations of the product itself, or of the aircraft on which the product is installed;

— a change in the key characteristics of the product such as but not limited to any declared limits that are intended to be recorded in the type certificate data sheet (TCDS);

— any change in the product design or its characteristics that may affect the criteria used to assess the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data (OSD) certification basis or the environmental protection requirements, including the potential impact of that non-compliance on product safety or environmental protection, as defined in 21.A.15(b)(6) and 21.B.100(a)(1) to (4);

Note: An update of the DOA dashboard after the first issuance of the certification programme only needs to be considered if there is a significant change in the performance.

— any change to the initial type-certification basis, OSD certification basis or environmental protection requirements, as applicable to the product, regardless whether the change is initiated by EASA or by the applicant;

— any change in the breakdown of the certification programme into compliance demonstration items (CDIs) or in the content of those CDIs;

— any change in the proposed means of compliance, including its/their methodology;

— any change in the structure of compliance documents that may affect the determination of EASA's level of involvement (LoI), as defined in 21.B.100;

— any relevant change to the design organisation approval (DOA) holder's personnel (and design organisation (DO) suppliers) who are involved in the project; and

— any changes to the schedule that impact on the EASA LoI.

Following each update to the certification programme as submitted by the applicant, EASA may update the determination of its LoI in accordance with 21.B.100(c).

GM No 1 to 21.A.15(d) Application for the approval of operational suitability data – MMEL for ELA1 and ELA2

ED Decision 2019/018/R

For ELA1 and ELA2, the applicant may develop a list of the required equipment to be included in the TCDS and/or AFM/POH. This list, in combination with the equipment required for the flight by the applicable implementing rules for a given type of operations, establishes the list of equipment that must be operative for all flights. The list of the other installed equipment that may be inoperative constitutes the MMEL.

GM No 2 to 21.A.15(d) Determination of type or variant

ED Decision 2016/007/R

The criteria for the determination whether an aircraft with a new type certificate (TC) is considered a new type or is a variant with reference to another aircraft type from the same TC holder for the purpose of the specific OSD constituent are provided in the applicable certification specifications for maintenance certifying staff data, flight crew data and cabin crew data.

GM No 3 to 21.A.15(d) OSD content

ED Decision 2016/007/R

The OSD will typically consist of elements that are required to be included by the TC applicant and elements that can be added at the request of the TC applicant. (See also GM No 4 to 21.A.15(d)).

Both the required elements and the additional elements will have a part that is mandatory to be used by the operator or training organisation (status of rule) and a part which is not mandatory to the operator or training organisation (status of AMC). For illustration of this concept, Figure 1 below is included.

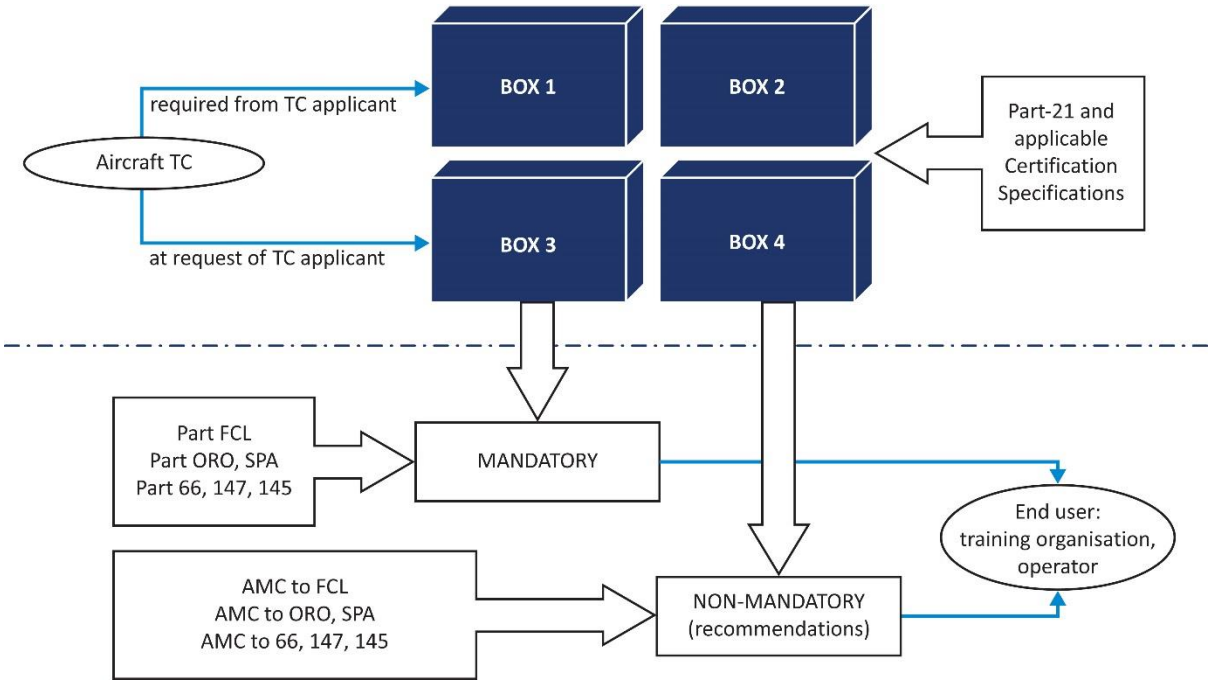


Figure 1: OSD boxes concept

Box 1: required from TC holder; mandatory for end-users.

Box 2: required from TC holder; not mandatory (recommendations) for end-users.

Box 3: at request of TC holder; mandatory for end-users.

The TC applicant may wish to apply for the approval of differences training between variants or types to reduce training, checking or currency requirements for operations of more than one type or variant. This is regarded as an optional element in addition to the required elements of Box 1 and 2.

Box 4: at request of TC holder; not mandatory (recommendations) for end-users.

The exact content of the four boxes in the above figure is determined by the certification specification that is applicable to the specific OSD constituent or the special condition in case of an 'other type-related operational suitability element'.

The status the data will have on the side of the operator or training organisation should be indicated in the OSD by segregating the data in a section called 'Mandatory' and a section called 'Non-mandatory (recommendations)'.

GM4 21.A.15(d) Application

ED Decision 2021/001/R

SCOPE OF OPERATIONAL SUITABILITY DATA

In the application for the approval of operational suitability data, the TC applicant may apply for the approval of different types of operations. If the aircraft is certified for certain types of operations (e.g. ETOPS, RNP, LVO), the impact on the OSD constituents of 21.A.15(d) should be addressed.

The five defined OSD constituents are listed in paragraph (2)(k) of Article 1 of Regulation (EU) No 748/2012. As explained in GM No 1 to 21.A.15(d), they may not all be applicable to all aircraft types. The content of each OSD constituent is defined in the relevant certification specification (CS) and will be approved under a type certificate (TC), supplemental type certificate (STC) or change to those certificates. As explained in GM No 3 to 21.A.15(d), each OSD constituent can have a part that is mandatory for the end user (operator, training organisation, etc.) and a part that is not mandatory (recommendation) for the end user. However, both the mandatory and the non-mandatory part together are the OSD constituent. Furthermore, the OSD constituent always includes the element required from the TC/STC applicant, as specified in the CS, and may include additional elements at the request of the TC/STC applicant, but still as defined in the CS.

GM 21.A.15(e) and (f) Period of validity for the application for a type certificate (TC) or restricted type certificate (RTC)

ED Decision 2019/018/R

Point 21.A.15(e) establishes a maximum period of validity for an application for a TC or an RTC. During this period, the type-certification basis, operational suitability data (OSD) certification basis, and the environmental protection requirements (hereinafter referred to as the 'certification basis'), established and notified by EASA in accordance with points 21.B.80, 21.B.82 and 21.B.85, remain effective. However, the period of validity of the certification basis is limited so that the standards notified as part of the certification basis at the time of application do not become outdated.

For various reasons (e.g. development, business, commercial, etc.), the applicant may not be able to complete the certification within the established time limit. In this case, the applicant has the following two options (see 21.A.15(f)(1) and (2)):

1. Submit a new application In this case, EASA establishes and notifies a new certification basis in accordance with points 21.B.80, 21.B.82 and 21.B.85, considering the standards that are available at the date of the new application.

   In accordance with point 21.A.15(e), the new application has a maximum period of validity that is equal to the first one, corresponding to the product category. Beyond this period of validity, the applicant may need to choose again between the two options of either submitting a new application or applying for an extension of the initial application.

2. Apply for an extension of the initial application

   In this case, the applicant proposes a 'new target date' to EASA for the issuance of the certificate, and selects a date that becomes the reference date for the establishment of the certification basis by EASA. For the purposes of this GM, the selected reference date is referred to as the 'new effectivity date' of the initial application.

   The 'new effectivity date' of the initial application may be any date in the past between the following time limits:

   — the 'new target date' for a TC proposed by the applicant minus the time limit used under 21.A.15(e) (e.g. 5 years for large aeroplanes and large rotorcraft, 3 years for the other products); and

   — the date on which the applicant applies for the extension of the initial application.

This calculation is visualised in Figure 1 below:

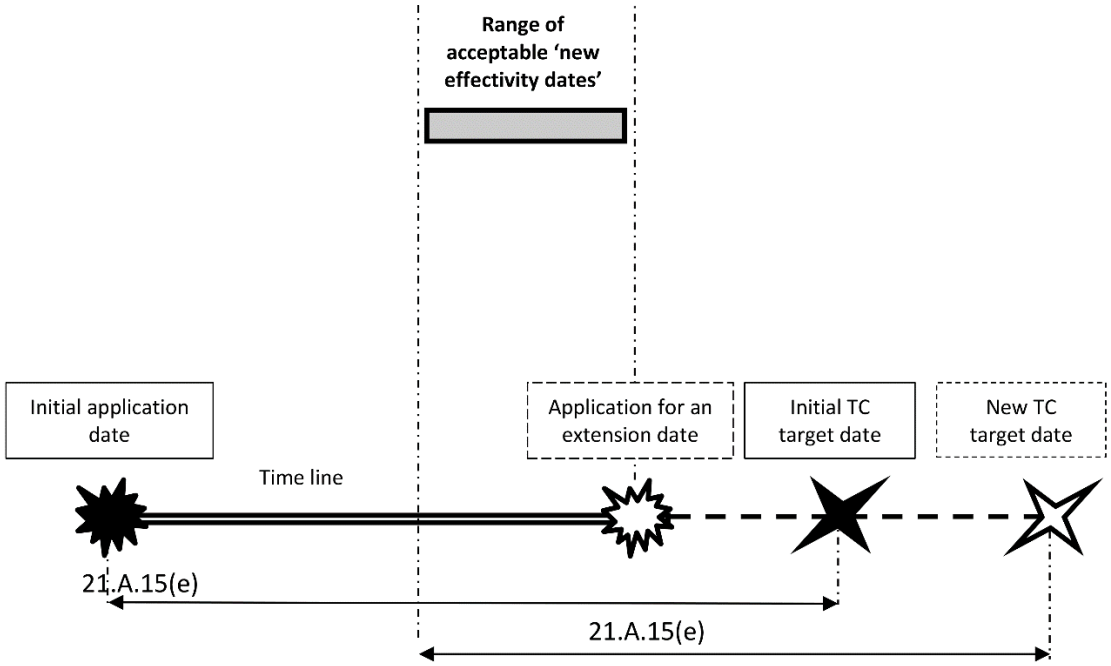


Figure 1

This ensures that the standards used to establish the certification basis are never older than the ones available at the start of the period of validity required by point 21.A.15(e).

If the applicant is not able to complete the product certification by the new target date, the applicant may choose again between the two options of either submitting a new application or applying for a new extension of the initial application.

21.A.19 Changes requiring a new type-certificate

Regulation (EU) No 748/2012

Any natural or legal person proposing to change a product shall apply for a new type-certificate if the Agency finds that the change in design, power, thrust, or mass is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

21.A.20 Demonstration of compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements

Regulation (EU) 2019/897

(a) Following the acceptance of the certification programme by the Agency, the applicant shall demonstrate compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified to the applicant by the Agency in accordance with points 21.B.80, 21.B.82, 21.B.85, and shall provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant shall report to the Agency any difficulty or event encountered during the process of demonstration of compliance that may have an appreciable effect on the risk assessment under point 21.A.15(b)(6) or on the certification programme, or may otherwise necessitate a change to the level of involvement of the Agency previously notified to the applicant in accordance with point 21.B.100(c).

(c) The applicant shall record justifications of compliance within the compliance documents as referred to in the certification programme.

(d) After completion of all demonstrations of compliance in accordance with the certification programme, including any inspections and tests in accordance with point 21.A.33, and after all flight tests in accordance with point 21.A.35, the applicant shall declare that:

1. it has demonstrated compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency, following the certification programme as accepted by the Agency; and

2. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(e) The applicant shall submit to the Agency the declaration of compliance provided for in point (d). Where the applicant holds an appropriate design organisation approval, the declaration of compliance shall be made in accordance with Subpart J and submitted to the Agency.

GM 21.A.20 Compliance demonstration process

ED Decision 2019/018/R

Point 21.A.20 applies to the compliance demonstration process for a type certificate (TC) (or a restricted type certificate (RTC)) and, by cross references to Part 21 Subpart D and E, to compliance demonstration processes for major changes to a TC (see point 21.A.97(b)(3)) and an STC (see point 21.A.115(b)(4)).

Applicants for a TC (or an RTC) should apply point 21.A.20 in full. Applicants for a major change to a TC (or an STC) are required (see points 21.A.97(b)(3) and 21.A.115(b)(4)) to apply point 21.A.20 as applicable to the change.

'As applicable to the change' means that:

— the certification programme to be followed is the one prepared for the major change or STC in accordance with point 21.A.93, as accepted by EASA; and

— the certification basis (consisting of the type-certification basis, operational suitability data (OSD) certification basis, and the environmental protection requirements) is the one established by EASA in accordance with point 21.A.101 and notified to the applicant in accordance with point 21.B.105 (for a major change to a TC) or point 21.B.109 (for an STC).

Point 21.A.20 also applies to major changes to a TC or an STC approved by design organisation approval (DOA) holders under their privilege as per point 21.A.263(c)(8) or (9) (see also points 21.A.97(b)(3) and 21.A.115(b)(4)). As in this case there is no application and no EASA involvement, point 21.A.20 should be applied with the following adaptions:

— the certification programme to be followed, including the certification basis and the detailed means of compliance, should be almost identical to the one accepted by EASA for a major change or an STC when approved for the scope of the privilege as per point 21.A.263(c)(8) or (9); it may

differ in some aspects (e.g. the detailed description of the changes), but it should be shown to remain in the frame of the corresponding justification document; and

— the means by which such compliance has been demonstrated (see point 21.A.20(a)) and the final declaration of compliance (see point 21.A.20(e)) should be kept on record and submitted to EASA only if EASA requests them during its DOA continued surveillance process.

GM 21.A.20(b) Reporting on the compliance demonstration process

ED Decision 2019/018/R

The applicant should report to EASA any unexpected difficulty or event encountered during the compliance demonstration that invalidates or appreciably affects the assumptions previously made, for example:

— an increase in the severity of the consequences of a certain condition (e.g. failure mode) of the product;

— significantly reduced margin(s) for the 'pass–fail' criteria of the compliance demonstration;

— changes to the test sequences and conditions that are not in line with the certification specifications or guidance;

— an unusual interpretation of the results of the compliance demonstration; and

— any significant failure or finding resulting from the tests performed as per points 21.A.33 or 21.A.35.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact on the certification programme and, if necessary, amend it as per point 21.A.15(c).

AMC 21.A.20(c) Compliance documentation

ED Decision 2019/018/R

1. Compliance documentation comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable type-certification basis, the operational suitability certification basis and environmental protection requirements is demonstrated.

2. Each compliance document should normally contain:

    — the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;

    — substantiation data demonstrating compliance (except test or inspection programmes/plans);

    — a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

    — the appropriate authorised signature.

3. Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21.A.55.

GM 21.A.20(d) Final statement

ED Decision 2019/018/R

All compliance demonstrations in accordance with the certification programme, including all the inspections and tests in accordance with point 21.A.33 and all flight tests in accordance with point 21.A.35, should be completed before the issuance of the final statement of compliance required by point 21.A.20(d).

If so agreed by EASA, some compliance documentation may be produced after the issuance of the final statement of compliance required by 21.A.20(d).

'No feature or characteristics' in point 21.A.20(d)2 means the following: while every effort is made to address in the applicable certification basis all the risks to product safety or to the environment that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant has to declare that they have not identified any such features or characteristics.

Point 21.A.20 also applies by reference to minor changes, in which case the risk to product safety or to environmental protection is quite low. Nevertheless, minor changes should not be approved if either the applicant/design organisation approval (DOA) holder approving minor changes under their privileges, or EASA, is aware of a feature or characteristic that may make the product unsafe for the uses for which certification is requested.

21.A.21 Requirements for the issuance of a type certificate or restricted type certificate

Regulation (EU) 2019/897

(a) In order to be issued a product type certificate or, when the aircraft does not meet the essential requirements of Annex II to Regulation (EU) 2018/1139 an aircraft restricted type certificate, the applicant shall:

1. demonstrate its capability in accordance with point 21.A.14;
2. comply with point 21.A.20;
3. demonstrate that the engine and propeller, if installed in the aircraft:
   (A) have a type-certificate issued or determined in accordance with this Regulation; or
   (B) have been demonstrated to be in compliance with the aircraft type-certification basis established and the environmental protection requirements designated and notified by the Agency as necessary to ensure the safe flight of the aircraft.

(b) By derogation from point (a)(2), at the applicant's request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have the aircraft type-certificate or restricted type-certificate issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

GM 21.A.21(a)(3)(i) Clarification of the term 'determined'

ED Decision 2021/011/R

A type certificate 'determined' in accordance with Part 21 means a type certificate, or a document that allows the issuance of a certificate of airworthiness, issued before 28 September 2003 by a Member State complying with Article 3(1)(a) of Regulation (EU) No 748/2012.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.31 Type design

Regulation (EU) 2019/897

(a) The type design shall consist of:

1. the drawings and specifications, and a listing of those drawings and specifications, necessary to define the configuration and the design features of the product shown to comply with the applicable type-certification basis and environmental protection requirements;
2. information on materials and processes and on methods of manufacture and assembly of the product necessary to ensure the conformity of the product;
3. an approved airworthiness limitations section of the instructions for continued airworthiness as defined by the applicable certification specifications; and
4. any other data allowing by comparison the determination of the airworthiness and, if relevant, the environmental characteristics of later products of the same type.

(b) Each type design shall be adequately identified.

21.A.33 Inspections and tests

Regulation (EU) 2019/897

(a) (Reserved)

(b) Before each test is undertaken during the demonstration of compliance required by point 21.A.20, the applicant shall have verified:

1. for the test specimen, that:

(i) the materials and processes adequately conform to the specifications for the proposed type design;

(ii) the parts of the products adequately conform to the drawings in the proposed type design; and

(iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and

2. for the test and measuring equipment to be used for the test, that those are adequate for the test and appropriately calibrated.

(c) On the basis of the verifications carried out in accordance with point (b), the applicant shall issue a statement of conformity listing any potential non-conformity, together with a justification that this will not affect the test results, and shall allow the Agency to make an inspection it considers necessary to check the validity of that statement.

(d) The applicant shall allow the Agency to:

1. review any data and information related to the demonstration of compliance; and

2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance.

(e) For all the tests and inspections witnessed or carried out by the Agency in accordance with point (d)(2):

1. the applicant shall submit to the Agency a statement of conformity provided for in point (c); and

2. no change that affects the validity of the statement of conformity shall be made to the test specimen, or the test and measuring equipment, between the time the statement of conformity provided for in point (c) was issued and the time the test specimen is presented to the Agency for test.

AMC 21.A.33 Inspections and tests

ED Decision 2019/018/R

Use of the term 'applicant': point 21.A.33 is applicable to type certification, major changes, major repairs and supplemental type certificates (STCs), and through reference in point 21.A.604 to ETSO for auxiliary power units (APUs). Despite using the word 'applicant', it is also applicable to major changes, major repairs and STCs approved under DOA privileges (see point 21.A.263(c)(5), (8) or (9)).

Proposed type design: this term defines the type design (or the portion of the type design) as it is determined at the time when the inspection or test is undertaken.

Statement of conformity: for each certification inspection or test, the statement of conformity issued in accordance with point 21.A.33(c) must address the conformity of the test specimen (see point 21.A.33(b)(1)) as well as of the test equipment and measuring equipment (see point 21.A.33(b)(2)).

Conformity of the test specimen: the statement of conformity required by point 21.A.33(c) is intended to ensure that the manufactured test specimen adequately represents the proposed type design. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the proposed type design at the time of the test. These are typically identified in the early stage of the test planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity in (a) as early as possible, the applicant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed and justified in the statement of conformity or by cross reference to the test plan or other documents.

Type certification is typically an iterative process in which the design is under continuous evolution. If the type design evolves after the time of the inspection or test, then the final type design should be checked against the proposed type design (as it was at the time of the inspection or test), and the differences (if any) should be analysed to ensure that the inspection or test results are representative of the final configuration. However, such changes made to the type design may lead to the invalidation of the inspection or test results and a need to repeat the inspection or test. It is recommended that the design organisation should have a thorough configuration management process to track the evolving type design.

Conformity of test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

    — type/model of sensors, together with their technical characteristics;

    — position and orientation of exciters and sensors; and

    — electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through certification test plans and supporting documentation, according to the design assurance system, if applicable. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The statement of conformity of point 21.A.33(c) should confirm that the test and measuring equipment conform to its purpose, and that the sensors and measuring system are appropriately

calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This can be done either in the statement of conformity or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test specimen, as well as the test and measuring equipment, are considered to be 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up does not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or masking any potential failure mode or behaviour).

Changes that affect the validity of the statement of conformity (see point 21.A.33(e)(2)): if changes need to be introduced to the test specimen or to the test and measurement equipment after the statement of conformity is issued (and before the test is undertaken), the statement of conformity must be updated. The updated statement of conformity must be made available to EASA before the test if EASA has informed the applicant that it will witness or carry out the tests.

Development versus certification tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for certification (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21.A.33.

Any planned test event should be classified in advance as either a development test or a certification test. Tests that support the compliance demonstration should be classified as certification tests.

Nevertheless, if agreed by EASA, it is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a certification test as long as it meets the requirements of point 21.A.33. For this reason, it is important to keep the configuration of such tests under the control of the design organisation.

In addition to this, the level of involvement (LoI) notified by EASA as per 21.B.100(c) should be taken into account: if EASA has determined that it will witness or conduct a certain test, this test may need to be repeated so that EASA can witness or conduct the test.

If the test specimen used for a certification test has already undergone a series of previous tests that may affect or ultimately invalidate its acceptance as required by point 21.A.33(b), this aspect should be considered when issuing the statement of conformity required by point 21.A.33(c), and specific analyses or inspections may be required to support such a statement.

Because of the above aspects, EASA advises applicants to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as certification tests.

Availability of compliance data (see point 21.A.33(d)(1)): data and information requested from the applicant for review should be made available in a reliable and efficient way that is agreed between the applicant and EASA.

Point 21.A.33(d)(1) refers to any data or information related to compliance data; the scope of that requirement is therefore not limited to inspections and tests. In particular, point 21.A.33(d)(1) is not limited to data and information related to compliance demonstration items (CDIs) in which EASA is involved.

GM 21.A.33(d) Inspections and tests

ED Decision 2019/018/R

The applicant should inform EASA sufficiently in advance about the execution of inspections and tests that are used for compliance demonstration purposes unless EASA has explicitly excluded these inspections and tests from its involvement according to 21.B.100.

Additionally, the applicant may propose to EASA to perform or witness flight or other tests of particular aspects of the product during its development and before the type design is fully defined. However, before EASA performs or witnesses any flight test, the applicant should have performed these tests already before EASA and should ensure that no features of the product preclude the safe conduct of the evaluation requested.

EASA may require any such tests to be repeated once the type design is fully defined to ensure that subsequent changes have not adversely affected the conclusions from any earlier evaluation.

A statement of conformity as per point 21.A.33(c) is also required for the above tests.

21.A.35 Flight Tests

Regulation (EU) No 748/2012

(a) Flight testing for the purpose of obtaining a type-certificate shall be conducted in accordance with conditions for such flight testing specified by the Agency.

(b) The applicant shall make all flight tests that the Agency finds necessary:

1. to determine compliance with the applicable type-certification basis and environmental protection requirements; and

2. to determine whether there is reasonable assurance that the aircraft, its parts and appliances are reliable and function properly for aircraft to be certificated under this Annex I (Part 21), except for,

(i) sailplanes and powered sailplanes,

(ii) balloons and airships defined in ELA1 or ELA2,

(iii) aeroplanes of 2 722 kg or less maximum take-off mass (MTOM).

(c) (Reserved)

(d) (Reserved)

(e) (Reserved)

(f) The flight tests prescribed in point (b)(2) shall include:

1. for aircraft incorporating turbine engines of a type not previously used in a type-certificated aircraft, at least 300 hours of operation with a full complement of engines that conform to a type-certificate; and

2. for all other aircraft, at least 150 hours of operation.

GM 21.A.35 Flight Tests

ED Decision 2012/020/R

Detailed material on flight testing is included in the applicable CS and GM.

GM 21.A.35(b)(2) Objective and Content of Function and Reliability Testing

ED Decision 2012/020/R

1. OBJECTIVE

The objective of this testing is to expose the aircraft to the variety of uses, including training, that are likely to occur when in routine service to provide an assurance that it performs its intended functions to the standard required for certification and should continue to do so in service.

2. CONTENT OF FUNCTION AND RELIABILITY TESTING

The testing should cover both routine operations and some simulation of abnormal conditions. The details of the programme should be agreed with the Agency prior to commencement of testing.

It may be possible to combine this testing with any required to demonstrate compliance with the applicable CS. This will be agreed on a case-by-case basis with the Agency.

Where possible, testing conditions should be defined with the co-operation of an operator.

A substantial proportion of the flying should be on a single aircraft. The flying should be carried out to a continuous schedule on an aircraft that is very close to the final type design, operated as though it were in service and should include a range of representative ambient operating conditions and airfields.

GM 21.A.35(f)(1) Flying Time for Function and Reliability Testing

ED Decision 2012/020/R

All flying carried out with engines and associated systems not significantly different from the final type-certificate standard may count towards the 300 hours airframe flight time required by 21.A.35(f)(1). At least 150 of the 300 flying hours should be conducted on a dedicated production configured aircraft. The requirement for 300 hours relevant flight time whenever a new turbine engine is incorporated applies regardless of whether the airframe/engine combination is subject to a new type-certificate or is to be certificated as a change or supplement to an existing type-certificate.

GM 21.A.35(f)(2) Flying Time for Function and Reliability Testing

ED Decision 2012/020/R

All flying carried out on an aircraft not significantly different from the final type design may count towards the 150 hours airframe flight time required by 21.A.35(f)(2).

21.A.41 Type-certificate

Regulation (EU) 2021/699

The type-certificate and restricted type-certificate shall include the type design, the operating limitations, the instructions for continued airworthiness, the type-certificate data sheet for airworthiness and emissions, the applicable type-certification basis and environmental protection requirements with which the Agency records compliance, and any other conditions or limitations prescribed for the product in the applicable certification specifications and environmental protection requirements. The aircraft type-certificate and restricted type-certificate shall include in addition the applicable operational suitability data certification basis, the operational suitability data and the type-certificate data sheet for noise. The aircraft type-certificate and restricted type-certificate data sheet shall include the record of CO_2 emissions compliance and the engine type-certificate data sheet shall include the record of exhaust emissions compliance.

21.A.44 Obligations of the holder

Regulation (EU) 2022/201

Each holder of a type-certificate or restricted type-certificate shall:

(a) undertake the obligations laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9, 21.A.62 and 21.A.65, and, for this purpose, shall continue to meet the qualification requirements for eligibility under point 21.A.13; and

(b) specify the marking in accordance with Subpart Q.

21.A.47 Transferability

Regulation (EU) 2022/201

The transfer of a type-certificate or a restricted type-certificate or an ETSO authorisation for an auxiliary power unit may only be made to a natural or legal person that is able to undertake the obligations laid down in point 21.A.44, and, for this purpose, has demonstrated its capability in accordance with point 21.A.14.

21.A.51 Duration and continued validity

Regulation (EU) No 748/2012

(a) A type-certificate and restricted type-certificate shall be issued for an unlimited duration. They shall remain valid subject to:

1. the holder remaining in compliance with this Annex 1 (Part 21); and
2. the certificate not being surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the type-certificate and restricted type-certificate shall be returned to the Agency.

21.A.62 Availability of operational suitability data

Regulation (EU) No 69/2014

The holder of the type-certificate or restricted type-certificate shall make available:

(a) at least one set of complete operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known EU operators of the aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and

(b) any change to the operational suitability data to all known EU operators of the aircraft; and

(c) on request, the relevant data referred to in points (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of this set of operational suitability data; and

2. any person required to comply with one or more elements of this set of operational suitability data.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

ED Decision 2014/007/R

(a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.

(b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

21.A.65 Continuing structural integrity for aeroplanes structures

Regulation (EU) 2021/699

The holder of the type-certificate or restricted type-certificate for a large aeroplane shall ensure that the continuing structural integrity programme remains valid throughout the operational life of the aeroplane, taking into account service experience and current operations.

AMC1 21.A.65 Continuing structural integrity programme for aeroplane structures

ED Decision 2021/007/R

Type-certificate (TC) or restricted type-certificate (RTC) holders for large aeroplanes should implement a process to ensure the continuing structural integrity of the aeroplane's structures following its entry into service.

For those large aeroplanes subject to point 26.300 of Part-26, compliance with point 21.A.65 of Part 21 is demonstrated by complying with point 26.305 of Part-26 within the timescale indicated therein.

For other large aeroplanes, the process should be established considering the points described below:

(a) Overall objectives

The objective of point 21.A.65 of Part 21 is to ensure that the continuing structural integrity programme remains valid throughout the operational life of the aeroplane and will preclude unsafe levels of fatigue cracking and other forms of structural degradation.

The intent is for (R)TC holders for large aeroplanes to monitor the continued validity of the assumptions upon which the ICA related to the aeroplane structures are based, and to ensure that unsafe levels of fatigue cracking or other structural deterioration will be precluded in service.

To achieve this objective, (R)TC holders are expected to work together with aircraft operators.

The process should apply to all structures whose failure could contribute to a catastrophic failure, and it is not limited to metallic structures or fatigue cracking, but should also encompass composite and hybrid structures and associated failure modes.

(b) Description of the process to maintain the validity of the continuing structural integrity programme

The process to maintain the validity of the continuing structural integrity programme is either continuous with each service finding, or is a regular review following several findings, or a combination of both. It should include the following:

(1) a plan to audit and report to EASA the effectiveness of the continuing structural integrity programme, including the continuing validity of the assumptions upon which it is based, prior to reaching any significant point in the life of the aeroplane;

(2) criteria for summarising findings of fatigue, environmental or accidental damage and their causes, and recording them in a way that allows any potential interaction to be evaluated;

(3) criteria to assess and record the relevance of each potential contributing factor to the finding, including operational usage, fatigue load spectra, environmental conditions, material properties, manufacturing processes and the fatigue- and damage-tolerance analytical methods of analysis and their implementation;

(4) criteria for establishing and revising sampling programmes to supplement the inspections and other procedures established in compliance with the applicable fatigue- and damage-tolerance requirements;

(5) criteria for establishing when structures should be modified, or the inspection programme revised, in the light of in-service damage findings;

(6) sunset criteria: the extent to which the above elements of the process require definition may be tailored to the size of the fleet and its expected useful remaining life.

(7) Additional means of compliance may be found in paragraph 5 and Appendix 5 to AMC 20-20B.

(SUBPART C — NOT APPLICABLE)

SUBPART D — CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.A.90A Scope

Regulation (EU) No 69/2014

This Subpart establishes the procedure for the approval of changes to type-certificates, and establishes the rights and obligations of the applicants for, and holders of, those approvals. This Subpart also defines standard changes that are not subject to an approval process under this Subpart. In this Subpart, references to type-certificates include type-certificate and restricted type-certificate.

GM 21.A.90A Scope

ED Decision 2019/018/R

The term 'changes to the type certificate' is consistently used in Part 21 Subpart D and E, as well as in the related AMC and GM. This term does not refer to changing the document that reflects the type certificate (TC) but to the elements of the TC as defined in 21.A.41. It means that the processes for the approval of changes, as described in the said two Subparts, do not only apply to changes to the type design, but may also apply to changes to:

— the operating limitations;

— the type certificate data sheet (TCDS) for airworthiness and emissions;

— the applicable type-certification basis and environmental protection requirements with which the applicant has to demonstrate compliance;

— any other conditions or limitations prescribed for the product by EASA;

— the applicable operational suitability data (OSD) certification basis;

— the OSD; and

— the TCDS for noise.

NOTE: OSD is only applicable to aircraft TCs and not to engine or propeller TCs. Therefore, changes to OSD are only relevant for changes to aircraft TCs.

21.A.90B Standard changes

Regulation (EU) 2021/699

(a) Standard changes are changes to a type-certificate:

1. in relation to:

(i) aeroplanes of 5 700 kg Maximum Take-Off Mass (MTOM) or less;

(ii) rotorcraft of 3 175 kg MTOM or less;

(iii) sailplanes, powered sailplanes, balloons and airships, as defined in ELA1 or ELA2,

2. that follow design data included in the certification specifications issued by the Agency, containing acceptable methods, techniques and practices for carrying out and identifying standard, including the associated instructions for continued airworthiness; and

3. that are not in changes conflict with TC holders data.

(b) Points 21.A.91 to 21.A.109 are not applicable to standard changes.

GM 21.A.90B Standard changes — Certification Specifications

ED Decision 2015/016/R

CS-STAN contains the certification specifications referred to in 21.A.90B(a)2. Guidance on the implementation of Standard Changes and Standard Repairs can be found in AMC M.A.801 of the AMC to Part-M.

21.A.90C Stand-alone changes to the Instructions for Continued Airworthiness

Regulation (EU) 2021/699

(a) Stand-alone changes to the instructions for continued airworthiness are changes that are not directly prepared as a result of a change to the type design or repair design.

(b) Stand-alone changes to the instructions for continued airworthiness can only be made by the holder of the design approval for which those instructions have been established.

(c) Points 21.A.91 to 21.A.109 shall not apply to stand-alone changes to the instructions for continued airworthiness that:

1. do not affect the airworthiness limitations section of the instructions for continued airworthiness, and

2. do not require the design approval holder to perform any additional demonstration of compliance with the certification basis.

(d) Stand-alone changes to the instructions for continued airworthiness referred to in point (c) shall be approved by the design approval holder under procedures agreed with the Agency.

GM1 21.A.90C Stand-alone changes

ED Decision 2021/007/R

Changes to the ICA are considered to be stand-alone changes when they are not directly prepared together with a change to the type design. Stand-alone changes to the ICA are usually prepared and issued, for example, for the purpose of making corrections, improvements, to include feedback from users, or to provide alternatives.

Also, when the ICA are completed after the product (or change to the product) was approved, this is considered to be a stand-alone change to the ICA.

When a non-ALS ICA change is triggered by a change to the type design, this does not affect the overall classification of the type certificate change as per point 21.A.91.

Stand-alone changes are usually straightforward changes, and are not considered to require additional work in order to show compliance. However, they must be managed in accordance with a process accepted by EASA under point 21.A.239 or point 21.A.14(b), for discharging the obligation to keep the ICA up to date.

Examples of changes that may require additional activities in order to show compliance are changes to the CDCCL, and EWIS ICA.

21.A.91 Classification of changes to a type-certificate

Regulation (EU) 2019/897

Changes to a type-certificate are classified as minor and major. A “minor change” has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, operational suitability data, or other characteristics affecting the airworthiness of the product or its environmental characteristics. Without prejudice to point 21.A.19, all other changes are “major changes” under this Subpart. Major and minor changes shall be approved in accordance with points 21.A.95 or 21.A.97, as appropriate, and shall be adequately identified.

GM 21.A.91 Classification of changes to a type certificate (TC)

ED Decision 2019/018/R

1. PURPOSE OF CLASSIFICATION

Classification of changes to a type certificate (TC) into MAJOR or MINOR is to determine the approval route to be followed in Part-21 Subpart D, i.e., either 21.A.95 or 21.A.97, or alternatively whether application and approval has to be made in accordance with Part-21 Subpart E.

2. INTRODUCTION

2.1 21.A.91 proposes criteria for the classification of changes to a TC as minor or major.

(a) This GM is intended to provide guidance on the term ‘appreciable effect’ affecting the airworthiness of the product or affecting any of the other characteristics mentioned in 21.A.91, where ‘airworthiness’ is interpreted in the context of a product in conformity with type design and in condition for safe operation. It provides complementary guidelines to assess a change to the TC in order to fulfil the requirements of 21.A.91 and 21.A.117 where classification is the first step of a procedure.

Note: For classification of Repairs see GM 21.A.435(a).

(b) Although this GM provides guidance on the classification of major changes, as opposed to minor changes as defined in 21.A.91, the GM and 21.A.91 are deemed entirely compatible.

2.2 For an ETSO authorisation, 21.A.611 gives specific requirements for design changes to ETSO articles.

For APU, this GM 21.A.91 should be used.

3. ASSESSMENT OF A CHANGE FOR CLASSIFICATION

3.1 Changes to the TC

21.A.91 addresses all changes to any of the aspects of a TC. This includes changes to a type design, as defined in 21.A.31, as well as to the other constituents of a TC, as defined in 21.A.41.

3.2 Reserved

3.3 Classification process (see also the flow chart 'Classification process' in Appendix A to GM 21.A.91)

21.A.91 requires all changes to be classified as either major or minor, using the criteria of 21.A.91.

Wherever there is doubt as to the classification of a change, EASA should be consulted for clarification.

When the strict application of the paragraph 3.4 criteria results in a major classification, the applicant may request reclassification, if justified, and EASA could take the responsibility for reclassifying the change.

A simple design change planned to be mandated by an airworthiness directive may be reclassified as minor due to the involvement of EASA in the continued airworthiness process when this is agreed between EASA and the DOA holder.

The reasons for a classification decision should be recorded.

3.4 Complementary guidance for classification of changes

A change to the TC is judged to have an 'appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, exhaust emission, operational suitability or other characteristics affecting the airworthiness, environmental protection or operational suitability of the product' and, therefore, should be classified as major, in particular but not only, when one or more of the following conditions are met:

(a) where the change requires an adjustment of the type-certification basis or the OSD certification basis (special conditions or equivalent safety findings) other than elect to comply with later certification specifications;

(b) where the applicant proposes a new interpretation of the certification specifications used for the type certification basis or the OSD certification basis that has not been published as AMC material or otherwise agreed with the Agency;

(c) where the demonstration of compliance uses methods that have not been previously accepted as appropriate for the nature of the change;

(d) where the extent of new substantiation data necessary to comply with the applicable certification specifications and the degree to which the original substantiation data has to be re-assessed and re-evaluated is considerable;

(e) where the change alters the airworthiness limitations or the operating limitations;

(f) where the change is made mandatory by an airworthiness directive or the change is the terminating action of an airworthiness directive (ref. 21.A.3B), see Note 1; and

(g) where the design change introduces or affects functions where the failure effect is classified as catastrophic or hazardous.

Note 1: A change previously classified as minor and approved prior to the airworthiness directive issuance decision needs no reclassification. However, EASA retains the right to review the change and reclassify/reapprove it if found necessary.

Note 2: The conditions listed in (a) through (g) above are an explanation of the criteria noted in 21.A.91.

For an understanding of how to apply the above conditions, it is useful to take note of the examples given in Appendix A to GM 21.A.91

3.5 Complementary guidance on the classification of changes to OSD

This paragraph provides firstly general guidance on minor OSD change classification, and secondly additional guidance specific to each OSD constituent.

Changes to OSD are considered minor when they:

— incorporate optional information (representing improvements/enhancements);

— provide clarifications, interpretations, definitions or advisory text; or

— do not change the intent of the OSD document, e.g. changes to:

  — titles, numbering, formatting, applicability;

  — order, sequence, pagination; or

  — sketches, figures, units of measurement, and correction of editorial mistakes such as:

    — spelling; or

    — reference numbers.

Given the structure and individual intent of the separate OSD constituents, the interpretation of ‘appreciable’ is also affected by the specific nature of the applicable certification specifications (CS) for that constituent. Therefore, specific guidance on each of the OSD constituents is provided hereafter.

(a) Master minimum equipment list (MMEL)

(1) A change to the MMEL is judged to have an ‘appreciable effect on the operational suitability of the aircraft’ and, therefore, should be classified as major, in particular but not only when one or more of the following conditions are met:

(i) where the change requires an adjustment of the OSD certification basis;

(ii) where the applicant proposes changes to the means of compliance with the requirements used for the OSD certification basis (i.e. MMEL safety methodology);

(iii) where the extent of substantiation data and the degree to which the substantiation data has to be assessed and evaluated is considerable, in particular but not only when:

(A) the substantiation data involving the review of failure conditions that are classified as hazardous or catastrophic has to be evaluated;

(B) the assessment of the failure effects (including next worst failure/event effects) on crew workload and the applicable crew procedures has to be evaluated; or

(C) the capability of the aircraft to perform types of operation (e.g. extended-range twin operations (ETOPS), instrument flight rules (IFR)) under MMEL is extended.

(2) A change to the MMEL is judged not to have an 'appreciable effect on the operational suitability of the aircraft' and, therefore, should be classified as minor, in particular but not only when one or more of the following conditions are met:

Modifications to an existing item when:

(i) the change only corresponds to the applicability of an item for configuration management purposes;

(ii) the change corresponds to the removal of an item;

(iii) the change corresponds to the increase in the number of items required for dispatch; and

(iv) the change corresponds to a reduction in the rectification interval of an item.

Addition of a new item when:

(v) it is considered as non-safety-related (refer to CS-MMEL, GM2 MMEL.110); or

(vi) it is indicated as eligible for minor change classification in 1 to GM1 CS-MMEL-145.

(b) Flight crew data (FCD)

(1) FCD change related to change to the type design

When classifying the FCD change as minor or major, the method of CS-FCD, Subpart D should be used.

(i) An analysis should be performed to assess the change impact on the FCD through the allocation of difference levels realised with operator difference requirement (ODR) tables as per CS FCD.400. In this case, the base aircraft is the aircraft without the type design change, whereas the candidate aircraft is the aircraft which includes the type design change.

(A) If a no more than level B difference is assigned for training, checking and currency for the candidate aircraft, the related FCD change should be classified as minor.

(B) If a difference level C, D or E for training, checking and currency is assigned to the candidate aircraft, the related FCD change should be classified as major.

(ii) Notwithstanding the above, the change to FCD should be classified as major when a T1 or T2 test is found necessary by the applicant to confirm that the aircraft with the type design change is not a new type for pilot type rating.

(2) Stand-alone changes to FCD are not related to any type design changes. They may be triggered for example by in-service experience or by the introduction of data at the request of the applicant after type certification.

(i) Introduction of credits in training, checking or currency should be classified as major. Example: addition of further-differences training, common take-off and landing credits, etc.

(ii) Stand-alone changes to FCD that correspond to a change of the intent of a data should be classified as major. Example: addition of a training area of special emphasis (TASE) or prerequisite, expansion of a TASE.

(c) Cabin crew data (CCD)

(1) OSD change related to change to the type design

When classifying the OSD CCD change as minor or major, the method from CS-CCD, Subpart B should be used.

(i) An analysis should be performed to assess the change impact on the OSD CCD through the identification of the difference and its impact on operation in the aircraft difference table (ADT) as per CS CCD.200. In this case, the base aircraft is the aircraft without the type design change, whereas the candidate aircraft is the aircraft which includes the type design change.

(A) If the difference has no impact on the operation of an element of the ADT for the candidate aircraft, the related OSD CCD change should be classified as minor.

(B) If the difference has an impact on the operation of an element of the ADT for the candidate aircraft, the related OSD CCD change should be classified as major.

(ii) Notwithstanding the above, the change to OSD CCD should be classified as major when an ADT analysis is found necessary by the applicant to confirm that the aircraft with the type design change is not a new type for cabin crew.

(2) Stand-alone changes to OSD CCD are not related to any type design changes. They may be triggered for example by in-service experience or by the introduction of data at the request of the applicant after type certification.

(i) Stand-alone changes to cabin aspects of special emphasis (CASE) should be classified as major. Example: addition of further CASE, expansion of CASE.

(ii) When classifying stand-alone changes to type-specific data for cabin crew the method from CS-CCD, Subpart B should be used. An analysis should be performed to assess the change impact on the type-specific data through the identification of the difference and its impact on operation in the ADT as per CS CCD.200.

(A) If the change does not concern a determination element of CS CCD.205, the stand-alone change should be classified as minor.

(B) If the change has no impact on the operation of an element of the ADT, the stand-alone change should be classified as minor.

(C) If the change has an impact on the operation of an element of the ADT, the stand-alone change should be classified as major.

(d) Simulator data (SIMD)

The OSD constituent 'simulator data' does not include the data package that is necessary to build the simulator. It includes only the definition of the scope of validation source data to support the objective qualification of a simulator. So, when this guidance discusses changes to 'simulator data', this concerns only changes to the 'definition of scope of validation source data' and not changes to the data package.

(1) A change to the SIMD should be classified as major, in particular but not only when one or more of the following conditions are met:

(i) when a change to the SIMD introduces validation source data from an engineering platform where the process to derive such data has not been audited by the Agency in the initial SIMD approval; or

(ii) when the process to derive validation source data from an engineering platform is changed.

(2) A change to the SIMD could be classified as minor, in particular but not only when one or more of the following conditions are met:

(i) changes to engineering validation data independent of the aircraft due to improvements or corrections in simulation modelling (e.g. aerodynamics, propulsion);

(ii) configuration changes to the aircraft where the process to derive validation source data from an engineering platform is unchanged;

(iii) changes to validation source data by using better, more applicable flight test data; or

(iv) editorial changes to the validation data roadmap (VDR).

(e) Maintenance certifying staff data (MCSD)

[Reserved]

3.6 Complementary guidance for the classification of changes to aircraft flight manuals (AFMs)

The following changes to the AFM are deemed to be minor:

(a) revisions to the AFM associated with changes to the type design that are classified as minor in accordance with point 21.A.91;

(b) revisions to the AFM that are not associated with changes to the type design (also identified as stand-alone revisions) which fall into one of the following categories:

(1) changes to limitations or procedures that remain within already certified limits (e.g. weight, structural data, noise, etc.);

(2) consolidation of two or more previously approved and compatible AFMs into one, or the compilation of different parts taken from previously approved and compatible AFMs that are directly applicable to the individual aircraft (customisation); and

(3) the introduction into a given AFM of compatible and previously approved AFM amendments, revisions, appendices or supplements; and

(c) administrative revisions to the AFM, defined as follows:

(1) for the AFMs issued by the TC holder:

(i) editorial revisions or corrections to the AFM;

(ii) changes to parts of the AFM that do not require approval by EASA;

(iii) conversions of previously Federal Aviation Administration (FAA)- or EASA-approved combinations of units of measurement added to the AFM in a previously approved manner;

(iv) the addition of aircraft serial numbers to an existing AFM where the aircraft configuration, as related to the AFM, is identical to the configuration of aircraft already covered by that AFM;

(v) the removal of references to aircraft serial numbers no longer applicable to that AFM; and

(vi) the translation of an EASA-approved AFM into the language of the State of design or State of registration;

(2) for AFM supplements issued by STC holders:

(i) editorial revisions or corrections to the AFM supplement;

(ii) changes to parts of the AFM supplement that are not required to be approved by EASA;

(iii) conversions of previously FAA- or EASA-approved combinations of units of measurement added to the AFM supplement in a previously approved manner;

(iv) the addition of aircraft serial numbers to an existing AFM supplement where the aircraft configuration, as related to the AFM supplement, is identical to that of the aircraft already in that AFM supplement; 'identical' means here that all the aircraft have to belong to the same type and model/variant;

(v) the addition of a new STC to an existing AFM supplement, when this supplement is fully applicable to the new STC;

(vi) the removal of references to aircraft serial numbers that are no longer applicable to that AFM supplement;

(vii) the translation of an EASA-approved AFM supplement into the language of the State of design or the State of registration.

3.7 Complementary guidance for classification of changes to environmental protection characteristics See Section 8 of Appendix A to GM 21.A.91.

Appendix A to GM 21.A.91 Examples of Major Changes per discipline

ED Decision 2021/007/R

The information below is intended to provide a few major change examples per discipline, resulting from application of 21.A.91 and paragraph 3.3 conditions. It is not intended to present a comprehensive list of all major changes. Examples are categorised per discipline and are applicable to all products (aircraft, engines and propellers). However a particular change may involve more than one discipline, e.g., a change to engine controls may be covered in engines and systems (software).

Those involved with classification should always be aware of the interaction between disciplines and the consequences this will have when assessing the effects of a change (i.e., operations and structures, systems and structures, systems and systems, etc.; see example in paragraph 2 (ii).

Specific rules may exist which override the guidance of these examples.

In the Part 21 a negative definition is given of minor changes only. However in the following list of examples it was preferred to give examples of major changes.

Where in this list of examples the words 'has effect' or 'affect(s)' are used, they have always to be understood as being the opposite of 'no appreciable effect' as in the definition of minor change in 21.A.91. Strictly speaking the words 'has appreciable effect' and 'appreciably affect(s)' should have been used, but this has not been done to improve readability.

1. Structure

(i) changes such as a cargo door cut-out, fuselage plugs, change of dihedral, addition of floats;

(ii) changes to materials, processes or methods of manufacture of primary structural elements, such as spars, frames and critical parts;

(iii) changes that adversely affect fatigue or damage tolerance or life limit characteristics;

(iv) changes that adversely affect aeroelastic characteristics.

2. Cabin Safety

(i) changes which introduce a new cabin layout of sufficient change to require a re-assessment of emergency evacuation capability or which adversely affect other aspects of passenger or crew safety.

Items to consider include, but are not limited to, :

— changes to or introduction of dynamically tested seats.

— change to the pitch between seat rows.

— change of distance between seat and adjacent obstacle like a divider.

— changes to cabin lay outs that affect evacuation path or access to exits.

— installation of new galleys, toilets, wardrobes, etc.

— installation of new type of electrically powered galley insert.

(ii) changes to the pressurisation control system which adversely affect previously approved limitations.

3. Flight

Changes which adversely affect the approved performance, such as high altitude operation, brake changes that affect braking performance.

Changes which adversely affect the flight envelope.

Changes which adversely affect the handling qualities of the product including changes to the flight controls function (gains adjustments, functional modification to software) or changes to the flight protection or warning system.

4. Systems

For systems assessed under CS 25.1309, the classification process is based on the functional aspects of the change and its potential effects on safety.

(i) Where failure effect is 'Catastrophic' or 'Hazardous', the change should be classified as major.

(ii) Where failure effect is 'major', the change should be classified as major if:

— aspects of the compliance demonstration use means that have not been previously accepted for the nature of the change to the system; or

— the change affects the pilot/system interface (displays, controls, approved procedures); or

— the change introduces new types of functions/systems such as GPS primary, TCAS, Predictive windshear, HUD.

The assessment of the criteria for software changes to systems also needs to be performed.

When software is involved, account should be taken also of the following guidelines:

Where a change is made to software produced in accordance with the guidelines of the latest edition of AMC 20-115 (see AMC-20 document) the change should be classified as major if either of the following apply, and the failure effect is Catastrophic, Hazardous or Major:

(i) the executable code for software, determined to be Level A or Level B in accordance with the guidelines, is changed unless that change involves only a variation of a parameter value within a range already verified for the previous certification standard; or

(ii) the software is upgraded to or downgraded from Level A, Level B or Level C; or

(iii) the executable code, determined to be level C, is deeply changed, e.g., after a software re-engineering process accompanying a change of processor.

For software developed to guidelines other than the latest edition of AMC 20-115, the applicant should assess changes in accordance with the foregoing principles.

For other codes the principles noted above may be used. However, due consideration should be given to specific certification specifications/interpretations.

In the context of a product information security risk assessment (PISRA), a change that may introduce the potential for unauthorised electronic access to product systems should be considered to be 'major' if there is a need to mitigate the risks for an identified unsafe condition. The following examples do not provide a complete list of conditions to classify a modification as major, but rather they present the general interactions between security domains. Examples of modifications that should be classified as 'major' are when any of the following changes occur:

— A new digital communication means, logical or physical, is established between a more closed, controlled information security domain, and a more open, less controlled security domain.

  — For example, in the context of large aircraft, a communication means is established between the aircraft control domain (ACD) and the airline information services domain (AISD), or between the AISD and the passenger information and entertainment services domain (PIESD) (see ARINC 811).

    As an exception, new simplex digital communication means (e.g. ARINC 429) from a controlled domain to a more open domain is not considered as major modification, if it has been verified that the simplex control cannot be reversed by any known intentional unauthorised electronic interaction (IUEI).

— A new service is introduced between a system of a more closed, controlled information security domain and a system of a more open, less controlled security domain, which allows the exploitation of a vulnerability of the service that has been introduced, creating a new attack path.

  For example:

  — opening and listening on a User Datagram Protocol (UDP) port in an end system of an already certified topology;

  — activating a protocol in a point-to-point communication channel.

— The modification of a service between a system of a more closed, controlled security domain and a system of a more open, less controlled security domain.

— The modification of a security control between a system of a more closed, controlled information security domain and a system of a more open, less controlled security domain.

5. Propellers

Changes to:

— diameter

— airfoil

— planform

— material

— blade retention system, etc.

6. Engines

Changes:

(i) that adversely affect operating speeds, temperatures, and other limitations.

(ii) that affect or introduce parts identified by CS E-510 where the failure effect has been shown to be hazardous.

(iii) that affect or introduce engine critical parts (CS E-515) or their life limits.

(iv) to a structural part which requires a re-substantiation of the fatigue and static load determination used during certification.

(v) to any part of the engine which adversely affects the existing containment capability of the structure.

(vi) that adversely affect the fuel, oil and air systems, which alter the method of operation, or require reinvestigation against the type-certification basis.

(vii) that introduce new materials or processes, particularly on critical components.

7. Rotors and drive systems

Changes that:

(i) adversely affect fatigue evaluation unless the service life or inspection interval are unchanged. This includes changes to materials, processes or methods of manufacture of parts, such as

— rotor blades

— rotor hubs including dampers and controls

— gears

— drive shafts

— couplings

(ii) affect systems the failure of which may have hazardous or catastrophic effects. The design assessment will include:

— cooling system

— lubrication system

— rotor controls

(iii) adversely affect the results of the rotor drive system endurance test, the rotor drive system being defined in CS 27/29.917.

(iv) adversely affect the results of the shafting critical speed analysis required by CS 27/29.931.

8. Environment

The introductory text to Appendix A to GM 21.A.91 describes how in Part 21 a negative definition is given of minor changes only. This philosophy is similar to the manner in which the ICAO Standards and Recommended Practices for environmental protection (ICAO Annex 16) and the associated Guidance Material (ICAO Environmental Technical Manual) define changes affecting a product's environmental characteristics in terms of 'no-acoustical changes', 'no-

emissions changes' and 'no-CO_2 changes' (i.e. changes which do not appreciably affect the product's environmental characteristics).

Following the general philosophy of this Appendix, however, it is preferred to give examples of changes which might have an appreciable effect on a product's environmental characteristics (i.e. the effect might be greater than the no-acoustic change, no-emissions change and no-CO_2 change criteria) and might therefore lead to a 'major change' classification.

Where a change is made to an aircraft or aircraft engine, the effect of the change on the product's environmental characteristics should be taken into account. Examples of changes that might have an appreciable effect on the product's environmental characteristics, and might therefore be classified as major changes, are listed below. The examples are not exhaustive and will not, in every case, result in an appreciable change to the product's environmental characteristics, and therefore, will not per se and in every case result in a 'major change' classification.

An appreciable effect is considered to be one which exceeds the ICAO criteria for a no-acoustical change, a no-emissions change or a no-CO_2 change. For the definition of a no-acoustical change refer to the section of the ICAO Environmental Technical Manual, Volume I (ICAO Doc 9501, Volume I – Procedures for the Noise Certification of Aircraft) concerning changes to aircraft type designs involving no-acoustical changes (see also the definitions of a 'derived version' in ICAO Annex 16, Volume I). For the definition of a no-emissions change, refer to the section of the ICAO Environmental Technical Manual, Volume II (ICAO Doc 9501, Volume II – Procedures for the Emissions Certification of Aircraft Engines) concerning no-emissions changes. For the definition of a no-CO_2 change, refer to ICAO Doc 9501 'Environmental Technical Manual', Volume III 'Procedures for the CO_2 Emissions Certification of Aeroplanes', 1st Edition 2018, concerning no-CO_2 changes.

(i) Noise: A change that introduces either:

— an increase in the noise certification level(s); or

— a reduction in the noise certification level(s) for which the applicant wishes to take credit.

Examples of noise-related changes that might lead to a major change classification are:

(1) For jet and heavy (maximum take-off mass greater than 8 618 kg) propeller-driven aeroplanes:

— A change that might affect the aircraft's take-off performance including:

— a change to the maximum take-off mass;

— a change to V2 ('take-off safety speed'); or

— a change to the lift augmentation devices, including their configuration under normal take-off operating conditions.

— A change that might affect the aircraft's landing performance including:

— a change to the maximum landing mass;

— a change to VREF (reference landing speed); or

— a change to the lift augmentation devices, including their deployment under normal landing operating conditions.

— A change to the Centre of Gravity (CG) limits;

— A change that increases the aircraft's drag;

— A change that alters the external profile of the aircraft, including the installation or change of shape or size of any item on the external surface of the aircraft that might protrude into the airflow such as winglets and vortex generators; generally the installation of small antennas does not represent an acoustical change;

— A change that introduces an open-ended hollow cavity at more or less right angles to the airflow (e.g. hollow pins in undercarriage assemblies);

— A change of engine or, if fitted, propeller type;

— A change in engine thrust rating;

— A change to the engine rotating parts or stators, such as geometry, blade profile or blade number;

— A change to the aerodynamic flow lines through the engine;

— A change that affects the engine thermodynamic cycle, including a change to the engine's bypass ratio;

— A change to the engine nacelle, including a change to the acoustic liners;

— A change to the engine exhaust;

— A change to the engine bleed valves, including bleed valve scheduling;

— A change in the operation of engine power off-takes (e.g. the operation of the Environmental Control System (ECS) during a normal take-off or approach);

— A change to the Auxiliary Power Unit (APU), including associated operating limitations (e.g. a change that allows the APU to be operated during a normal approach when previously it was not allowed);

— A change to the propeller pitch and/or propeller speed during a normal take-off or approach;

— A change that causes a change to the angle at which air flows into the propeller.

(2) For light (maximum take-off mass 8 618 kg or less) propeller-driven aeroplanes:

— A change that might affect the aircraft's take-off performance including:

  — a change to the maximum take-off mass;

  — a change to the take-off distance;

  — a change to the rate of climb; or

  — a change to Vy (best rate of climb speed).

— A change that increases the aircraft's drag (e.g. the installation of external cargo pods, external fuel tanks, larger tyres to a fixed undercarriage, floats etc.);

— A change of engine or propeller type;

— A change in take-off power including a change in engine speed (tachometer 'red line') or, for piston engines, a change to the manifold pressure limitations;

— A change to the highest power in the normal operating range (‘top of green arc’);

— In the case of an aircraft where take-off power/engine speed is time limited, a change in the period over which take-off power/engine speed may be applied;

— A change to the engine inlet or exhaust including, if fitted, the inlet or exhaust muffler;

— A change in propeller diameter, tip shape, blade thickness or the number of blades;

— The installation of a variable or adjustable pitch propeller in place of a fixed pitch propeller and vice versa;

— A change that causes a change to the angle at which air flows into the propeller.

(3) For helicopters:

— A change that might affect the take-off and/or landing performance, including a change in take-off mass and VY (best rate of climb speed);

— A change to VNE (never-exceed airspeed) or to VH (airspeed in level flight obtained using the torque corresponding to minimum engine installed, maximum continuous power available for sea level pressure, 25°C ambient conditions at the relevant maximum certificated mass);

— A change to the maximum take-off engine power or maximum continuous power;

— A change to the gearbox torque limits;

— A change of engine type;

— A change to the engine intake or exhaust;

— A change to the maximum normal operating rpm of the main or tail rotors;

— A change to the main or tail rotors, including a change in diameter, blade thickness or blade tip profile.

Note: The effect on the helicopter’s noise characteristics of either carrying external loads or the installation of external equipment need not be considered.

(ii) Emissions: A change that introduces an increase or decrease in the emissions certification levels. Examples of smoke and gaseous engine emission-related changes that might lead to a major change classification are:

— A change in engine thrust rating;

— A change to the aerodynamic flow lines through the engine;

— A change that affects the engine thermodynamic cycle, specifically relevant engine cycle parameters (e.g. combustor pressure P3, combustor entry temperature T3, Air Fuel Ratio (AFR));

— A change to the compressor that might influence the combustor inlet conditions and engine overall pressure ratio;

— A change to the combustor design (geometry);

— A change to the cooling of the combustor;

— A change to the air mass flow through the combustor;

— A change that affects the fuel spray characteristics.

(iii) CO_2: a change that introduces either:

— an increase in the CO_2 emissions certification level; or

— a decrease in the CO_2 emissions certification level for which an applicant wishes to take credit.

Examples of CO_2 emission-related changes that may lead to a 'major change' classification are:

— a change to the maximum take-off mass;

— a change that may affect the aeroplane's specific air range performance, including one or several of the following:

— a change that increases the aircraft's drag;

— a change of engine or, if fitted, propeller type;

— a change in the engine design that affects the engine specific fuel consumption in cruise.

— a change to the aeroplane's reference geometric factor (RGF).

9. Power plant Installation

Changes which include:

(i) control system changes which affect the engine/propeller/airframe interface;

(ii) new instrumentation displaying operating limits;

(iii) modifications to the fuel system and tanks (number, size and configuration);

(iv) change of engine/propeller type.

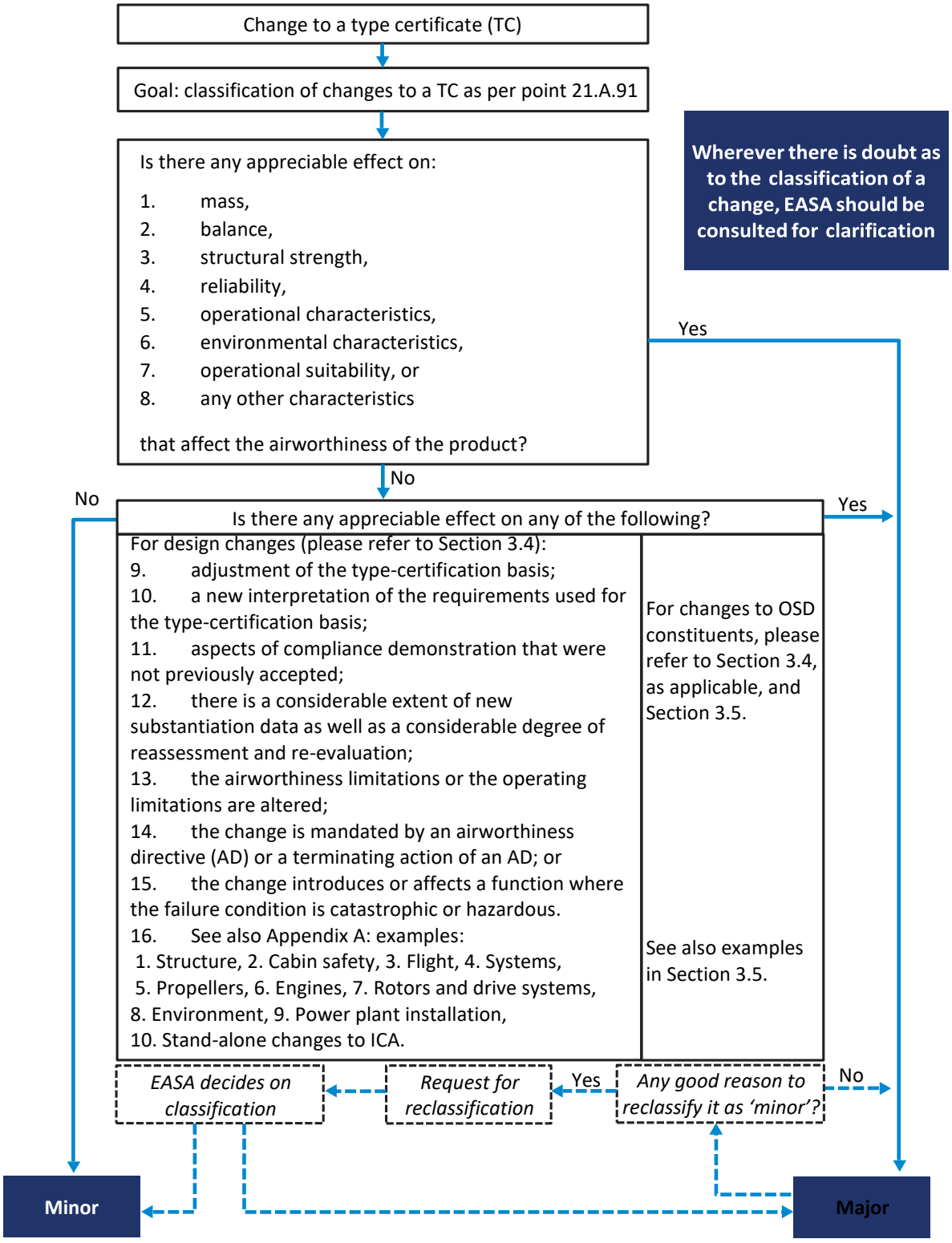
10. Stand-alone changes to non-ALS ICA that require additional work to demonstrate compliance with the applicable certification basis as follows:

(i) changes related to accomplishment instructions (e.g. to the aircraft maintenance manual) related to the CDCCL, or the EWIS ICA, for which the technical content (e.g. gaps, steps) of the procedures is changed;

(ii) the introduction of novel technology for inspection purposes related to an ALS task;

(iii) changes that adversely affect the certification assumptions: e.g. some specific inspection procedures, such as inspection procedures for use after a hard landing, may include a decision-making chart based on the level of exceedance of the load in comparison with the certified limit loads; such criteria, and adverse changes, need to be agreed with EASA.

Classification Process



21.A.92 Eligibility

Regulation (EU) No 69/2014

(a) Only the type-certificate holder may apply for approval of a major change to a type-certificate under this Subpart; all other applicants for a major change to a type-certificate shall apply under Subpart E.

(b) Any natural or legal person may apply for approval of a minor change to a type-certificate under this Subpart.

21.A.93 Application

Regulation (EU) 2021/699

(a) An application for approval of a change to a type-certificate shall be made in a form and manner established by the Agency.

(b) An application shall include, or be supplemented after the initial application by, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:

1. a description of the change identifying:

   (i) the configuration(s) of the product in the type certificate upon which the change is to be made;

   (ii) all areas of the product in the type-certificate, including the approved manuals, that are changed or affected by the change; and

   (iii) when the change affects the operational suitability data, any necessary changes to the operational suitability data;

2. an identification of any reinvestigations necessary to demonstrate compliance of the change and areas affected by the change with the type-certification basis, operational suitability data certification basis and environmental protection requirements; and

3. for a major change to a type-certificate:

   (i) a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in point 21.A.101;

   (ii) a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;

   (iii) a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on product safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1)–(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and

   (iv) a project schedule including major milestones.

(c) An application for a change to a type-certificate of a large aeroplane or a large rotorcraft shall be valid for five years and an application for a change to any other type-certificate shall be valid for three years. In the case where the change has not been approved, or it is evident that it will not be approved, within the time limit provided for in this point, the applicant may:

1. submit a new application for a change to the type-certificate and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105 for the date of the new application; or

2. apply for an extension of the time period provided for in the first sentence of point (c) for the original application and propose a new date for the issuance of the approval. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105, for a date to be selected by the applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the approval by more than five years for an application for a change to type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for a change to any other type-certificate or restricted type certificate.

AMC 21.A.93(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application forms for the approval of major changes/major repair designs (FO.CERT.00031)[2] or for the approval of minor changes/minor repair designs (FO.CERT.00032)[3], which may be downloaded from the EASA website.

The forms should be completed in accordance with the instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[4].

AMC 21.A.93(b) Certification programme for a change to a TC or an STC

ED Decision 2019/018/R

The description of the change should include an explanation of the purpose of the change, the pre-modification and post-modification configuration(s) of the product, schematics/pictures, and any other detailed features and boundaries of the physical change (this may be supplemented by drawings or outlines of the design, if this helps to understand the design change), as well as the identification of the changes in areas of the product that are functionally affected by the change, and the

1 https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

2 https://www.easa.europa.eu/document-library/application-forms/focert00031 (changes to the link provided may not be reflected in this document).

3 https://www.easa.europa.eu/document-library/application-forms/focert00032 (changes to the link provided may not be reflected in this document).

4 https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

identification of any changes to the approved manuals. Guidance on areas that are changed and affected by the change is found in GM 21.A.101, Section 3.9.1.

Identification of reinvestigations referred to in point 21.A.93(b)(2), necessary to demonstrate compliance, does not mean the demonstration of compliance itself, but the list of affected items of the applicable certification basis for which a new demonstration is necessary, together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

Before submitting the application for a change, the analysis and classification activities of points 21.A.91 and 21.A.101 should be performed using the corresponding GM. For repair designs, the analysis of point 21.A.91 should be performed using GM 21.A.435(a).

For a major change, AMC 21.A.15(b) should be used as applicable to the change.

GM No 1 to 21.A.93(b)(1)(iii) Interaction of changes to the type design and changes to operational suitability data (OSD)

ED Decision 2019/018/R

In general, it has to be assumed that changes to the type design can have an effect on the OSD.

Due to the alleviating nature of the OSD constituent master minimum equipment list (MMEL), the impact of design changes on the MMEL can be treated differently from the impact on other OSD constituents. Therefore, a separate GM No 2 to 21.A.93(b)(1)(iii) is available to explain the interaction between design changes and the MMEL. The following guidance is, therefore, only applicable to the other OSD constituents: flight crew data (FCD), cabin crew data (CCD), simulator data (SIMD), and maintenance certifying staff data (MCSD).

In assessing the interactions between the changes to the type design and to the OSD, the following can be taken into consideration (see Figure 1):

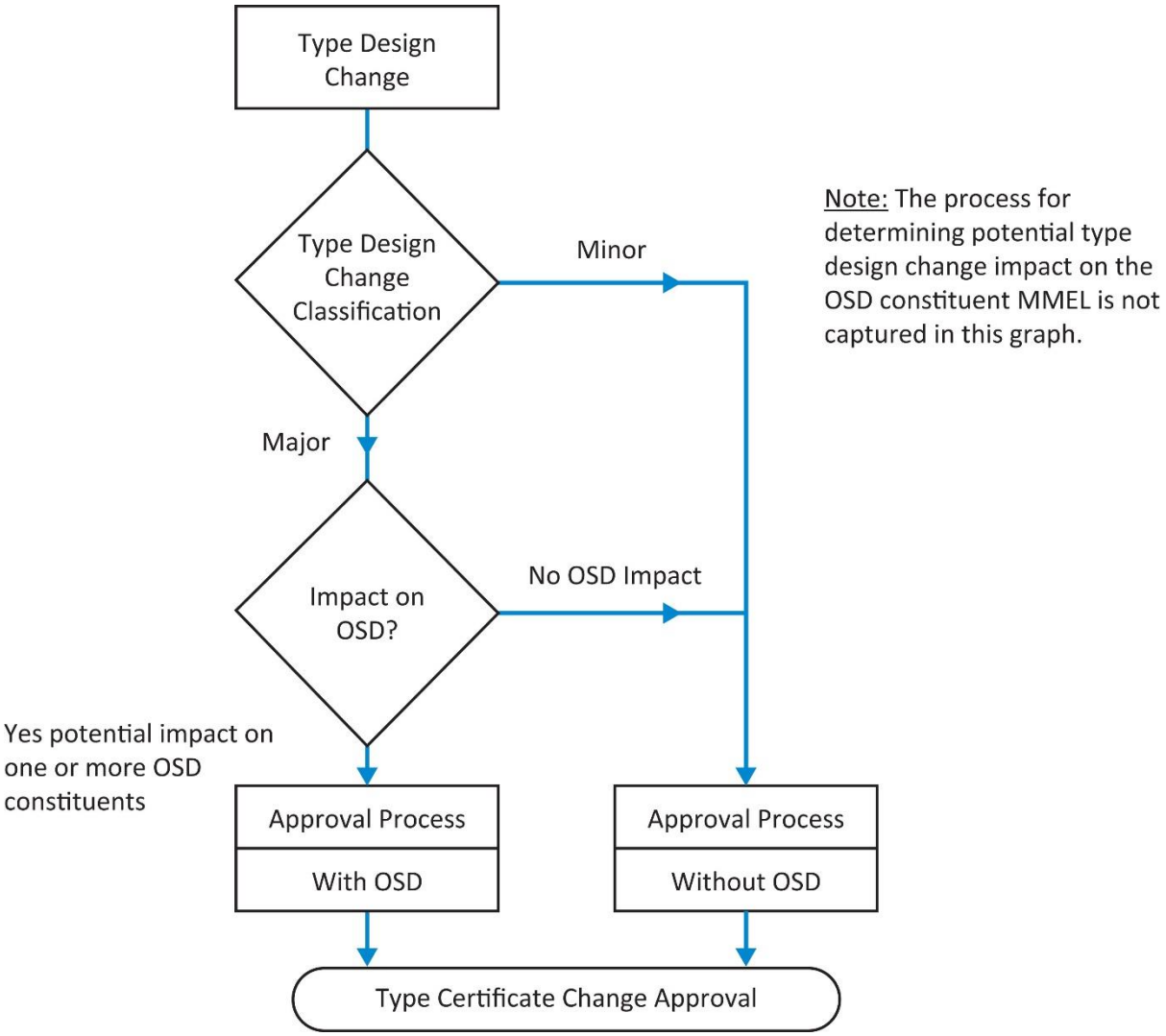


Figure 1

(a) Changes to the type certificate (TC) that only include a minor change to the type design ('stand-alone' type design changes) do not have an effect on the OSD. No dedicated assessment of the effects of the minor type design change on the OSD is needed in this case.

(b) TC changes that only include a major type design change do not need to be assessed for their effect on the OSD in case the experience of the applicant has demonstrated that similar changes do not have an effect on the OSD. Examples of major type design changes and their expected effect on OSD constituents are identified in Table 1 below.

Table 1: Examples of major type design changes and their expected impact on OSD constituents

Discipline	Example of major type design change	Expected impact on OSD constituent			
		FCD	SIMD	CCD	MCSD
Structure	(i) Changes such as a cargo door cut-out, fuselage plugs, change to dihedral, addition of floats.	No	No	No	tbd[1]
	(ii) Changes to material, processes or methods of manufacture, or to primary structural elements such as spars, frames and critical parts.	No	No	No	tbd
	(iii) Changes that adversely affect fatigue or damage tolerance or life limit characteristics.	No	No	No	tbd
	(iv) Changes that adversely affect aeroelastic characteristics.	No	No	No	tbd
	(v) Aircraft weight changes such as maximum zero fuel weight (MZFW) changes or reduction in maximum take-off weight (MTOW) for operational considerations.	No	No	No	No
Cabin safety	(i) Changes which introduce a new cabin layout of a sufficient extent to require a reassessment of the emergency evacuation capability, or which adversely affect other aspects of passenger or crew safety in aeroplanes with more than 19 passenger seats.	No	No	Yes, potential impact	No
	(ii) Changes which introduce new cabin layout of a sufficient extent to require a reassessment of the emergency evaluation capability, or which adversely affect other aspects of passenger or crew safety in aeroplanes with 19 or less passenger seats.	No	No	No (unless assessment identifies need for CCD	No
	(iii) Installation of observer seat.	No	No	Yes, potential impact	No
Flight	(i) Software changes that do not affect the pilot interface.	No	No	No	No
	(ii) Software changes that affect the pilot interface.	Yes, potential impact	No	No	No
Systems	(i) Updating the aircraft cockpit voice recorder (CVR) or flight data recorder (FDR) to meet a later standard.	No	No	No	No

[1] To be determined under rulemaking task RMT.0106 (21.039(e)).

Discipline	Example of major type design change	Expected impact on OSD constituent			
		FCD	SIMD	CCD	MCSD
Propellers	(i) Changes to: — diameter, — aerofoil, — planform, — material, and — blade retention system.	No	No	No	No
Engines	(i) Power limit change	No	No	No	No
Rotors and drive systems	*[Reserved]*				
Environment	(i) A change that introduces either an increase in the noise certification level(s) or a reduction in the noise certification level(s) for which the applicant wishes to take credit.	No	No	No	No
Power plant installation	(i) Modifications to the fuel system and tanks (number, size, or configuration)	No	No	No	tbd
Avionics	Comprehensive flight deck upgrade, such as conversion from entirely-federated, independent electromechanical flight instruments to highly-integrated and combined electronic display systems with extensive use of software and/or complex electronic hardware	Yes, potential impact	No	No	tbd

(c) Design changes to aircraft for which OSD is not required in accordance with Article 7(a)(2) of Regulation (EU) No 748/2012, as amended by Regulation (EU) No 69/2014, cannot trigger the need to establish OSD.

(d) The OSD constituents SIMD and MCSD were not required to be included in the 'catch-up' OSD in accordance with Article 7(a)(2) of Regulation (EU) No 748/2012, as amended by Regulation (EU) No 69/2014. No design change can trigger the need to add that constituent.

(e) When the design change makes an OSD constituent applicable (see GM No 1 to 21.A.15(d) – Clarification of the applicability of operational suitability data (OSD) constituents) where it was not applicable before, that OSD constituent should be added to the application for the approval of the change to the TC.

GM No 2 to 21.A.93(b)(1)(iii) Interaction of changes to the type design and changes to the master minimum equipment list (MMEL)

ED Decision 2019/018/R

In general, it has to be assumed that changes to the type certificate (TC) that affect the type design can have an effect on the MMEL.

Due to its alleviating nature, the MMEL is developed to improve aircraft use, thereby providing a more convenient and economical air transportation for the public.

Therefore, not introducing MMEL relief for new equipment, system or function has no effect on the safety of the operation. The introduction of MMEL relief for new equipment can, therefore, be treated as a stand-alone MMEL change, separately from the design change, and can be processed at a later date than the date of entry into service of the aircraft including the design change.

Not modifying an MMEL item whose validity is altered by a type design modification may, however, have an effect on the safety of the operation. The applicant for a change to the TC that changes the type design should, therefore, identify whether this change needs to be supplemented by a change to the MMEL. However, the update of an MMEL relief for an already addressed equipment, system or function can be treated at a later date than the date of entry into service of the aircraft including the design change, provided that the change to the MMEL is of an alleviating nature. When the change to the MMEL is not of an alleviating nature, it has to be approved according to point 21.A.97(b)(2) and (c).

It may be assumed that a change to the type design requires a change to the MMEL if any of the following conditions are fulfilled:

(a) the change affects an existing MMEL item in a more restrictive manner: there is a change to equipment, system or function linked to an MMEL item, or a change to the operational limitations and procedures linked to an MMEL item;

(b) the change invalidates the assumptions used to justify an existing MMEL item, and requires a more restrictive MMEL item; and

(c) the change invalidates any dispatch conditions of the MMEL.

Examples of the above three conditions, where no change to the MMEL is required:

(a) introduction of new equipment, system or function in the type design;

(b) the change has no adverse impact on the qualitative and quantitative assessment used to justify an MMEL item; and

(c) the dispatch conditions do not need to be more restrictive if the current intent of (o) or (m) procedures (as referred in CS MMEL.125) is not impacted.

The following diagram summarises the interaction between type design changes and changes to MMEL (see Figure 1).

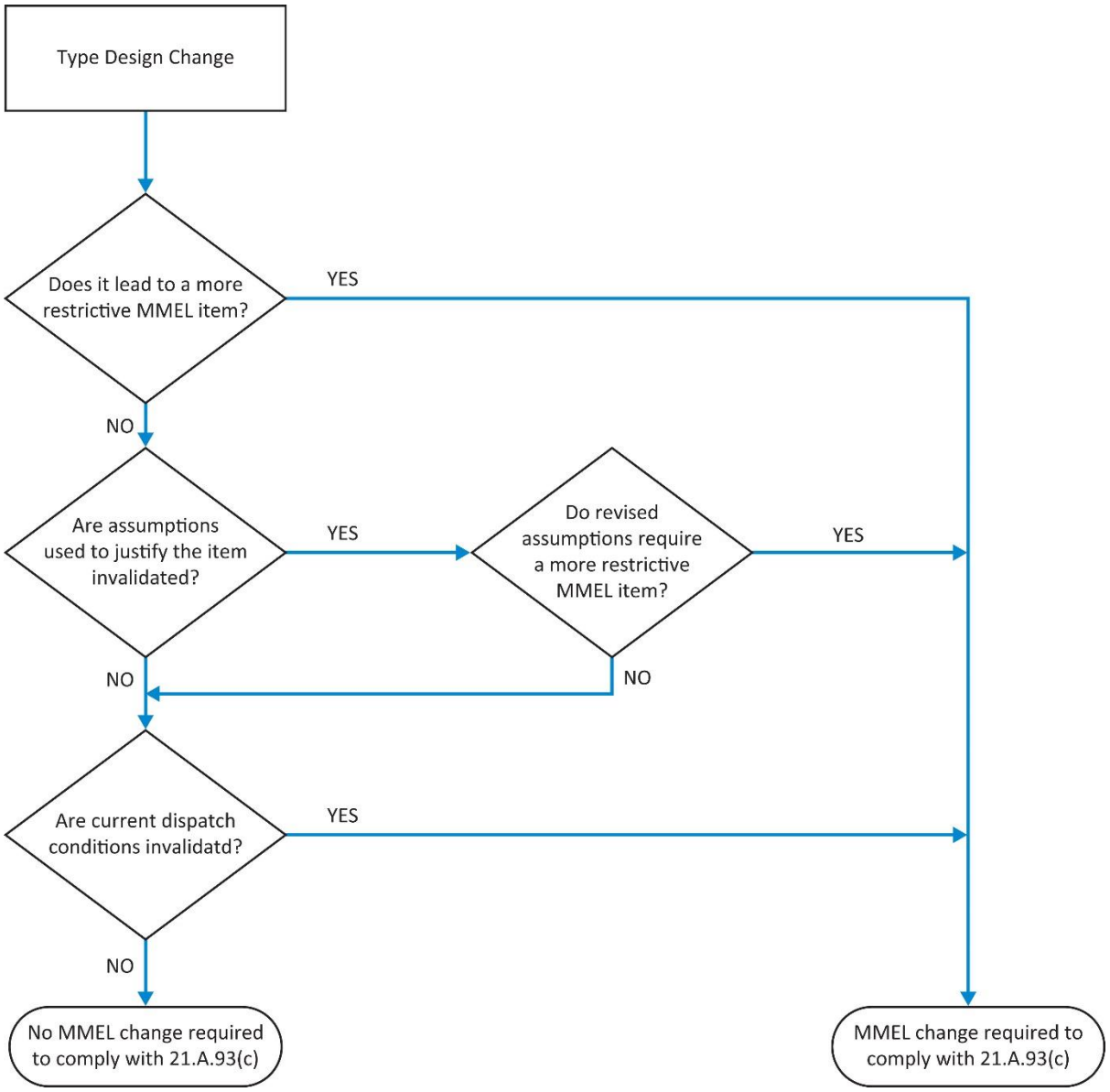


Figure 1

GM 21.A.93(c) Period of validity for the application

ED Decision 2019/018/R

For guidance on the determination of the period of validity for the application, refer to GM 21.A.15(e) and (f).

21.A.95 Requirements for approval of a minor change

Regulation (EU) 2019/897

(a) Minor changes to a type-certificate shall be classified and approved by:

1. the Agency; or
2. an approved design organisation within the scope of its privileges provided for in points (1) and (2) of point 21.A.263(c), as recorded in the terms of approval.

(b) A minor change to a type-certificate shall only be approved:

1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and the environmental protection requirements incorporated by reference in the type-certificate;

2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data comply with the operational suitability data certification basis incorporated by reference in the type-certificate;

3. when compliance with the type-certification basis that applies in accordance with point (1) has been declared and the justifications of compliance have been recorded in the compliance documents; and

4. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(c) By derogation from point (1) in point (b), certification specifications which became applicable after those incorporated by reference in the type-certificate can be used for approval of a minor change, provided they do not affect the demonstration of compliance.

(d) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), a minor change to an aircraft type-certificate may be approved before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.

(e) The applicant shall submit to the Agency the substantiation data for the change and a statement that compliance has been demonstrated in accordance with point (b).

(f) An approval of a minor change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

AMC 21.A.95 Requirements for the approval of a minor change

ED Decision 2019/018/R

(a) Applicability of point 21.A.95

Point 21.A.95 has to be complied with by applicants for the approval of a minor change to a type certificate (TC), and by design organisation approval (DOA) holders that approve minor changes under their own privileges.

Point 21.A.95(e), however, only applies to projects for which an application is submitted to EASA. For DOA holders that approve minor changes under their privileges, the substantiating data and the statement of compliance required by point 21.A.95(e) should be produced but do not need to be submitted to EASA. They should be, however, kept on record and submitted to EASA on request during its DOA continued surveillance process.

(b) The approval process

The approval process comprises the following steps:

Note: Steps 1, 2 and 5 should be followed only by applicants for minor changes approved by EASA. DOA holders that approve minor changes under their privileges should refer to AMC No 1 to 21.A.263(c)(2) or AMC No 2 to 21.A.263(c)(2), as applicable to their approval process.

(1) Application

When the minor change is approved by EASA, an application should be submitted to EASA as described in point 21.A.93(a) and (b) and in AMC 21.A.93(a).

(2) Certification programme

The certification programme should consist of the information defined in points 21.A.93(b)(1) and 21.A.93(b)(2). Please refer to AMC 21.A.93(b) for further information.

(3) Certification basis

(4) Demonstration of compliance

(5) Statement of compliance

(c) Certification basis

The certification basis for a minor change consists of a subset of the elements of the product's certification basis 'incorporated by reference in the type certificate' (see also the additional guidance below on the meaning of certification specifications that became applicable after those 'incorporated by reference in the type certificate'), which have been identified in accordance with point 21.A.93(b)(2) due to a reinvestigation of compliance being necessary because compliance was affected by the minor change (see also additional guidance below on the meaning of 'specific configurations').

The certification basis 'incorporated by reference in the type certificate' is the certification basis for the product as recorded in the type certificate data sheet (TCDS) for the product type/model in the configuration(s) identified in accordance with point 21.A.93(b)(1)(i).

The certification basis contains the applicable airworthiness and (for aircraft only) operational suitability data certification specifications (CS-OSD), environmental protection requirements specified by reference to their amendment level, as complemented by special conditions, equivalent safety findings, deviations, an 'elect to comply', etc., as applicable. See also the additional guidance below on the meaning of 'Minor changes affecting OSD constituents'.

By derogation from the above, CSs that became applicable after those incorporated by reference in the TC may be used for the approval of a minor change (see the guidance below on certification specifications that became applicable after those 'incorporated by reference in the type certificate').

If other changes are required for the embodiment of the minor change, the certification basis corresponding to the product modified by these other changes should also be considered when determining the certification basis for the minor change.

(d) Demonstration of compliance required by point 21.A.95(b)(1) and (2)

The applicant needs to demonstrate compliance with the certification basis established for the minor change for all areas that are either physically changed or functionally affected by the minor change.

(1) Means of compliance: the applicant should define and record the means (calculation, test or analysis, etc.) by which compliance is demonstrated. Appendix A to AMC 21.A.15(b) may be used to describe how compliance is demonstrated.

(2) Compliance documents: the compliance demonstration should be recorded in compliance documents. For minor changes, one comprehensive compliance document

may be sufficient, provided that it contains evidence of all aspects of the compliance demonstration. AMC 21.A.20(c) can also be used, where applicable.

See also the additional guidance in item (e).

(3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

See also additional guidance below on embodiment/installation instructions (item (f)).

(e) Definition of the change to the type certificate

The change to the type certificate should be defined in accordance with GM 21.A.90A.

(f) Embodiment/installation instructions

The instructions for the embodiment/installation of the change (e.g. service bulletin, modification bulletin, production work order, etc.) should be defined. This may include the installation procedure, the required material, etc.

(g) Minor changes affecting OSD constituents (i.e. master minimum equipment list (MMEL))

Some minor changes to the type design may only have an effect on the MMEL (see GM No 1 to 21.A.93(b)(1)(iii)). In such cases, GM No 2 to 21.A.93(b)(1)(iii) is also applicable. This also means that a dedicated assessment of the effects of the minor type design change on the other OSD constituents is not needed.

(h) Meaning of 'specific configurations' in point 21.A.95(f)

These 'specific configurations' are defined as the combination of the product type/model (on which the minor change will be installed) with (if applicable) the list of those already approved changes (minor, major, supplemental type certificate (STC)) that are required for the installation of the minor change.

(i) Certification specifications that became applicable after those incorporated by reference in the type certificate

(1) Minor changes are those changes that do not affect the airworthiness of the product and thus are, by definition, non-significant as per point 21.A.101. This means that the certification basis for the minor change may consist of the items of the certification basis incorporated by reference in the TCDS of the product type/model, and normally it should not be necessary for a minor change to use certification specifications that became applicable after those that are incorporated by reference in the type certificate.

(2) On the other hand, the applicant may elect to use later amendments of the affected certification specifications for the compliance demonstration. This does not affect the classification of the change; however, the applicant should also comply with any other certification specifications that EASA considers to be directly related.

(3) If other changes are required for the installation of the minor change (as explained in 'specific configurations'), the certification basis for the minor change should also take into account the corresponding certification basis.

(j) Meaning of 'no feature or characteristics' in point 21.A.95(b)(4)

See GM 21.A.20(d).

GM 21.A.95(b) Requirements for the approval of a minor change

ED Decision 2019/018/R

The level of detail of the documents that are referred to in 21.A.93(b) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.97 Requirements for approval of a major change

Regulation (EU) 2019/897

(a) Major changes to a type-certificate shall be classified and approved by:

1. the Agency; or
2. an approved design organisation within the scope of its privileges provided for in points (1) and (8) of point 21.A.263(c), as recorded in the terms of approval.

(b) A major change to a type-certificate shall only be approved:

1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101;
2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101; and
3. when compliance with points (1) and (2) has been demonstrated in accordance with point 21.A.20, as applicable to the change.

(c) By derogation from points (2) and (3) of point (b), at the applicant's request included in the declaration referred to in point 21.A.20(d), a major change to an aircraft type-certificate may be approved before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.

(d) An approval of a major change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

AMC 21.A.97 Requirements for the approval of a major change

ED Decision 2019/018/R

1. For major changes approved by EASA, the applicant should use all the AMC 21.A.20(c), as well as the GM 21.A.20.

2. For the application of point 21.A.97(c), see GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b).

3. In accordance with point 21.A.97(c), the compliance demonstration process always takes into account the specific configuration(s) in the type certificate (TC) to which the major change under approval is applied. These configurations may be defined by type models/variants or by design changes to the type design. The demonstration of compliance covers these applicable specific configurations. Consequently, the approval of the major change excludes any other configurations, in particular those that already exist but are not considered in the compliance demonstration process, as well as those that may be certified in future.

4. For major changes approved by the design organisation approval (DOA) holder on the basis of their privilege as per point 21.A.263(c)(8), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

GM 21.A.97(b) Requirements for the approval of a major change

ED Decision 2019/018/R

The level of detail of the documents that are referred to in 21.A.93(b) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source

data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.101 Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate

Regulation (EU) 2022/201

(a) A major change to a type-certificate and areas affected by the change shall comply with either the certification specifications applicable to the changed product on the date of the application for the change or certification specifications which became applicable after that date in accordance with point (f) below. The validity of the application shall be determined in accordance with point 21.A.93(c). In addition, the changed product shall comply with the environmental protection requirements designated by the Agency in accordance with point 21.B.85.

(b) Except as provided in point (h), by derogation from point (a), an earlier amendment to a certification specification referred to in point (a) and to any other certification specification which is directly related may be used in any of the following situations, unless the earlier amendment became applicable before the date at which the corresponding certification specifications incorporated by reference in the type-certificate became applicable:

1. a change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency shall consider the change in the context of all previous relevant design changes and all related revisions to the applicable certification specifications incorporated by reference in the type-certificate for the product. Changes meeting one of the following criteria shall automatically be considered significant:

   (i) the general configuration or the principles of construction are not retained;

   (ii) the assumptions used for certification of the product to be changed do not remain valid;

2. each area, system, part or appliance that the Agency finds not affected by the change;

3. each area, system, part or appliance that is affected by the change for which the Agency finds that compliance with the certification specifications referred to in point (a) does not contribute materially to the level of safety of the changed product or is impractical.

(c) By derogation from point (a), in the case of a change to an aircraft other than a rotorcraft of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine rotorcraft of 1 361 kg (3 000 lb) or less maximum weight, the change and areas affected by the change shall comply with the type-certification basis incorporated by reference in the type-certificate. However, if the Agency finds that the change is significant in an area, the Agency may require that the change and areas affected by the change comply with an amendment to a certification specification of the type-certification basis incorporated by reference in the type-certificate and with any other certification specification which is directly related, unless the Agency also finds that compliance with that amendment does not contribute materially to the level of safety of the changed product or is impractical.

(d) If the Agency finds that the certification specifications applicable on the date of the application for the change do not provide adequate standards with respect to the proposed change, the change and areas affected by the change shall also comply with any special conditions, and amendments to those special conditions, prescribed by the Agency in accordance with point 21.B.75, to provide a level of safety equivalent to that established by the certification specifications applicable on the date of the application for the change.

(e) By derogation from points (a), (b) and (c), the change and areas affected by the change may comply with an alternative to a certification specification designated by the Agency if proposed by the applicant, provided that the Agency finds that the alternative provides a level of safety which is:

1. in the case of a type-certificate:

   (i) equivalent to that of the certification specifications designated by the Agency under (a), (b) or (c) above; or

   (ii) compliant with the essential requirements of Annex II to Regulation (EU) 2018/1139;

2. in the case of a restricted type-certificate, adequate with regard to the intended use.

(f) If an applicant chooses to comply with a certification specification set out in an amendment that becomes applicable after submitting the application for a change to a type-certificate, the change and areas affected by the change shall also comply with any other certification specification which is directly related.

(g) When the application for a change to a type-certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the operational suitability data, the operational suitability data certification basis shall be established in accordance with points (a)-(f).

(h) For large aeroplanes subject to point 26.300 of Annex I to Commission Regulation (EU) 2015/640[1], the applicant shall comply with certification specifications that provide at least an equivalent level of safety to points 26.300 and 26.330 of Annex I to Regulation (EU) 2015/640, except for applicants for supplemental type-certificates who are not required to take into account point 26.303.

[1] Commission Regulation (EU) 2015/640 of 23 April 2015 on additional airworthiness specifications for a given type of operations and amending Regulation (EU) No 965/2012 (OJ L 106, 24.4.2015, p. 18).

GM 21.A.101 Establishing the certification basis of changed aeronautical products

ED Decision 2019/018/R

Foreword

This guidance material (GM) provides guidance for the application of the 'Changed Product Rule (CPR)', pursuant to point 21.A.101, *Designation of the applicable certification specifications and environmental protection requirements*, and 21.A.19, *Changes requiring a new type certificate*, for changes made to type-certified aeronautical products.

1. INTRODUCTION

1.1. Purpose.

This GM provides guidance for establishing the certification basis for changed aeronautical products pursuant to point 21.A.101, *Designation of the applicable certification specifications and environmental protection requirements*. The guidance is also intended to help applicants and approved design organisations to determine whether it will be necessary to apply for a new type certificate (TC) under point 21.A.19, *Changes requiring a new type certificate*. The guidance describes the process for establishing the certification basis for a change to a TC, for a supplemental type certificate (STC), or for a change to an STC, detailing the requirements (evaluations, classifications, and decisions) throughout the process.

1.2. Applicability.

1.2.1 This GM is for an applicant that applies for changes to TCs under Subpart D, for STCs, or changes to STCs under Subpart E, or for changes to European Technical Standard Order Authorisations (ETSOAs) for auxiliary power units (APUs) under Subpart O. This GM is also for approved design organisations that classify changes and approve minor changes under their 21.A.263(c)(1) and (2) privileges.

1.2.2 This GM applies to major changes under point 21.A.101 for aeronautical products certified under Part 21, and the certification specifications (CSs) applicable to the changed product (CS-23, CS-25, CS-27, CS-29, CS-MMEL, CS-FCD, CS-CCD, etc.). References to 'change' include the change and areas affected by the change pursuant to point 21.A.101.

1.2.3 Minor changes are within the scope of 21.A.101 and this GM but are automatically considered to not be significant under the 'does not contribute materially to the level of safety' provision of point 21.A.101(b).

1.2.4 This GM also applies to changes to restricted type certificates.

1.2.5 The term 'aeronautical product', or 'product', means a type-certified aircraft, aircraft engine, or propeller and, for the purpose of this GM, an ETSOA'd APU.

1.2.6 This GM primarily provides guidance for the designation of applicable airworthiness certification specifications and other airworthiness standards for the type-certification basis for the changed product. However, portions of this GM, as specified in GM1 21.A.101(g), can be applied by analogy to establish the operational suitability data (OSD) certification basis for the changed product. This GM is not intended to be used to determine the

applicable environmental protection requirements (aircraft noise, fuel venting, and engine exhaust emissions and aeroplane CO_2 emissions requirements) for changed products, as they are designated through point 21.B.85.

1.2.7 This GM is not mandatory and is not an EU regulation. This GM describes an acceptable means, but not the only means, to comply with point 21.A.101. However, an applicant who uses the means described in this GM must follow it entirely.

1.3. Reserved.

1.4. GM Content

This GM contains 5 chapters and 10 appendices.

1.4.1 This chapter clarifies the purpose of this GM, describes its content, specifies the intended audience affected by this GM, clarifies which changes are within the scope of this GM, and references the definitions and terminology used in this GM.

1.4.2 Chapter 2 provides a general overview of points 21.A.101 and 21.A.19, clarifies the main principles and safety objectives, and directs an applicant to the applicable guidance contained in subsequent chapters of this GM.

1.4.3 Chapter 3 contains guidance for the implementation of point 21.A.101(b) to establish the certification basis for changed aeronautical products. It describes in detail the various steps for developing the certification basis, which is a process that applies to all changes to aeronautical products. Chapter 3 also addresses the point 21.A.19 considerations for identifying the conditions under which an applicant for a change is required to submit an application for a new TC, and it provides guidance regarding the stage of the process at which this assessment is performed.

1.4.4 Chapter 4 provides guidance about products excepted from the requirement of point 21.A.101(a).

1.4.5 Chapter 5 contains considerations for:

— design-related operating requirements,

— defining a baseline product,

— predecessor standards,

— using special conditions under point 21.A.101(d),

— documenting revisions to the TC basis,

— incorporating STCs into the type design,

— removing changes,

— determining a certification basis after removing an approved change, and

— sequential changes.

1.4.6 Appendix A contains examples of typical type design changes for small aeroplanes, large aeroplanes, rotorcraft, engines, and propellers. The European Union Aviation Safety Agency (EASA) has categorised these examples into individual tables according to the classifications of design change: 'substantial', 'significant', and 'not significant'.

1.4.7 Appendix B contains application charts for applying the point 21.A.101 process, including the excepted process.

1.4.8 Appendix C contains one method for determining the changed and affected areas of a product.

1.4.9 Appendix D contains additional guidance on affected areas that is not discussed in other parts of this GM.

1.4.10 Appendix E provides detailed guidance with examples for evaluating the 'impracticality' exception in the rule.

1.4.11 Appendix F provides guidance with examples on the use of relevant service experience in the certification process as one way to demonstrate that a later amendment may not contribute materially to the level of safety, allowing the use of earlier certification specifications.

1.4.12 Appendix G provides an example CPR decision record.

1.4.13 Appendix H provides examples of documenting a proposed certification basis list.

1.4.14 Appendix I lists the Part 21 points related to this GM.

1.4.15 Appendix J lists the definitions and terminology applicable for the application of the rule.

1.5. Terms Used in this GM.

1.5.1 The following terms are used interchangeably and have the same meaning: 'specifications', 'standards', 'certification specifications' and 'certification standards'. They refer to the elements of the type-certification basis for airworthiness or OSD certification basis.

1.5.2 The term 'certification basis' refers to the type-certification basis for airworthiness provided for in point 21.B.80 and the operational suitability data (OSD) certification basis provided for in point 21.B.82.

For more terms, consult Appendix J.

2. OVERVIEW OF POINTS 21.A.19 AND 21.A.101

2.1. Point 21.A.19.

2.1.1 Point 21.A.19 requires an applicant to apply for a new TC for a changed product if EASA finds that the change to the design, power, thrust, or weight is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

2.1.2 Changes that require a substantial re-evaluation of the compliance findings of the product are referred to as 'substantial changes'. For guidance, see paragraph 3.3 in Chapter 3 of this GM. Appendix A of this GM provides examples of changes that will require a new TC.

2.1.3 If EASA determines through point 21.A.19 that a proposed change does not require a new TC, see point 21.A.101 for the applicable requirements to develop the certification basis for the proposed change. For guidance, see Chapter 3 and the examples in Appendix A of this GM.

2.2. Point 21.A.101.

2.2.1 Point 21.A.101(a).

Point 21.A.101(a) requires a change to a TC, and the areas affected by the change to comply with the certification specifications that are applicable to the changed product and that are in effect on the date of application for the change (i.e. the latest certification standards in effect at the time of application), unless the change meets the criteria for the exceptions identified in point 21.A.101(b) or (c), or unless an applicant chooses to comply with the certification specifications of later effective amendments* in accordance with point 21.A.101(f). The intent of point 21.A.101 is to enhance safety by incorporating the latest requirements into the certification basis for the changed product to the greatest extent practicable.

*NOTE: Certification specifications that were amended after the date of application.

2.2.2 Point 21.A.101(b).

Point 21.A.101(b) pertains to when an applicant may show that a changed product complies with an earlier amendment of a certification specification, provided that the earlier amendment is considered to be adequate and meets the criteria in point 21.A.101(b)(1), (2) or (3). When changes involve features or characteristics that are novel and unusual in comparison with the airworthiness standard at the proposed amendment, more recent airworthiness standards and/or special conditions will be applied for these features.

An applicant is considered to comply with the earlier amendment of the certification specifications consistent with point 21.A.101(b), when:

(a) a change is not significant (see point 21.A.101(b)(1));

(b) an area, system, part or appliance is not affected by the change (see point 21.A.101(b)(2));

(c) compliance with a later amendment for a significant change does not contribute materially to the level of safety (see point 21.A.101(b)(3)); or

(d) compliance with the latest amendment would be impractical (see point 21.A.101(b)(3)).

Earlier amendments may not precede the amendment level of the certification basis of the identified baseline product.

Points 21.A.101(b)(1)(i) and (ii) pertain to changes that meet the automatic criteria where the change is significant.

2.2.3 Point 21.A.101(c).

Point 21.A.101(c) provides an exception from the requirements of point 21.A.101(a) for a change to certain aircraft with less than the specified maximum weight. An applicant who applies for a change to an aircraft (other than rotorcraft) of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine-powered rotorcraft of 1 361 kg (3 000 lb) or less maximum weight, can show that the changed product complies with the standards incorporated by reference in the type certificate. An applicant can also elect to comply or may be required to comply with the later standards. See paragraph 4.1 of this GM for specific guidance on this provision.

2.2.4 Point 21.A.101(d).

Point 21.A.101(d) provides for the use of special conditions, under 21.B.75, when the proposed certification basis and any later certification specifications do not provide adequate standards for the proposed change because of a novel or unusual design feature.

2.2.5 Point 21.A.101(e).

Point 21.A.101(e) provides the legal basis under which an applicant may propose to certify a change and the areas affected by the change against alternative requirements to the certification specifications established by EASA.

2.2.6 Point 21.A.101(f).

Point 21.A.101(f) requires that if an applicant chooses (elects) to comply with a certification specification or an amendment to the certification specifications that is effective after the filing of the application for a change to a TC, the applicant shall also comply with any other certification specifications that EASA finds are directly related. The certification specifications which are directly related must be, for the purpose of compliance demonstration, considered together at the same amendment level to be consistent.

2.2.7 Point 21.A.101(g).

Point 21.A.101(g) pertains to the designation of the applicable OSD certification basis when the application for a change to a type certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the OSD. It implies that the same requirements of paragraphs (a) and (f) that are applicable to the establishment of the airworthiness type-certification basis also apply to the establishment of the OSD certification basis. For specific guidance, see GM1 21.A.101(g).

3. PROCESS FOR ESTABLISHING THE CERTIFICATION BASIS FOR CHANGED PRODUCTS

3.1. Overview.

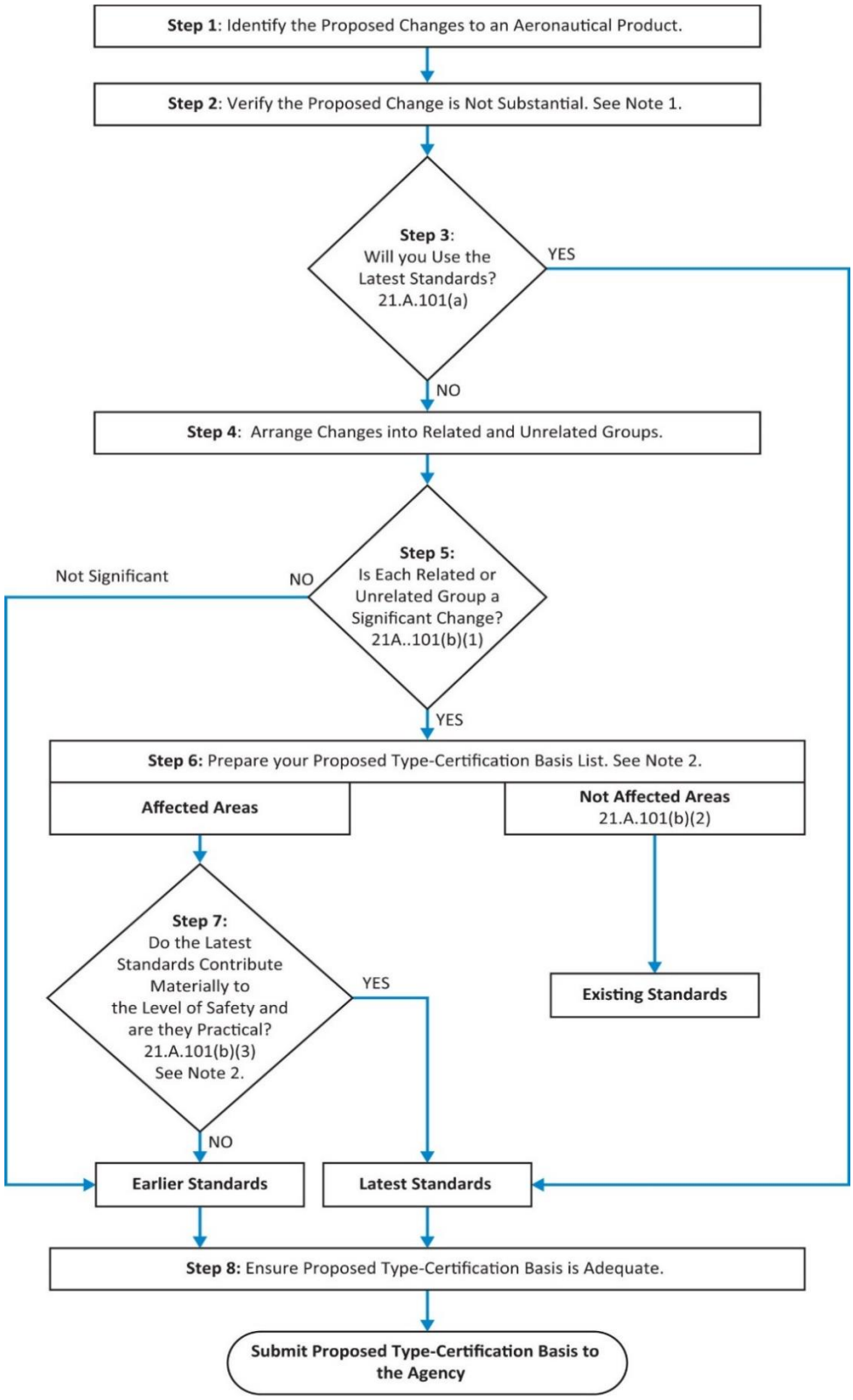
3.1.1 The applicant and EASA both have responsibilities under point 21.A.101(a) and (b). As an applicant for the certification of a change, the applicant must demonstrate that the change and areas affected by the change comply with the latest applicable certification specifications unless the applicant proposes exception(s) under point 21.A.101(b). An applicant proposing exception(s) should make a preliminary classification whether the change is

'significant' or 'not significant', and propose an appropriate certification basis. EASA is responsible for determining whether the applicant's classification of the change, and proposal for the certification basis, are consistent with the applicable rules and their interpretation. The EASA determination does not depend on whether the TC holder or applicant for an STC is originating the change. The certification basis can vary depending on the magnitude and scope of the change. The steps below present a streamlined approach for making this determination.

3.1.2 The tables in appendix A of this GM are examples of classifications of typical type design changes. See paragraph 3.6.3 of this chapter for instructions on how to use those tables.

3.1.3 If a proposed change is not in the examples provided in appendix A, the applicant may use the following steps in conjunction with the flow chart in Figure 3-1 of this GM to develop the appropriate certification basis for the change. For clarification, the change discussed in the flow chart also includes areas affected by the change. See paragraph 3.9.1 of this GM for guidance about affected areas.

Figure 3-1. Developing a Proposed Certification Basis for a Changed Product Pursuant to point 21.A.101



Notes:

1. Changed products that are substantially changed do not follow this flowchart. Refer to 21.A19.
2. Process and propose each applicable standard individually. If Standards are linked together, then they should be assessed together.

3.2. Step 1. Identify the proposed changes to an aeronautical product.

— Identify the type design being changed (the baseline product).

— Identify the proposed change.

— Use high-level descriptors.

3.2.1 **Identify the type design being changed (the baseline product)**.

Prior to describing the proposed change(s), it is important to clearly identify the specific type design configuration being changed.

Note: For additional guidance on the baseline product, see paragraph 5.3 of this GM.

3.2.2 **Identify the proposed change**.

3.2.2.1 The purpose of this process step is to identify and describe the change to the aeronautical product. Changes to a product can include physical design changes and functional changes (e.g. operating envelope or performance changes). An applicant must identify all changes and areas affected by the change, including those where they plan to use previously approved data. EASA considers all of these changes and areas affected by the change to be part of the entire proposed type design and they are considered as a whole in the classification of whether the proposed change is substantial, significant, or not significant. The change can be a single change or a collection of changes. In addition to the proposed changes, an applicant should consider the cumulative effect of previous relevant changes incorporated since the last time the certification basis was upgraded. An applicant for a change must consider all previous relevant changes and the amendment level of the certification specifications in the certification basis used for these changes.

3.2.2.2 When identifying the proposed changes, an applicant should consider previous relevant changes that create a cumulative effect, as these may influence the decisions regarding the classification of the change later in the process. By ‘previous relevant changes,’ EASA means changes where effects accumulate, such as successive thrust increases, incremental weight increases, or sectional increases in fuselage length. An applicant must account for any previous relevant changes to the area affected by the proposed change that did not involve an upgrade of the certification basis in the proposed change.

3.2.2.3 **Example:**

An applicant proposes a 5 per cent weight increase, but a previous 4 per cent and another 3 per cent weight increase were incorporated into this aircraft without upgrading the existing certification basis. In the current proposal for a 5 per cent weight increase, the cumulative effects of the two previous weight increases that did not involve an upgrade of

the certification basis will now be accounted for as an approximate 12 per cent increase in weight. Note that the cumulative effects the applicant accounts for are only those incremental increases since the last time the airworthiness certification specifications in the type-certification basis applicable to the area affected by the proposed change were upgraded.

3.2.3 Use High-Level Descriptors.

To identify and describe the proposed changes to any aeronautical product, an applicant should use a high-level description of the change that characterises the intent of, or the reason for, the change. No complex technical details are necessary at this stage. For example, a proposal to increase the maximum passenger-carrying capacity may require an addition of a fuselage plug, and as such, a 'fuselage plug' becomes one possible high-level description of this change. Similarly, a thrust increase, a new or complete interior, an avionics system upgrade, or a passenger-to-cargo conversion are all high-level descriptions that characterise typical changes to the aircraft, each driven by a specific goal, objective, or purpose.

3.2.4 Evolutionary changes that occur during the course of a certification program may require re-evaluation of the certification basis, and those changes that have influence at the product level may result in re-classification of the change.

3.3. Step 2. Verify the proposed change is not substantial.

3.3.1 Point 21.A.19 requires an applicant to apply for a new TC for a changed product if the change to design, power, thrust, or weight is so extensive that a substantially complete investigation of compliance with the applicable regulations is required. A new TC could be required for either a single extensive change to a previously type-certified product or for a changed design derived through the cumulative effect of a series of design changes from a previously type-certified product.

3.3.2 A 'substantially complete investigation' of compliance is required when most of the existing substantiation is not applicable to the changed product. In other words, an applicant may consider the change 'substantial' if it is so extensive (making the product sufficiently different from its predecessor) that the design models, methodologies, and approaches used to demonstrate a previous compliance finding could not be used in a similarity argument. EASA considers a change 'substantial' when these approaches, models, or methodologies of how compliance was shown are not valid for the changed product.

3.3.3 If it is not initially clear that a new TC is required, Appendix A of this GM provides some examples of substantial changes to aid in this classification. A substantial change requires an application for a new TC. See points 21.B.80, 21.B.82, 21.B.85 and 21.A.19. If the change is not substantial, proceed to step 3.

3.4. Step 3. Will the applicant use the latest standards?

An applicant can use the latest certification specifications for their proposed change and the area affected by the change. If they use the latest certification specifications, they will have met the intent of point 21.A.101 and no further classification (significant or not significant) and justification is needed. Even though an applicant elects to use the latest certification specifications, the applicant will still be able to apply point 21.A.101 for future similar changes, and use the exceptions under point 21.A.101(b). However, the decision to comply with the latest certification specifications sets a new basis for all future related changes to the same affected area for that amended TC.

— If using the latest certification specifications, an applicant should proceed to Step 6 (in paragraph 3.9 of this GM).

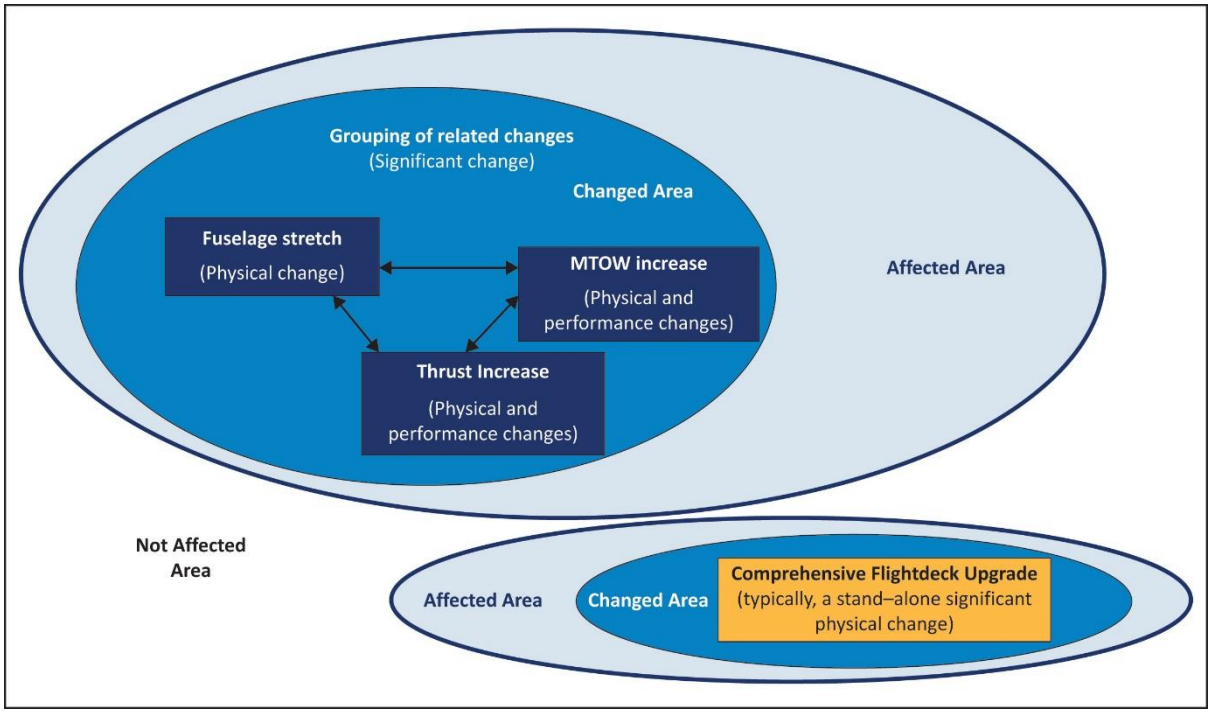
— If not using the latest certification specifications, an applicant should proceed to Step 4 below.

3.5. Step 4. Arrange changes into related and unrelated groups.

3.5.1 An applicant should now determine whether any of the changes identified in Step 1 are related to each other. Related changes are those that cannot exist without another, are co-dependent, or a prerequisite of another. For example, a need to carry more passengers could require the addition of a fuselage plug, which will result in a weight increase, and may necessitate a thrust increase. Thus, the fuselage plug, weight increase, and thrust increase are all related, high-level changes needed to achieve the goal of carrying more passengers. A decision to upgrade the flight deck to more modern avionics at the same time as these other changes may be considered unrelated, as the avionics upgrade is not necessarily needed to carry more passengers (it has a separate purpose, likely just modernisation). The proposed avionics upgrade would then be considered an unrelated (or a stand-alone) change. However, the simultaneous introduction of a new cabin interior is considered related since occupant safety considerations are impacted by a cabin length change. Even if a new cabin interior is not included in the product-level change, the functional effect of the fuselage plug has implications on occupant safety (e.g. the dynamic environment in an emergency landing, emergency evacuation, etc.), and thus the cabin interior becomes an affected area. Figure 3-2 below illustrates the grouping of related and unrelated changes using the example of increasing the maximum number of passengers.

Note: An applicant who plans changes in sequence over time should refer to the discussion on ‘sequential design changes’ in paragraph 5.13 of this GM.

Figure 3-2. Related and Unrelated Changes for Example of Increasing the Maximum Number of Passengers



3.5.2 Once the change(s) is (are) organised into groupings of those that are related and those that are unrelated (or stand-alone), an applicant should proceed to Step 5 below.

3.6. Step 5. Is each group of related changes or each unrelated (stand-alone) change a significant change?

3.6.1 The applicant is responsible for proposing the classification of groups of related changes or unrelated changes as 'significant' or 'not significant'. Significant changes are product-level changes that could result from an accumulation of changes, or occur through a single significant change that makes the changed product distinct from its baseline product. The grouping of related and unrelated changes is particularly relevant to EASA's significant Yes/No decision (point 21.A.101(b)(1)) described in Step 1 of Figure 3-1. EASA evaluates each group of related changes and each unrelated (stand-alone) change on its own merit for significance. Thus, there may be as many evaluations for significance as there are groupings of related and unrelated changes. Step 1 of Figure 3-1 explains the accumulation of changes that an applicant must consider. Additionally, point 21.A.101(b)(1) defines a change as 'significant' when at least one of the three automatic criteria applies:

3.6.1.1 Changes where the general configuration is not retained (significant change to general configuration).

A change to the general configuration at the product level is one that distinguishes the resulting product from other product models, for example, performance or interchangeability of major components. Typically, for these changes, an applicant

will designate a new product model, although this is not required. For examples, see appendix A of this GM.

3.6.1.2 Changes where the principles of construction are not retained (significant change to principles of construction).

A change at the product level to the materials and/or construction methods that affects the overall product's operating characteristics or inherent strength and would require extensive reinvestigation to demonstrate compliance is one where the principles of construction are not retained. For examples, see appendix A of this GM.

3.6.1.3 Product-level changes that invalidate the assumptions used for certification of the baseline product.

Examples include:

— change of an aircraft from an unpressurised to pressurised fuselage,

— change of operation of a fixed-wing aircraft from land-based to water-based, and

— operating envelope expansions that are outside the approved design parameters and capabilities.

For additional examples, see appendix A of this GM.

3.6.2 The above criteria are used to determine whether each change grouping and each stand-alone change is significant. These three criteria are assessed at the product level. In applying the automatic criteria and the examples in appendix A of this GM, an applicant should focus on the change and how it impacts the existing product (including its performance, operating envelope, etc.). A change cannot be classified or reclassified as a significant change on the basis of the importance of a later amendment.

3.6.3 Appendix A of this GM includes tables of typical changes (examples) for small aeroplanes, transport aeroplanes, rotorcraft, engines, and propellers that meet the criteria for a significant design change. The Appendix also includes tables of typical design changes that EASA classifies as not significant. The tables can be used in one of two ways:

3.6.3.1 To identify the classification of a proposed design change listed in the table, or

3.6.3.2 In conjunction with the three automatic criteria, to help classify a proposed design change not listed in the table by comparison to determinations made for changes with similar type and magnitude.

3.6.4 In many cases, a significant change may involve more than one of these criteria and will be obvious and distinct from other product improvements or production changes. There could be cases where a change to a single area, system, component, or appliance may not result in a product-level change. There could also be other cases where the change to a single system or component might result in a significant change due to its effect on the product overall. Examples may include the addition of winglets or leading-edge slats, or a change to primary flight controls of a fly-by-wire system.

3.6.5 If an unrelated (stand-alone) change or a grouping of related changes is classified as —

Significant (point 21.A.101(a)):

You must comply with the latest airworthiness standards for certification of the change and areas affected by change, unless you justify use of one of the exceptions provided in point 21.A.101(b)(2) or (3) to show compliance with earlier amendment(s). The final certification basis may consist of a combination of the requirements recorded in the certification basis ranging from the original aircraft certification basis to the most current regulatory amendments

Not Significant (point 21.A.101(b)(1)):

You may comply with the existing certification basis unless the standards in the proposed certification basis are deemed inadequate. In cases where the existing certification basis is inadequate or no regulatory standards exist, later requirements and/or special conditions will be required. See paragraph 3.11 of this GM for a detailed discussion.

3.6.6 A new model designation to a changed product is not necessarily indicative that the change is significant under point 21.A.101. Conversely, retaining the existing model designation does not mean that the change is not significant. Significance is determined by the magnitude of the change.

3.6.7 EASA determines the final classification of whether a change is significant or not significant. To assist an applicant in its assessment, EASA has predetermined the classification of several typical changes that an applicant can use for reference, and these examples are listed in appendix A of this GM.

3.6.8 At this point, the determination of significant or not significant for each of the groupings of related changes and each stand-alone change is completed. For significant changes, an applicant that proposes to comply with an earlier certification specification should use the procedure outlined in paragraph 3.7 below. For changes identified as not significant, see paragraph 3.8 below.

3.7. Proposing an amendment level for a significant change.

3.7.1 Without prejudice to the exceptions provided for in point 21.A.101(b) or (c), if the classification of a group of related changes or a stand-alone unrelated change is significant, all areas, systems, components, parts, or appliances affected by the change must comply with the certification specifications at the amendment level in effect on the date of application for the change, unless the applicant elects to comply with certification specifications that have become effective after that date (see point 21.A.101(a)).

3.7.2 In certain cases, an applicant will be required by EASA to comply with certification specifications that have become effective after the date of application (see point 21.A.101(a)):

3.7.2.1 If an applicant elects to comply with a specific certification specification or a subset of certification specifications at an amendment which has become effective after the date of application, the applicant must comply with any other certification specification that EASA finds is directly related (see point 21.A.101(f)).

3.7.2.2 In a case where the change has not been approved, or it is clear that it will not be approved under the time limit established, the applicant will be required to comply with an upgraded certification basis established according to points 21.B.80, 21.B.82 and 21.B.85 from the certification specifications that have become effective since the date of the initial application.

3.7.3 Applicants can justify the use of one of the exceptions in point 21.A.101(b)(2) or (3) to comply with an earlier amendment, but not with an amendment introduced earlier than the existing certification basis. See paragraphs 3.9 and 3.10 of this GM. Applicants who elect to comply with a specific certification specification or a subset of certification specifications at an earlier amendment will be required to comply with any other certification specification that EASA finds are directly related.

3.7.4 The final certification basis may combine the latest, earlier (intermediate), and existing certification specifications, but cannot contain certification specifications preceding the existing certification basis.

3.8. Proposing an amendment level for a not significant change.

3.8.1 When EASA classifies the change as not significant, the point 21.A.101(b) rule allows compliance with earlier amendments, but not prior to the existing certification basis. Within this limit, the applicant may propose an amendment level for each certification specification for the affected area. However, each applicant should be aware that EASA will review their proposals for the certification basis to ensure that the certification basis is adequate for the proposed change under Step 8. (See paragraph 3.11 of this GM.)

3.8.2 Even for a not significant change, an applicant may elect to comply with certification specifications which became applicable after the date of application. Applicants may propose to comply with a specific certification specification or a subset of certification specifications at a certain amendment of their choice. In such a case, any other certification specifications of that amendment that are directly related should be included in the certification basis for the change.

3.9. Step 6. Prepare the proposed certification basis list.

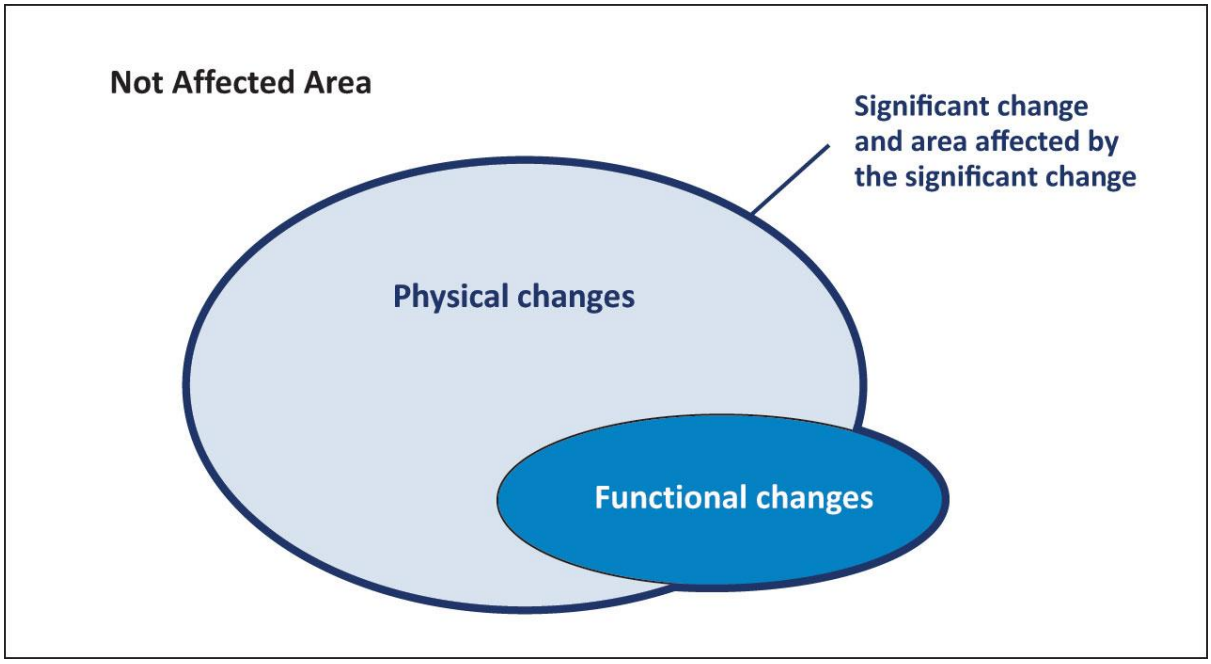
As part of preparing the proposed certification basis list, an applicant must identify any areas, systems, parts or appliances of the product that are affected by the change and the corresponding certification specifications associated with these areas. For each group, the applicant must assess the physical and/or functional effects of the change on any areas, systems, parts or appliances of the product. The characteristics affected by the change are not only physical changes, but also functional changes brought about by the physical changes. Examples of physical aspects are structures, systems, parts and appliances, including software in combination with the affected hardware. Examples of functional characteristics are performance, handling qualities, aeroelastic characteristics, and emergency egress. The intent is to encompass all aspects where there is a need for re-evaluation, that is, where the substantiation presented for the product being changed should be updated or rewritten. Appendix H of this GM contains two examples of how to document a proposed certification basis list.

3.9.1 An area affected by the change is any area, system, component, part, or appliance of the aeronautical product that is physically and/or functionally changed.

3.9.2 Figure 3-33 of this GM illustrates concepts of physical and functional changes of an affected area. Appendix C of this GM contains a method used to define the change and areas affected by the change. This Appendix is meant to assist applicants when they propose large, complex changes. For each change, it is important for the applicant to properly assess the effects of such change on any areas, systems, parts or appliances of the product because areas that have not been physically changed may still be considered part of the affected area. If a new compliance finding is required, regardless of its amendment level, it is an affected area.

Figure 3-3. Affected Areas versus Not Affected Areas

The Aeronautical Product



3.9.3 An area not affected by a change can remain at the existing certification basis, provided that the applicant presents to EASA an acceptable justification that the area is not affected.

3.9.4 For sample questions to assist in determining affected areas, see paragraph D.1 of appendix D of this GM.

3.9.5 Consider the following aspects of a change: **Physical aspects**.

The physical aspects include direct changes to structures, systems, equipment, components, and appliances, and may include software/airborne electronic hardware changes and the resulting effects on systems functions.

3.9.5.1 Performance/functional characteristics.

The less obvious aspect of the word ‘areas’ covers general characteristics of the type-certified product, such as performance features, handling qualities, emergency egress, structural integrity (including load carrying), aeroelastic characteristics, or crashworthiness. A product-level change may affect these characteristics. For example, adding a fuselage plug could affect performance and handling qualities, and thus the certification specifications associated with these aspects would be considered to be part of the affected area. Another example is the addition of a fuel tank and a new fuel conditioning unit. This change affects the fuel transfer and fuel quantity indication system, resulting in the aircraft’s unchanged fuel tanks being affected. Thus, the entire fuel system (changed and unchanged areas) may become part of the affected area due to the change to functional characteristics. Another example is changing

turbine engine ratings and operating limitations, affecting the engine rotors' life limits.

3.9.6 All areas affected by the proposed change must comply with the latest certification specifications, unless the applicant shows that demonstrating compliance with the latest amendment of a certification specification would not contribute materially to the level of safety or would be impractical. Step 7 below provides further explanation.

3.9.7 The applicant should document the change and the area affected by the change using high-level descriptors along with the applicable certification specifications and their proposed associated amendment levels. The applicant proposes this change to the certification basis that EASA will consider for documentation in the type certificate data sheet (TCDS) or STC, if they are different from that recorded for the baseline product in the TCDS.

3.10. Step 7. Do the latest standards contribute materially to the level of safety and are they practical?

Pursuant to point 21.A.101(a), compliance with the latest certification specifications is required. However, exceptions may be allowed pursuant to point 21.A.101(b)(3). The applicant must provide justification to support the rationale for the application of earlier amendments for areas affected by a significant change in order to document that compliance with later standards in these areas would not contribute materially to the level of safety or would be impractical. Such a justification should address all the aspects of the area, system, part or appliance affected by the significant change. See paragraphs 3.10.1 and 3.10.1.4 of this GM.

3.10.1 Do the latest standards contribute materially to the level of safety?

Applicants could consider compliance with the latest standards to 'not contribute materially to the level of safety' if the existing type design and/or relevant experience demonstrates a level of safety comparable to that provided by the latest standards. In cases where design features provide a level of safety greater than the existing certification basis, applicants may use acceptable data, such as service experience, to establish the effectiveness of those design features in mitigating the specific hazards by a later amendment. Applicants must provide sufficient justification to allow EASA to make this determination. An acceptable means of compliance is described in appendix E of this GM. Justification is sufficient when it provides a summary of the evaluation that supports the determination using an agreed evaluation method, such as that in appendix E of this GM. This exception could be applicable in the situations described in the paragraphs below.

Note: Compliance with later standards is not required where the amendment is of an administrative nature and made only to correct inconsequential errors or omissions, consolidate text, or to clarify an existing requirement.

3.10.1.1 Improved design features.

Design features that exceed the existing certification basis standards, but do not meet the latest certification specifications, can be used as a basis for granting an exception

under point 21.A.101(b)(3) since complying with the latest amendment of the certification specifications would not contribute materially to the level of safety of the product. If EASA accepts these design features as justification for an exception, the applicant must incorporate them in the amended type design configuration and record them, where necessary, in the certification basis. The description of the design feature would be provided in the TCDS or STC at a level that allows the design feature to be maintained, but does not contain proprietary information. For example[1], an applicant proposes to install winglets on a Part 25 aeroplane, and part of the design involves adding a small number of new wing fuel tank fasteners. Assuming that the latest applicable amendment of § 25.981 is Amendment 25-102, which requires structural lightning protection, the applicant could propose an exception from these latest structural lightning protection requirements because the design change uses new wing fuel tank fasteners with cap seals installed. The cap seal is a design feature that exceeds the requirement of § 25.981 at a previous amendment level, but does not meet the latest Amendment 25-102. If the applicant can successfully substantiate that compliance with Amendment 25-102 would not materially increase the level of safety of the changed product, then this design feature can be accepted as an exception to compliance with the latest amendment.

3.10.1.2 Consistency of design.

This provision gives the opportunity to consider the consistency of design. For example, when a small fuselage plug is added, additional seats and overhead bins are likely to be installed, and the lower cargo hold extended. These components may be identical to the existing components. The level of safety may not materially increase by applying the latest certification specifications in the area of the fuselage plug. Compliance of the new areas with the existing certification basis may be acceptable.

3.10.1.3 Service experience.

3.10.1.3.1 Relevant service experience, such as experience based on fleet performance or utilisation over time (relevant flight hours or cycles), is one way of showing that the level of safety will not materially increase by applying the latest amendment, so the use of earlier certification specifications could be appropriate. Appendix F of this GM provides additional guidance on the use of service experience, along with examples.

[1] This example is taken from the FAA experience gained prior to EASA's start, therefore the references to the FAA sections and amendments are kept.

3.10.1.3.2 When establishing the highest practicable level of safety for a changed product, EASA has determined that it is appropriate to assess the service history of a product, as well as the later airworthiness standards. It makes little sense to mandate changes to well-understood designs, whose service experience has been acceptable, merely to comply with new standards. The clear exception to this premise is if the new standards were issued to address a deficiency in the design in question, or if the service experience is not applicable to the new standards.

3.10.1.3.3 There may be cases for rotorcraft and small aeroplanes where relevant data may not be sufficient or not available at all because of the low utilisation and the insufficient amount and type of data available. In such cases, other service history information may provide sufficient data to justify the use of earlier certification specifications, such as: warranty, repair, and parts usage data; accident, incident, and service difficulty reports; service bulletins; airworthiness directives; or other pertinent and sufficient data collected by the manufacturers, authorities, or other entities.

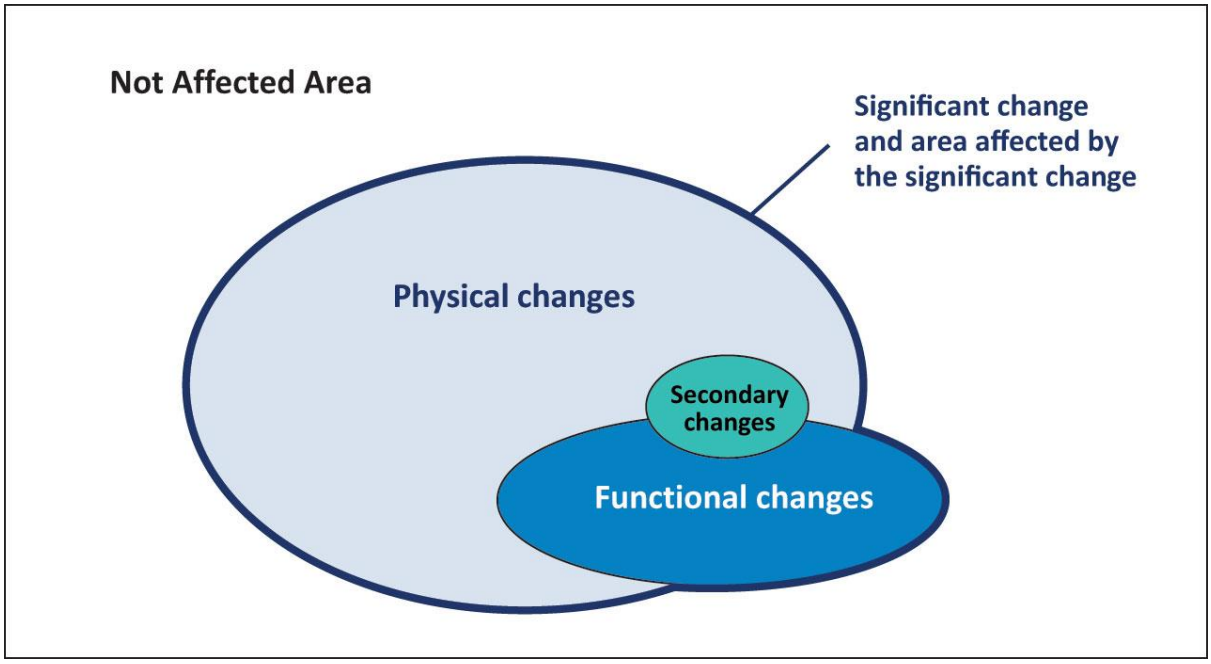
3.10.1.3.4 EASA will determine whether the proposed service experience levels necessary to demonstrate the appropriate level of safety as they relate to the proposed design change are acceptable.

3.10.1.4 Secondary changes.

3.10.1.4.1 The change proposed by the applicant can consist of physical and/or functional changes to the product. See Figure 3-4 below. There may be aspects of the existing type design of the product that the applicant may not be proposing to change directly, but that are affected by the overall change. For example, changing an airframe's structure, such as adding a cargo door in one location, may affect the frame or floor loading in another area. Further, upgrading engines with new performance capabilities could require additional demonstration of compliance for minimum control speeds and aeroplane performance certification specifications. For many years, EASA has required applicants to consider these effects, and this practice is unchanged under the procedures of point 21.A.101.

Figure 3-4. Change-Affected Areas with Secondary Changes

The Aeronautical Product



3.10.1.4.2 For each change, it is important that the effects of the change on other systems, components, equipment, or appliances of the product are properly identified and assessed. The intent is to encompass all aspects where there is a need for re-evaluation, that is, where the substantiation presented for the product being changed should be reviewed, updated, or rewritten.

3.10.1.4.3 In assessing the areas affected by the change, it may be helpful to identify secondary changes. A secondary change is a change to physical and/or functional aspects that is part of, but consequential to, a significant physical change, whose only purpose is to restore, and not add or increase, existing functionality or capacity. The term ‘consequential’ is intended to refer to:

— a change that would not have been made by itself; it achieves no purpose on its own;

— a change that has no effect on the existing functionality or capacity of areas, systems, structures, components, parts, or appliances affected by the change; or

— a change that would not create the need for: (1) new limitations or would affect existing limitations; (2) a new aircraft flight manual (AFM) or instructions for continued airworthiness (ICA) or a change to the AFM or ICA; or (3) special conditions, equivalent safety findings, or deviations.

3.10.1.4.4 A secondary change is not required to comply with the latest certification specifications because it is considered to be 'not contributing materially to the level of safety' and, therefore, eligible for an exception under point 21.A.101. Determining whether a change meets the description for a secondary change, and is thus eligible for an exception, should be straightforward. Hence, the substantiation or justification need only be minimal. If this determination is not straightforward, then the proposed change is not a secondary change.

3.10.1.4.5 In some cases, a secondary area of change that restores functionality may in fact contribute materially to the level of safety by meeting a later amendment. If this is the case, it is not considered a secondary change.

3.10.2 Are the latest specifications practical?

The intent of point 21.A.101 is to enhance safety by applying the latest certification specifications to the greatest extent practicable. The concepts of contributing materially and practicality are linked. If compliance with the latest certification specifications does contribute materially to the level of safety, then the applicant may assess the incremental costs to see whether they are commensurate with the increase in safety. The additional resource requirements could include those arising from changes required for compliance and the effort required to demonstrate compliance, but excluding resource expenditures for prior product changes. The cost of changing compliance documentation and/or drawings is not an acceptable reason for an exception.

3.10.2.1 Applicants should support their position that compliance is impractical with substantiating data and analyses. While evaluating that position and the substantiating data regarding impracticality, EASA may consider other factors (e.g. the costs and safety benefits for a comparable new design).

3.10.2.2 A review of large aeroplane projects showed that, in certain cases where EASA allowed an earlier amendment of applicable certification specifications, the applicants made changes that nearly complied with the latest amendments. In these cases, the applicants successfully demonstrated that full compliance would require a substantial increase in the outlay or expenditure of resources with a very small increase in the level of safety. These design features can be used as a basis for granting an exception under point 21.A.101(b)(3) on the basis of 'impracticality.'

3.10.2.3 Appendix E of this GM provides additional guidance and examples for evaluating the impracticality of applying the latest certification specifications to a changed product for which compliance with the latest certification specifications would contribute materially to the level of safety of the product.

3.10.2.3.1 The exception of impracticality is a qualitative and quantitative cost–safety benefit assessment for which it is difficult to specify clear criteria. Experience to date with applicants has shown that a justification of impracticality is more feasible when both the applicant and EASA agree during a discussion at an early stage that the effort (in terms of cost, changes to manufacturing, etc.) required to comply would not be commensurate with a small incremental safety gain. This would be clear even without the need to perform any detailed cost–safety benefit analysis (although an applicant could always use cost analysis to support an appropriate amendment level). However, there should be enough detail in the applicant's rationale to justify the exception.

Note: An applicant should not base an exception due to impracticality on the size of the applicant's company or their financial resources. The applicant must evaluate the costs to comply with a later amendment against the safety benefit of complying with the later amendment.

3.10.2.3.2 For example, a complex redesign of an area of the baseline aircraft may be required to comply with a new requirement, and that redesign may affect the commonality of the changed product with respect to the design and manufacturing processes of the existing family of models. Relevant service experience of the existing fleet of the baseline aircraft family would be required to show that there has not been a history of problems associated with the hazard that the new amendment in question was meant to address. In this way, the incremental cost/impact to the applicant is onerous, and the incremental safety benefit realised by complying with the later amendment would be minimal. This would be justified by demonstrated acceptable service experience in relation to the hazard that the new rule addresses.

3.11. Step 8. Ensure the proposed certification basis is adequate.

EASA considers a proposed certification basis for any change (whether it is significant or not significant) to be adequate when:

— the certification standards provide an appropriate level of safety for the intended change, and

— the change and the areas affected by the change do not result in unsafe design features or characteristics for the intended use.

3.11.1 For a change that contains new design features that are novel and unusual for which there are no later applicable certification specifications at a later amendment level, EASA will designate special conditions pursuant to point 21.B.75. EASA will impose later certification specifications that contain adequate or appropriate safety standards for this feature, if they exist, in lieu of special conditions. An example is adding a flight-critical system, such as an electronic air data display on a CS-25 large aeroplane whose existing certification basis does not cover protection against lightning and high-

intensity radiated fields (HIRF). In this case, EASA will require compliance with the certification specifications for lightning and HIRF protection, even though EASA determined that the change is not significant.

3.11.2 For new design features or characteristics that may pose a potential unsafe condition for which there are no later applicable certification specifications, new special conditions may be required to address points 21.B.107(a)(3) or 21.B.111(a)(3).

3.11.3 In cases where inadequate or no standards exist for the change to the existing certification basis, but adequate standards exist in a later amendment of the applicable certification specifications, the later amendment will be made part of the certification basis to ensure the adequacy of the certification basis.

3.11.4 EASA determines the final certification basis for a product change. This may consist of a combination of those standards ranging from the existing certification basis of the baseline product to the latest amendments and special conditions.

4. Excepted Products under point 21.A.101(c)

4.1. Excepted products.

For excepted products as defined in paragraph 4.1.1 below, the starting point for regulatory analysis is the existing certification basis for the baseline product.

4.1.1 Point 21.A.101(c) provides an exception to the compliance with the latest certification specifications required by point 21.A.101(a) for aircraft (other than rotorcraft) of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine rotorcraft of 1 361 kg (3 000 lb) or less maximum weight. In these cases, the applicant may elect to comply with the existing certification basis. However, the applicant has the option of applying later, appropriate certification specifications.

4.1.2 If EASA finds that the change is significant in an area, EASA may require the applicant to comply with a later certification specification and with any certification specification that EASA finds is directly related. Starting with the existing certification basis, EASA will progress through each later certification specification to determine the amendment appropriate for the change. However, if an applicant proposes, and EASA finds, that complying with the later amendment or certification specification would not contribute materially to the level of safety of the changed product or would be impractical, EASA may allow the applicant to comply with an earlier amendment appropriate for the proposed change. The amendment may not be earlier than the existing certification basis. For excepted products, changes that meet one or more of the following criteria, in the area of change, are automatically considered significant:

4.1.2.1 The general configuration or the principles of construction are not retained.

4.1.2.2 The assumptions used for certification of the area to be changed do not remain valid.

4.1.2.3 The change contains new features (not foreseen in the existing certification basis and for which appropriate later certification specifications exist). In this case, EASA will designate the applicable certification specifications, starting with the existing certification basis and progressing to the most appropriate later amendment level for the change.

4.1.2.4 The change contains a novel or unusual design feature. In this case, EASA will designate the applicable special conditions appropriate for the change, pursuant to point 21.A.101(d).

4.1.3 The exception for products under point 21.A.101(c) applies to the aircraft only. Changes to engines and propellers installed on these excepted aircraft are assessed as separate type-certified products using point 21.A.101(a) and (b).

5. Other Considerations

5.1. Design-related requirements from other aviation domains.

Some implementing rules in other aviation domains (air operations, ATM/ANS) (e.g. Commission Regulation (EU) No 965/2012 on air operations or Commission Regulation (EU) 2015/640 on additional airworthiness specifications for a given type of operations (Annex I (Part-26)) impose airworthiness standards that are not required for the issue of a TC or STC (e.g. CS-26, CS-ACNS, etc.). If not already included in the certification basis, any such applicable airworthiness standard may be added to the type certification basis by mutual agreement between the applicant and EASA. The benefit of adding these airworthiness standards to the type certification basis is to increase awareness of these standards, imposed by other implementing rules, during design certification and future modifications to the aircraft. The use of exceptions under point 21.A.101(b) is not intended to alleviate or preclude compliance with operating regulations.

5.2. Reserved.

5.3. Baseline product.

A baseline product consists of one unique type design configuration, an aeronautical product with a specific, defined, approved configuration and certification basis that the applicant proposes to change. As mentioned in paragraph 3.2.1 of this GM, it is important to clearly identify the type design configuration to be changed. EASA does not require an applicant to assign a new model name for a changed product. Therefore, there are vastly different changed products with the same aircraft model name, and there are changed products with minimal differences that have different model names. Since the assignment of a model name is based solely on an applicant's business decision, the identification of the baseline product, for the purposes of point 21.A.101, is, as defined below.

The baseline product is an approved type design that exists at the date of application and is representative of:

— a single certified build configuration, or

— multiple approvals over time (including STC(s) or service bulletins) and may be representative of more than one product serial number.

Note: The type design configuration, for this purpose, could also be based on a proposed future configuration that is expected to be approved at a later date but prior to the proposed changed product.

5.4. Predecessor standards.

The certification specifications in effect on the date of application for a change are those in CS-22, CS-23, CS-25, CS-27, CS-29, CS-CCD, CS-FCD, CS-MMEL, etc., issued by EASA after 2003. However, the type-certification basis of some 'grandfathered' products, i.e. those with a pre-EASA TC deemed to have been issued in accordance with Commission Regulation (EU) No 748/2012 (see Article 3), may consist of other standards issued by or recognised in the EU Member States. These standards may include Joint Aviation Requirements (JARs) issued by the Joint Aviation Authorities (JAA) or national regulations of an EU Member State (e.g. BCARs) or national regulations of a non-EU State of Design with which an EU Member State had concluded a bilateral airworthiness agreement (e.g. US FARs, CARs etc.). Consequently, when using one of the exception routes allowing electing to comply with earlier standards, the predecessor standards may be applicable. Such predecessor standards are not recognised under point 21.A.101(a), but may be allowed under point 21.A.101(b) or (c).When choosing the amendment level of a standard, all related standards associated with that amendment level would have to be included.

5.5. Special conditions, point 21.A.101(d).

Point 21.A.101(d) allows for the application of special conditions, or for changes to existing special conditions, to address the changed designs where neither the proposed certification basis nor any later certification specifications provide adequate standards for an area, system, part or appliance related to the change. The objective is to achieve a level of safety consistent with that provided for other areas, systems, parts or appliances affected by the change by the other certification specifications of the proposed certification basis. The application of special conditions to a design change is not, in itself, a reason to classify it as either a substantial change or a significant change. Whether the change is significant, with earlier certification specifications allowed through exceptions, or not significant, the level of safety intended by the special conditions must be consistent with the agreed certification basis.

5.6. Reserved.

5.7. Reserved.

5.8. Reserved.

5.9. Documentation.

5.9.1 Documenting the proposal.

In order to efficiently determine and agree upon a certification basis with EASA, the following information is useful to understand the applicant's position:

— The current certification basis of the product being changed, including the amendment level.

— The amendment level of all the applicable certification specifications at the date of application.

— The proposed certification basis, including the amendment levels.

— Description of the affected area.

— Applicants who propose a certification basis that includes amendment levels earlier than what was in effect at the date of application should include the exception as outlined in point 21.A.101(b) and their justification if needed.

Please see appendix H for examples of optional tools an applicant can use to document your proposed certification basis.

5.9.2 Documenting the significant/not significant decision.

5.9.2.1 EASA determines whether the changes are significant or not significant, and this decision is documented in the Certification Review Item(s). However, EASA provides an optional decision record for the applicant to make a predetermination to facilitate EASA decision. This form is provided in appendix G of this GM and follows the flow chart in Figure 3-1 of this GM. If it is used, the applicant should submit it along with the certification plan.

5.9.2.2 Changes that are determined to be significant changes under point 21.A.101, the exceptions, and the agreement of affected and unaffected areas is typically documented through the Certification Review Item (CRI) A-01 process. An example tool is provided in appendix H of this GM.

5.9.3 Documenting the certification basis.

5.9.3.1 EASA will amend the certification basis for all changes that result in a revision to the product's certification basis on the amended TCDS or STC. In case of a significant change, EASA will document the resulting certification basis in CRI A-01.

5.9.3.2 EASA will document the certification basis of each product model on all STCs, including approved model list STCs.

5.10. Incorporation of STCs into the Type Design.

The incorporation of STCs into the product type design may generate an additional major change when that change is needed to account for incompatibility between several STCs that were initially not intended to be applied concurrently.

5.10.1 If the incorporation of the STC(s) does not generate an additional major change, the incorporation is not evaluated pursuant to point 21.A.101. The existing certification basis should be updated to include the later amendments of the STC(s) being incorporated.

5.10.2 If the incorporation of the STC(s) generates an additional major change, the change must be evaluated pursuant to point 21.A.101, and the existing certification basis should be updated to include the amendments resulting from the application of point 21.A.101.

5.11. Removing changes.

Approved changes may be removed after incorporation in an aeronautical product. These changes will most commonly occur via an STC or a service bulletin kit.

5.11.1 The applicant should identify a product change that they intend at its inception to be removable as such, and should develop instructions for its removal during the initial certification. EASA will document the certification basis for both the installed and removed configuration separately on the TCDS or STC.

5.11.2 If specific removal instructions and a certification basis corresponding to the removed condition are not established at the time of the initial product change certification, the removal of changes or portions of those changes may constitute a significant change to type design. A separate STC or an amended TC may be required to remove the modifications and the resulting certification basis established for the changed product.

5.12. The certification basis is part of the change.

A new change may be installed in a product during its production or via a service bulletin or STC. In terms of point 21.A.101, each of the approved changes has its own basis of certification. If an applicant chooses to remove an approved installation (e.g. an interior installation, avionics equipment) and install a new installation, a new certification basis may be required for the new installation, depending on whether the change associated with the new installation is considered significant compared to the baseline configuration that the applicant chooses. If the new installation is a not significant change, the unmodified product's certification basis may be used (not the previous installation certification basis), provided the certification basis is adequate. For example, a large aeroplane is certified in a 'green' configuration. The aeroplane certification basis does not include CS 25.562. An interior is installed under an STC, and the applicant elects to include CS 25.562 (dynamic seats) in the certification basis to meet specific operational requirements. At a later date, the aeroplane is sold to another operator who does not have the same operational requirements. A new interior is installed; there will be no requirement for CS 25.562 to be included in the new certification basis.

5.13. Sequential changes — cumulative effects.

5.13.1 Any applicant who intends to accomplish a product change by incorporating several changes in a sequential manner should identify this to EASA up front when the first application is made. In addition, the cumulative effects arising from the initial change, and from all of the follow-on changes, should be included as part of the description of the change in the initial proposal. The classification of the intended product change will not be evaluated solely on the basis of the first application, but rather on the basis of all the required changes needed to accomplish the intended product change. If EASA determines that the current application is a part of a sequence of related changes, then EASA will re-evaluate the determination of significance and the resulting certification basis as a group of related changes.

5.13.2 Example: Cumulative effects — advancing the certification basis.

The type certificate for aeroplane model X lists three models, namely X-300, X-200, and X-100. The X-300 is derived from the X-200, which is derived from the original X-100 model. An applicant proposes a change to the X-300 aeroplane model. During the review of the X-300 certification basis and the certification specifications affected by the proposed change, it was identified that one certification specification, CS 25.571 (damage tolerance requirements), remained at the same amendment level as the X-100 original certification basis (exception granted on the X-200). Since the amendment level for this particular certification specification was not changed for the two subsequent aeroplane models (X-200 and X-300), the applicant must now examine the cumulative effects of these two previous changes that are related to the proposed change and the damage tolerance requirements to determine whether the amendment level needs to advance.

Appendix A to GM 21.A.101 Classification of design changes

ED Decision 2017/024/R

The following tables of 'substantial', 'significant', and 'not significant' changes are adopted by the FAA, Agência Nacional de Aviação Civil (ANAC), the European Aviation Safety Agency (EASA), and Transport Canada Civil Aviation (TCCA) through international collaboration. The classification may change due to cumulative effects and/or combinations of individual changes.

A.1 Examples of Substantial, Significant, and Not Significant Changes for Small Aeroplanes (CS-23).

A.1.1 Table A-1 contains examples of changes that are 'substantial' for small aeroplanes (CS-23).

Table A-1. Examples of Substantial Changes for Small Aeroplanes (CS-23)

Example	Description of Change	Notes
1.	Change to wing location (tandem, forward, canard, high/low).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Fixed wing to tilt wing.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
3.	A change to the number of engines.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

4.	Replacement of piston or turboprop engines with turbojet or turbofan engines.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
5.	Change to engine configuration (tractor/pusher).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
6.	Increase from subsonic to supersonic flight regime.	
7.	Change from an all-metal to all-composite aeroplane.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
8.	Certifying a CS-23 (or predecessor basis, such as JAR-23) aeroplane into another certification category, such as CS-25.	—

A.1.2 Table A-2 contains examples of changes that are 'significant' for small aeroplanes (CS-23).

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Conventional tail to T-tail or V-tail, or vice versa.	Yes	No	Yes	Change to general configuration. Requires extensive, structural flying qualities and performance reinvestigation. Requires new aeroplane flight manual (AFM) to address performance and flight characteristics.
2.	Changes to wing configuration, such as change to dihedral, changes to wing span, flap or aileron span, addition of winglets, or increase of more than 10 per cent of the original wing sweep at the quarter chord.	Yes	No	Yes	Change to general configuration. Likely requires extensive changes to wing structure. Requires new AFM to address performance and flight characteristics. Note: Small changes to the wingtip or winglet are not significant changes. See table for 'not significant' changes.
3.	Changes to tail configuration, such as the addition of tail strakes or angle of incidence of the tail.	Yes	No	Yes	Change to general configuration. Likely requires extensive changes to tail structure. Requires new AFM to address performance and flight characteristics. Note: Small changes to tail are not significant changes.
4.	Tricycle/tail wheel undercarriage change or addition of floats.	Yes	No	No	Change to general configuration. Likely, at aeroplane level, general configuration and certification assumptions remain valid.

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
5.	Passenger-to-freighter configuration conversion that involves the introduction of a cargo door or an increase in floor loading of more than 20 per cent, or provision for carriage of passengers and freight together.	Yes	No	Yes	Change to general configuration affecting load paths, aeroelastic characteristics, aircraft-related systems, etc. Change to design assumptions.
6.	Replace reciprocating engines with the same number of turbo-propeller engines.	Yes	No	No	Requires extensive changes to airframe structure, addition of aircraft systems, and new AFM to address performance and flight characteristics.
7.	Addition of a turbo-charger that changes the power envelope, operating range, or limitations.	No	No	Yes	Invalidates certification assumptions due to changes to operating envelope and limitations. Requires new AFM to address performance and flight characteristics.
8.	The replacement of an engine of higher rated power or increase thrust would be considered significant if it would invalidate the existing substantiation, or would change the primary structure, aerodynamics, or operating envelope sufficiently to invalidate the assumptions of certification.	No	Yes	Yes	Invalidates certification assumptions. Requires new AFM to address performance and flight characteristics. Likely changes to primary structure. Requires extensive construction reinvestigation.
9.	A change to the type of material, such as composites in place of metal, or one composite fibre material system with another (e.g. carbon for fiberglass), for primary structure would normally be assessed as a significant change.	No	Yes	Yes	Change to principles of construction and design from conventional practices. Likely change to design/certification assumptions.
10.	10. A change involving appreciable increase in design speeds V^D, V^B, V^{MO}, V^C, or V^A.	No	No	Yes	Certification assumptions invalidated. Requires new AFM to address performance and flight characteristics.
11.	Installation of a short take-off and landing (STOL) kit.	No	No	Yes	Certification assumptions invalidated. Requires new AFM to address performance and flight characteristics.
12.	A change to the rated power or thrust could be a significant change if the applicant is taking credit for increased design speeds per example 10 of this table.	No	No	Yes	Certification assumptions invalidated. Requires new AFM to address performance and flight characteristics.

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
13.	Fuel state, such as compressed gaseous fuels or fuel cells. This could completely alter the fuel storage and handling systems and possibly affect the aeroplane structure.	No	No	Yes	Changes to design/certification assumptions. Extensive alteration of fuel storage and handling systems.
14.	A change to the flight control concept for an aircraft, e.g. to fly-by-wire (FBW) and side-stick control, or a change from hydraulic to electronically actuated flight controls, would in isolation normally be regarded as a significant change.	No	No	Yes	Changes to design and certification assumptions. Requires extensive systems architecture and integration reinvestigation. Requires new AFM.
15.	Change to aeroplane's operating altitude, or cabin operating pressure greater than 10 per cent in maximum cabin pressure differential.	No	No	Yes	This typically invalidates certification assumptions and the fundamental approach used in decompression, structural strength, and fatigue. May require extensive airframe changes affecting load paths, fatigue evaluation, aeroelastic characteristics, etc. Invalidates design assumptions.
16.	Addition of a cabin pressurisation system.	No	Yes	Yes	Extensive airframe changes affecting load paths, fatigue evaluation, aeroelastic characteristics, etc. Invalidates design assumptions.
17.	Changes to types and number of emergency exits or an increase in maximum certified passenger capacity.	Yes	No	Yes	Emergency egress certification specifications exceed those previously substantiated. Invalidates assumptions of certification.
18.	A change to the required number of flight crew that necessitates a complete flight deck rearrangement, and/or an increase in pilot workload.	No	No	Yes	Extensive changes to avionics and aircraft systems. Invalidates certification assumptions. Requires new AFM.
19.	Expansion of an aircraft's operating envelope.*	No	No	Yes* *Some changes may be deemed 'not significant' depending on the extent of the expansion.	An expansion of operating capability is a significant change (e.g. an increase in maximum altitude limitation, approval for flight in icing conditions, or an increase in airspeed limitations).
20.	Replacement of an aviation gasoline engine with an engine of approximately the same horsepower utilising, e.g. diesel, hybrid, or electrical power.	No	No	Yes	A major change to the aeroplane. The general configuration and principles of construction will usually remain valid; however, the assumptions for certification are invalidated.

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
21.	Comprehensive flight deck upgrade, such as conversion from entirely federated, independent electromechanical flight instruments to highly integrated and combined electronic display systems with extensive use of software and/or complex electronic hardware.	No	No	Yes	Affects avionics and electrical systems integration and architecture concepts and philosophies. This drives a reassessment of the human–machine interface, flight-crew workload, and re-evaluation of the original design flight deck assumptions.
22.	Introduction of autoland.	No	No	Yes	Invalidates original design assumptions.
23.	Conversion from a safe life design to a damage-tolerance-based design.	No	No	Yes	Where the airframe-established safe life limits change to damage-tolerance principles, then use of an inspection program in lieu of the safe life design limit invalidates the original assumptions used during certification.
24.	Extensive structural airframe modification, such as a large opening in the fuselage.	Yes	No	No	Requires extensive changes to fuselage structure, affects aircraft systems, and requires a new AFM to address performance and flight characteristics.
25.	Fuselage stretch or shortening in the cabin or pressure vessel.	Yes	No	Yes	Cabin interior changes are related changes since occupant safety considerations are impacted by a cabin length change. Even if a new cabin interior is not included in the product-level change, the functional effect of the fuselage plug has implications on occupant safety (e.g. the dynamic environment in an emergency landing, emergency evacuation, etc.), and thus the cabin interior becomes an affected area.
26.	Conversion from normal category to commuter category aeroplane.	Yes	No	Yes	Requires compliance with all commuter regulatory standards. In many cases, this change could be considered a substantial change to the type design. Therefore, a proposed change of this nature would be subject to EASA determination under 21.A.19.
27.	Installation of a full authority digital engine control (FADEC) on an aeroplane that did not previously have a FADEC installed.	No	No	Yes	—

A.1.3 Table A-3 contains examples of changes that are 'not significant' for small aeroplanes (CS-23).

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Addition of wingtip modifications (not winglets).	No	No	No	A major change to the aeroplane. Likely, the original general configuration, principles of construction, and certification assumptions remain valid.
2.	Installation of skis or wheel skis.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
3.	Forward looking infrared (FLIR) or surveillance camera installation.	No	No	No	Additional flight or structural evaluation may be necessary, but the change does not alter basic aeroplane certification.
4.	Litter, berth, and cargo tie down device installation.	No	No	No	Not an aeroplane-level change.
5.	Not an aeroplane-level change.	No	No	No	Not an aeroplane-level change.
6.	Replacement of one propeller type with another (irrespective of increase in number of blades).	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
7.	Addition of a turbo-charger that does not change the power envelope, operating range, or limitations (e.g. a turbo-normalised engine, where the additional power is used to enhance high-altitude or hot-day performance).	No	No	No	Not an aeroplane-level change.
8.	Substitution of one method of bonding for another (e.g. change to type of adhesive).	No	No	No	Not an aeroplane-level change.
9.	Substitution of one type of metal for another.	No	No	No	Not an aeroplane-level change.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
10.	Any change to construction or fastening not involving primary structure.	No	No	No	Not an aeroplane-level change.
11.	A new fabric type for fabric-skinned aircraft.	No	No	No	Not an aeroplane-level change.
12.	Increase in flap speed or undercarriage limit speed.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
13.	Structural strength increases.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
14.	Instrument flight rules (IFR) upgrades involving installation of components (where the original certification does not indicate that the aeroplane is not suitable as an IFR platform, e.g. special handling concerns).	No	No	No	Not an aeroplane-level change.
15.	Fuel tanks where fuel is changed from gasoline to diesel fuel and tank support loads are small enough that an extrapolation from the previous analysis would be valid. Chemical compatibility would have to be substantiated.	No	No	No	Not an aeroplane-level change.
16.	Limited changes to a pressurisation system, e.g. number of outflow valves, type of controller, or size of pressurised compartment, but the system must be re-substantiated if the original test data are invalidated.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
17.	Install a different exhaust system.	No	No	No	Not an aeroplane-level change.
18.	Changes to engine cooling or cowling.	No	No	No	Not an aeroplane-level change.
19.	Changing fuels of substantially the same type, such as AvGas to AutoGas, AvGas (80/87) to AvGas (100LL), ethanol to isopropyl alcohol, Jet B to Jet A.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
20.	Fuels that specify different levels of 'conventional' fuel additives that do not change the primary fuel type. Different additive levels (controlled) of MTBE, ETBE, ethanol, amines, etc., in AvGas would not be considered a significant change.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
21.	A change to the maximum take-off weight of less than 5 per cent, unless assumptions made in justification of the design are thereby invalidated.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
22.	An additional aileron tab (e.g. on the other wing).	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
23.	Larger diameter flight control cables with no change to routing, or other system design.	No	No	No	Not an aeroplane-level change.
24.	Autopilot installation (for IFR use, unless the original certification indicates that the aeroplane is not suitable as an IFR platform).	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
25.	Increased battery capacity or relocate battery.	No	No	No	Not an aeroplane-level change.
26.	Replace generator with alternator.	No	No	No	Not an aeroplane-level change.
27.	Additional lighting (e.g. navigation lights, strobes).	No	No	No	Not an aeroplane-level change.
28.	Higher capacity brake assemblies.	No	No	No	Not an aeroplane-level change.
29.	Increase in fuel tank capacity.	No	No	No	Not an aeroplane-level change.
30.	Addition of an oxygen system.	No	No	No	Not an aeroplane-level change.
31.	Relocation of a galley.	No	No	No	Not an aeroplane-level change.
32.	Passenger-to-freight (only) conversion with no change to basic fuselage structure.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid. Requires certification substantiation applicable to freighter certification specifications.
33.	New cabin interior with no fuselage length change.	No	No	No	—
34.	Installation of new seat belt or shoulder harness.	No	No	No	Not an aeroplane-level change.
35.	A small increase in centre of gravity (CG) range.	No	No	No	At aeroplane level, no change to general configuration, principles of construction, and certification assumptions.
36.	Auxiliary power unit (APU) installation that is not flight-essential.	No	No	No	Although a major change to the aeroplane level, likely the original general configuration, principles of construction, and certification assumptions remain valid. Requires certification substantiation applicable to APU installation certification specifications.
37.	An alternative autopilot.	No	No	No	Not an aeroplane-level change.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
38.	Addition of Class B terrain awareness and warning system (TAWS).	No	No	No	Not an aeroplane-level change.
39.	Extending an established life limit.	No	No	No	This extension may be accomplished by various methods, such as ongoing fatigue testing, service life evaluation, component level replacement, and inspections based on damage-tolerance principles.
40.	Flight deck replacement of highly integrated and combined electronic display systems with other highly integrated and combined electronic display systems.	No	No	No	Not significant if the architecture concepts, design philosophies, human–machine interface, or flight-crew workload assumptions are not impacted.
41.	Interior cabin reconfigurations are generally considered not significant. This includes installation of in-flight entertainment (IFE), new seats, and rearrangement of furniture.	No	No	No	—
42.	Modification to ice protection systems.	No	No	No	Recertification required, but certification basis should be evaluated for adequacy.

A.2 Examples of Substantial, Significant, and Not Significant Changes for Large Aeroplanes (CS-25).

A.2.1 Table A-4 contains examples of changes that are 'substantial' for large aeroplanes (CS-25).

Table A-4. Examples of Substantial Changes for Large Aeroplanes (CS-25)

Example	Description of Change	Notes
1.	Change to the number or location of engines, e.g. four to two wing-mounted engines or two wing-mounted to two body-mounted engines.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Change from a high-wing to low-wing configuration.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
3.	Change from an all-metal to all-composite aeroplane.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
4.	Change of empennage configuration for larger aeroplanes (cruciform vs 'T' or 'V' tail).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
5.	Increase from subsonic to supersonic flight regime.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

A.2.2 Table A-5 contains examples of changes that are 'significant' for large aeroplanes (CS-25).

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Reduction in the number of flight crew (in conjunction with flight deck update).	No	No	Yes	Extensive changes to avionics and aircraft systems. Impact to flight-crew workload and human factors, pilot type rating.
2.	Modify an aeroplane to add certification for flight in icing conditions by adding systems, such as ice detection and ice protection.	Yes	No	Yes	New aircraft operating envelope. Requires major new systems installation and aircraft evaluation. Operating envelope changed.
3.	Conversion — passenger or combination freighter/passenger to all-freighter, including cargo door, redesign floor structure and 9g net or rigid barrier.	Yes	No	Yes	Extensive airframe changes affecting load paths, aeroelastic characteristics, aircraft-related systems for fire protection, etc. Design assumptions changed from passenger to freighter.
4.	Conversion from a cargo to passenger configuration.	Yes	No	Yes	Completely new floor loading and design. Redistribution of internal loads, change to cabin safety certification specifications, system changes.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
5.	Increase in cabin pressurisation greater than 10 per cent.	No	No	Yes	A change greater than 10 per cent in operational cabin pressure differential is a significant change since it requires extensive airframe changes affecting load paths, fatigue evaluation, or aeroelastic characteristics, invalidating the certification assumptions.
6.	Addition of leading-edge slats.	Yes	No	Yes	The addition of leading-edge slats is significant since it requires extensive changes to wing structure, adds aircraft systems, and requires a new AFM to address performance and flight characteristics.
7.	Fuselage stretch or shortening in the cabin or pressure vessel.	Yes	No	Yes	Cabin interior changes are related changes since occupant safety considerations are impacted by a cabin length change. Even if a new cabin interior is not included in the product-level change, the functional effect of the fuselage plug has implications on occupant safety (e.g. the dynamic environment in an emergency landing, emergency evacuation, etc.), and thus the cabin interior becomes an affected area.
8.	Extensive structural airframe modification, such as installation of a large telescope with large opening in the fuselage.	Yes	No	No	These types of structural modifications are significant since they require extensive changes to fuselage structure, affect aircraft systems, and require a new AFM to address performance and flight characteristics.
9.	Changing the number of axles or number of landing gear done in context with a product change that involves changing the aeroplane's gross weight.	Yes	No	No	This type of landing gear change with an increase in gross weight is significant since it requires changes to aircraft structure, affects aircraft systems, and requires AFM changes, which invalidate the certification assumptions.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
10.	Primary structure changes from metallic material to composite material.	No	Yes	No	Change to principles of construction and design from conventional practices.
11.	An increase in design weight of more than 10 per cent.	No	No	Yes	Design weight increases of more than 10 per cent result in significant design load increase that invalidates the assumptions used for certification, requiring re-substantiation of aircraft structure, aircraft performance, and flying qualities and associated systems.
12.	Installation of winglets, modification of existing winglets, or other changes to wing tip design.	Yes	No	Yes	Significant if it requires extensive changes to wing structure or aircraft systems, or if it requires a new AFM to address performance and flight characteristics. It may also affect the wing fuel tanks, including fuel tank lightning protection, fuel tank ignition source prevention, and fuel tank flammability exposure.
13.	Changes to wing span, chord, or sweep.	Yes	No	Yes	Significant if it requires extensive changes to wing structure or aircraft systems, or if it requires a new AFM to address performance and flight characteristics. It may also affect the wing fuel tanks, including fuel tank lightning protection, fuel tank ignition source prevention, and fuel tank flammability exposure.
14.	A change to the type or number of emergency exits or an increase in the maximum certified number of passengers.	Yes	No	Yes	—
15.	A comprehensive avionics upgrade that changes a federated avionics system to a highly integrated avionics system.	No	No	Yes	This change refers to the avionics system that feeds the output to displays and not the displays themselves.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
16.	An avionics upgrade that changes the method of input from the flight crew, which was not contemplated during the original certification.	No	No	Yes	A change that includes touchscreen technology typically does not invalidate the assumptions used for certification. A change that incorporates voice-activated controls or other novel human–machine interface would likely invalidate the assumptions used for certification.
17.	Change to primary flight controls to FBW system. (Some aeroplanes have some degree of FBW. Achieving full FBW may be a not significant change on some aeroplanes.)	No	No	Yes	When the degree of change is so extensive that it affects basic aircraft systems integration and architecture concepts and philosophies. This drives a complete reassessment of flight-crew workload, handling qualities, and performance evaluation, which are different from the original design assumptions.
18.	Replace reciprocating with turbo-propeller engines.	Yes	No	No	Requires extensive changes to airframe structure, addition of aircraft systems, and new AFM to address performance and flight characteristics.
19.	Maximum continuous or take-off thrust or power increase of more than 10 per cent or, for turbofans, an increase of the nacelle diameter.	No	No	Yes	A thrust or power increase of more than 10 per cent is significant because it does have a marked effect on aircraft performance and flying qualities, or requires re-substantiation of powerplant installation. An increase of the nacelle diameter as a result of an increase in the bypass ratio is significant because it results in airframe-level effects on aircraft performance and flying qualities. However, a small increase of the nacelle diameter would not have such an airframe-level effect and would not be considered a significant change.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
20.	Initial installation of an autoland system.	No	No	Yes	Baseline aeroplane not designed for autoland operation, potential flight-crew workload, and systems compatibility issues.
21.	Installation of a new fuel tank, e.g. installation of an auxiliary fuel tank in a cargo bay or installation of an auxiliary fuel tank that converts a dry bay into a fuel tank (such as a horizontal stabiliser tank).	No	No	Yes	Requires changes to airframe, systems, and AFM. Results in performance changes. These changes typically affect fuel tank lightning protection, fuel tank ignition source prevention, and fuel tank flammability exposure.
22.	Main deck cargo door installation.	Yes	No	No	Redistribution of internal loads, change to aeroelastic characteristics, system changes.
23.	Expansion of an aircraft's operating envelope.*	No	No	Yes* *Some changes may be deemed 'not significant' depending on the extent of the expansion.	An expansion of operating capability is a significant change (e.g. an increase in maximum altitude limitation, approval for flight in icing conditions, or an increase in airspeed limitations).
24.	Changing the floor from passenger-carrying to cargo-carrying capability.	Yes	No	Yes	Completely new floor loading and design. Redistribution of internal loads, change to cabin safety certification specifications, system changes. If a cargo handling system is installed, it would be a related change.
25.	Initial installation of an APU essential for aircraft flight operation.	No	No	Yes	Changes to emergency electrical power certification specifications, change to aircraft flight manual and operating characteristics.
26.	Conversion from hydraulically actuated brakes to electrically actuated brakes.	No	No	Yes	Assumptions of certification for aeroplane performance are changed.
27.	Installation of engine thrust reversers.	Yes	No	Yes	

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
28.	Request for extended-range operations (ETOPS) type design approval for: (a) aeroplanes without an existing ETOPS type design approval, and (b) extension of an aeroplane's diversion time.	No	No	Yes	An expansion of diversion capability for ETOPS would normally be a significant change. However, expanding the diversion capability for which it was originally designed is generally not a significant change. In this case, the assumptions used for certification of the basic product remain valid, and the results can be applied to cover the changed product with predictable effects or can be demonstrated without significant physical changes to the product.
29.	Installation of an engine with a FADEC on an aeroplane that did not previously have a FADEC engine installed.	No	No	Yes	A change from a mechanical control engine to a FADEC engine may be so extensive that it affects basic aircraft systems integration and architecture concepts and philosophies. This drives a complete reassessment of flight-crew workload, handling qualities, and performance evaluation, which are different from the original design assumptions.

A.2.3 Table A-6 contains examples of changes that are 'not significant' for large aeroplanes (CS-25).

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
1.	Alternate engine installation or hush kit at same position.	No	No	No	It is not significant so long as there is less than a 10 per cent increase in thrust or there is not a change to the principles of propulsion. A change to position to accommodate a different engine size could influence aeroplane performance and handling qualities and result in a significant change.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
2.	A small change to fuselage length due to re-fairing the aft body or radome.	No	No	No	For cruise performance reasons, where such changes do not require extensive structural, systems, aerodynamic, or AFM changes.
3.	Re-fairing of wing tip caps (for lights, fuel dump pipes) and addition of splitter plates to the trailing edge thickness of the cruise aerofoil.	No	No	No	Does not require extensive structural, AFM, or systems changes.
4.	Additional power used to enhance high-altitude or hot-day performance.	No	No	No	Usually no change to basic operating envelope. Existing certification data can be extrapolated. Could be significant product change if the additional power is provided by installation of a rocket motor or additional, on demand engine due to changes to certification assumptions.
5.	Installation of an autopilot system.	No	N/A	See notes	It may be possible that the modification is adaptive in nature, with no change to original certification assumptions. However, in certain cases the installation of an autopilot may include extensive changes and design features that change both the general configuration and the assumptions for certification (i.e. installation of the autopilot may introduce a number of additional mechanical and electronic failure modes and change the hazard classification of given aircraft-level failures).
6.	Change from assembled primary structure to monolithic or integrally machined structure.	No	No	No	Method of construction must be well understood.
7.	Modification to ice protection systems.	No	No	No	Recertification required, but certification basis is adequate.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
8.	Brakes: design or material change, e.g. steel to carbon.	No	No	No	Recertification required, but certification basis is adequate.
9.	Redesign floor structure.	No	No	No	By itself, not a significant product change. It is significant if part of a cargo conversion of a passenger aeroplane.
10.	New cabin interior with no fuselage length change.	No	No	No	A new cabin interior includes new ceiling and sidewall panels, stowage, galleys, lavatories, and seats. Novel or unusual design features in the cabin interior may require special conditions. Many interior-related certification specifications are incorporated in operational rules. Even though the design approval holder may not be required to comply with these certification specifications, the operator may be required to comply.
11.	A rearrangement of an interior (e.g. seats, galleys, lavatories, closets, etc.).	No	No	No	—
12.	Novel or unusual method of construction of a component.	No	No	No	The component change does not rise to the product level. Special conditions could be required if there are no existing certification specifications that adequately address these features.
13.	Initial installation of a non-essential APU.	No	No	No	A stand-alone initial APU installation on an aeroplane originally designed to use ground- or airport-supplied electricity and air conditioning. In this case, the APU would be an option to be independent of airport power.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
14.	Increasing the life limit as CS 25.571 fatigue testing progresses for a recently type-certified aeroplane.	No	No	No	For example, a recently type-certified aeroplane may undergo fatigue testing as part of compliance with CS 25.571. In this case, the TC holder may specify an initial life limit in the airworthiness limitations section (ALS) and gradually increase that life limit as fatigue testing progresses. Such change to the ALS is considered not significant.
15.	Extending limit of validity (LOV)	No	No	No	Extending an LOV without any other change to the aeroplane is not a significant change. However, if extending the LOV requires a physical design change to the aeroplane, the design change is evaluated to determine the level of significance of the design change.
16.	Airframe life extension.	No	No	No	This does not include changes that involve changes to design loads, such as pressurisation or weight increases. Also, this does not include changing from safe life to damage tolerance.
17.	Changes to the type or number of emergency exits by de-rating doors or deactivating doors with corresponding reduction in passenger capacity.	No	No	No	The new emergency egress does not exceed that previously substantiated because the certified number of passengers is reduced.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
18.	Request for ETOPS type design approval for a type design change of a product with an existing ETOPS type design approval.	No	No	No	A change to a product with an existing ETOPS type design approval without a change to diversion capability would normally not be significant. However, if the existing ETOPS type design approval was based on policy prior to the adoption of transport category ETOPS airworthiness standards, then there is not an adequate certification basis to evaluate the type design change for ETOPS. In this case, the change is still not significant, and the appropriate transport category ETOPS airworthiness standards would apply.
19.	An avionics change from federated electromechanical displays to federated electronic displays.	No	No	No	Changing an electromechanical display to an electronic display is not considered significant.
20.	An avionics change replacing an integrated avionics system with another integrated avionics system.	No	No	No	The assumptions used to certify a highly integrated avionics system should be the same for another highly integrated avionics system.

A.3 Examples of Substantial, Significant, and Not Significant Changes for Rotorcraft (CS-27 and CS-29).

A.3.1 Table A-7 contains examples of changes that are 'substantial' for rotorcraft (CS-27 and CS-29).

Table A-7. Examples of Substantial Changes for Rotorcraft (CS-27 and 29)

Example	Description of Change	Notes
1.	Change from the number and/or configuration of rotors (e.g. main & tail rotor system to two main rotors).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Change from an all-metal rotorcraft to all-composite rotorcraft.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

A.3.2 Table A-8 contains examples of changes that are 'significant' for rotorcraft (CS-27 and CS-29).

Table A-8. Examples of Significant Changes for Rotorcraft (CS-27 and CS-29)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Comprehensive flight deck upgrade, such as conversion from entirely federated, independent electromechanical flight instruments to highly integrated and combined electronic display systems with extensive use of software and/or complex electronic hardware.	No	No	Yes	Affects avionics and electrical systems integration and architecture concepts and philosophies. This drives a reassessment of the human–machine interface, flight-crew workload, and re-evaluation of the original design flight deck assumptions.
2.	Certification for flight into known icing conditions.	No	No	Yes	
3.	(Fixed) flying controls from mechanical to fly-by-wire.	No	No	Yes	This drives a complete reassessment of the rotorcraft controllability and flight control failure.
4.	Addition of an engine; e.g. from single to twin or reduction of the number of engines; e.g. from twin to single.	Yes	Yes	Yes	—
5.	A change of the rotor drive primary gearbox from a splash-type lubrication system to a pressure-lubricated system due to an increase in horsepower of an engine or changing from a piston engine to turbine engine.	No	Yes	Yes	—

Table A-8. Examples of Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
6.	A fuselage or tail boom modification that changes the primary structure, aerodynamics, and operating envelope sufficiently to invalidate the certification assumptions.	Yes	No	Yes	—
7.	Application of an approved primary structure to a different approved model (e.g. installation on a former model of a main rotor that has been approved on a new model, and that results in increased performance).	No	Yes	Yes	—
8.	Emergency medical service (EMS) configuration with primary structural changes sufficient to invalidate the certification assumptions.	No	No	Yes	Many EMS configurations will not be classified as significant. Modifications made for EMS are typically internal, and the general external configuration is normally not affected. These changes should not automatically be classified as significant. Note: Door addition or enlargement involving structural change would be significant.
9.	Skid landing gear to wheel landing gear or wheel landing to skid.	Yes	No	Yes	—
10.	Change of the number of rotor blades.	Yes	No	Yes	—
11.	Change of tail anti-torque device (e.g. tail rotor, ducted fan, or other technology).	Yes	Yes	No	—
12.	Passenger-configured helicopter to a firefighting-equipment-configured helicopter.	Yes	No	Yes	Depends on the firefighting configuration.
13.	Passenger-configured helicopter to an agricultural-configured helicopter.	Yes	No	Yes	Depends on the agricultural configuration.
14.	An initial Category A certification approval to an existing configuration.	No	No	Yes	—
15.	IFR upgrades involving installation of upgraded components for new IFR configuration.	No	No	Yes	Changes to architecture concepts, design philosophies, human-machine interface, or flight-crew workload.

Table A-8. Examples of Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
16.	Human external cargo (HEC) certification approval.	No	No	Yes	Must comply with the latest HEC certification specifications in order to obtain operational approval. Assumptions used for certification are considered invalidated when this leads to a significant re-evaluation, for example, of fatigue, quick-release systems, HIRF, one-engine-inoperative (OEI) performance, and OEI procedures.
17.	Reducing the number of pilots for IFR from two to one.	No	No	Yes	—
18.	An avionics upgrade that changes a federated avionics system to a highly integrated avionics system.	No	No	Yes	This change refers to the avionics system that feeds the output to displays and not the displays themselves.
19.	An avionics upgrade that changes the method of input from the flight crew, which was not contemplated during the original certification.	No	No	Yes	A change that includes touchscreen technology typically does not invalidate the assumptions used for certification. A change that incorporates voice-activated controls or other novel human-machine interface would likely invalidate the assumptions used for certification.

A.3.3 Table A-9 contains examples of changes that are 'not significant' changes for rotorcraft (CS-27 and CS-29).

Table A-9. Examples of Not Significant Changes for Rotorcraft (CS-27 and CS-29)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Emergency floats.	No	No	No	Must comply with the specific applicable certification specifications for emergency floats. This installation, in itself, does not change the rotorcraft configuration, overall performance, or operational capability. Expanding an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations, flight over water, or operations in snow conditions) are not by themselves so different that the original certification assumptions are no longer valid at the type-certified-product level.
2.	Forward looking infrared (FLIR) or surveillance camera installation.	No	No	No	Additional flight or structural evaluation may be necessary but the change does not alter the basic rotorcraft certification.
3.	Helicopter terrain awareness warning system (HTAWS) for operational credit.	No	No	No	Certified under rotorcraft HTAWS AMC guidance material and ETSO-C194. Does not alter the basic rotorcraft configuration.
4.	Health usage monitoring system (HUMS) for maintenance credit.	No	No	No	Certified under rotorcraft HUMS GM guidance material. Does not alter the basic rotorcraft configuration.
5.	Expanded limitations with minimal or no design changes, following further tests/justifications or different mix of limitations (CG limits, oil temperatures, altitude, minimum/maximum weight, minimum/ maximum external temperatures, speed, engine ratings).	No	No	No	Changes to an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations, flight over water, or operations in snow conditions) that are not so different that the original certification assumptions remain valid.
6.	Change from a single-channel FADEC to a dual-channel FADEC.				Change does not change the overall product configuration or the original certification assumptions.

Table A-9. Examples of Not Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
7.	Installation of a new engine type, equivalent to the former one, leaving aircraft installation and limitations substantially unchanged.	No	No	No	Refer to AMC 27 or AMC 29 for guidance. Does not alter the basic rotorcraft configuration, provided there is no additional capacity embedded in the new design.
8.	Windscreen installation.	No	No	No	Does not change the rotorcraft overall product configuration.
9.	Snow skis, 'Bear Paws.'	No	No	No	Must comply with specific certification specifications associated with the change. Expanding an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations, flight over water, or operations in snow conditions) are not by themselves so different that the original certification assumptions are no longer valid at the type-certified-product level.
10.	External cargo hoist.	No	No	No	Must comply with the specific applicable certification specifications for external loads. This installation, in itself, does not change the rotorcraft configuration, overall performance, or operational capability. Expanding an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations (excluding HEC), flight over water, or operations in snow conditions) are not by themselves so different that the original certification assumptions are no longer valid at the type-certified-product level.
11.	IFR upgrades involving installation of upgraded components to replace existing components.	No	No	No	Not a rotorcraft-level change.
12.	An avionics change from federated electromechanical displays to federated electronic displays.	No	No	No	Changing an electromechanical display to an electronic display on a single avionics display is not considered significant.
13.	An avionics change replacing an integrated avionics system with another integrated avionics system.	No	No	No	The assumptions used to certify a highly integrated avionics system should be the same for another highly integrated avionics system.

Table A-9. Examples of Not Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
14.	Flight deck replacement of highly integrated and combined electronic display systems with other highly integrated and combined electronic display systems.	No	No	No	Not significant if the architecture concepts, design philosophies, human–machine interface, flight-crew workload design and flight-deck assumptions are not impacted.
15.	IFR upgrades involving installation of upgraded components for new IFR configuration.	No	No	No	No changes to architecture concepts, design philosophies, human–machine interface, or flight-crew workload.
16.	Flight deck replacement or upgrade of avionics systems in non-Appendix 'B' (IFR) or non-CAT 'A' rotorcraft that can enhance safety or pilot awareness.	No	No	No	—
17.	Modifications to non-crashworthy fuel systems intended to improve its crashworthiness.	No	No	No	—
18.	Changing the hydraulic system from one similar type of fluid to another, e.g. a fluid change from a highly flammable mineral oil-based fluid (MIL-H-5606) to a less flammable synthetic hydrocarbon-based fluid (MIL-PRF-87257)	No	No	No	—
19.	An ETSO C-127 dynamic seat installed in a helicopter with an existing certification basis prior to addition of CS 29.562, Emergency landing dynamic conditions.	No	No	No	

A.4 Examples of Substantial, Significant, and Not Significant Changes for Engines (CS-E)

A.4.1 Table A-10 contains examples of changes that are 'substantial' for engines (CS-E).

Table A-10. Examples of Substantial Changes for Engines (CS-E)

Example	Description of Change	Notes
Turbine Engines		
1.	Traditional turbofan to geared-fan engine.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Low-bypass ratio engine to high-bypass ratio engine with an increased inlet area.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

Example	Description of Change	Notes
3.	Turbojet to turbofan.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
4.	Turboshaft to turbo-propeller.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
5.	Conventional ducted fan to unducted fan.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
6.	Turbine engine for subsonic operation to afterburning engine for supersonic operation.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

A.4.2 Table A-11 contains examples of changes that are 'significant' for engines (CS-E).

Table A-11. Examples of Significant Changes for Engines (CS-E)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
Turbine Engines					
1.	Increase/decrease in the number of compressor/turbine stages with resultant change to approved operational limitations.	Yes	No	Yes	Change is associated with other changes that would affect the rating of the engine and the engine dynamic behaviour, such as backbone bending, torque spike effects on rotors and casing, surge and stall characteristics, etc.
2.	New design fan blade and fan hub, or a bladed fan disk to a blisk, or a fan diameter change, that could not be retrofitted.	Yes	No	Yes	Change is associated with other changes to the engine thrust/power, ratings, and operating limitations; engine dynamic behaviour in terms of backbone bending, torque spike effects on casing, foreign object ingestion behaviour (birds, hail, rain, ice slab); blade-out test and containment; induction system icing capabilities; and burst model protection for the aircraft. If there is a diameter change, installation will be also affected.
3.	Hydromechanical control to FADEC/electronic engine control (EEC) without hydromechanical backup.	Yes	No	No	Change to engine control configuration. Not interchangeable. Likely fundamental change to engine operation.

Table A-11. Examples of Significant Changes for Engines (CS-E)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
4.	A change to the containment case from hard-wall to composite construction or vice versa that could not be retrofitted without additional major changes to the engine or restricting the initial limitations or restrictions in the initial installation manual.	No	Yes	Yes	Change to methods of construction that have affected inherent strength, backbone bending, blade-to-case clearance retention, containment wave effect on installation, effect on burst model, torque spike effects.
5.	A change to the gas generator (core, turbine/compressor/ combustor) in conjunction with changes to approved operating limitations.	No	No	Yes	Change is associated with other changes that would affect engine thrust/power and operating limitations, and have affected the dynamic behaviour of the engine, foreign object ingestion behaviour (birds, hail storm, rain, ice shed), induction system icing capabilities. Assumptions used for certification may no longer be valid.
6.	A change from traditional metal to composite materials on an assembly or structure that provides a load path for the engine affecting the engine dynamic behaviour and/or the engine inherent strength.	No	Yes	Yes	Change to principles of construction and design.
			Piston Engines		
7.	Convert from mechanical to electronic control system.	Yes	Yes	No	Change to engine configuration: installation interface of engine changed. Changes to principles of construction: digital controllers and sensors require new construction techniques and environmental testing.
8.	Add turbocharger that increases performance and changes to overall product.	Yes	No	Yes	Change to general configuration: installation interface of engine changed (exhaust system). Certification assumptions invalidated: change to operating envelope and performance.
9.	Convert from air-cooled cylinders to liquid-cooled cylinders.	Yes	No	Yes	Change to general configuration: installation interface of engine changed (cooling lines from radiator, change to cooling baffles). Certification assumptions invalidated: change to operating envelope and engine temperature certification specifications.

Table A-11. Examples of Significant Changes for Engines (CS-E)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
10.	A change from traditional metal to composite materials on an assembly or structure that provides a load path for the engine affecting the engine dynamic behaviour and/or the engine inherent strength.	No	Yes	Yes	Change to principles of construction and design.
11.	Convert from spark-ignition to compression-ignition.	Yes	No	Yes	Change to general configuration: installation interface of engine changed (no mixture lever). Certification assumptions invalidated: change to operating envelope and performance.

A.4.3 Table A-12 contains examples of changes that are 'not significant' for engines (CS-E).

Table A-12. Examples of Not Significant Changes for Engines (CS-E)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
Turbine Engines					
1.	Change to the material from one type of metal to another type of metal of a compressor drum.	No	No	No	No change to performance. Assumptions are still valid.
2.	Increase/decrease in the number of compressor/turbine stages without resultant change to operational performance envelope.	No	No	No	No change to performance. Assumptions are still valid.
3.	Hardware design changes to the FADEC/EEC, the introduction of which does not change the function of the system.	No	No	No	No change to configuration. Retrofitable. Assumptions used for certification are still valid. Possible changes to principles of construction are insignificant.
4.	Software changes.	No	No	No	—
5.	Rub-strip design changes.	No	No	No	Component-level change.

Table A-12. Examples of Not Significant Changes for Engines (CS-E)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
6.	A new combustor that does not change the approved limitations or dynamic behaviour.* (*Exclude life limits.)	No	No	No	Component-level change.
7.	Bearing changes.	No	No	No	Component-level change.
8.	New blade designs with similar material that can be retrofitted.	No	No	No	Component-level change.
9.	Fan blade redesign that can be retrofitted.	No	No	No	Component-level change.
10.	Oil tank redesign.	No	No	No	Component-level change.
11.	Change from one hydromechanical control to another hydromechanical control.	No	No	No	Component-level change.
12.	Change to limits on life-limited components supported by data that became available after certification.	No	No	No	Extending or reducing the life limits. For example, extending life limits based on credits from service experience or new fatigue data.
13.	Changes to limits on exhaust gas temperature.	No	No	No	
14.	Changes to the Airworthiness Limitations section with no configuration changes.	No	No	No	—
15.	Bump ratings within the product's physical capabilities that may be enhanced with gas path changes, such as blade re-staggering, cooling hole patterns, blade coating changes, etc.	No	No	No	—
			Piston Engines		
16.	New or redesigned cylinder head, valves, or pistons.	No	No	No	—
17.	Changes to crankshaft.	No	No	No	Component-level change.
18.	Changes to crankcase.	No	No	No	Component-level change.
19.	Changes to carburettor.	No	No	No	Component-level change.
20.	Changes to mechanical fuel injection system.	No	No	No	

Table A-12. Examples of Not Significant Changes for Engines (CS-E)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
21.	Changes to mechanical fuel injection pump.	No	No	No	Component-level change.
22.	Engine model change to accommodate new aircraft installation. No change to principles of operation of major subsystems; no significant expansion in power or operating envelopes or in limitations.	No	No	No	—
23.	A simple mechanical change, or a change that does not affect the basic principles of operation. For example, change from dual magneto to two single magnetos on a model.	No	No	No	—
24.	Subsystem change produces no changes to base engine input parameters, and previous analysis can be reliably extended. For example, a change to turbocharger where induction system inlet conditions remain unchanged, or if changed, the effects can be reliably extrapolated.	No	No	No	—
25.	Change to material of secondary structure or not highly loaded component. For example, a change from metal to composite material in a non-highly loaded component, such as an oil pan that is not used as a mount pad.	No	No	No	Component-level change.

Table A-12. Examples of Not Significant Changes for Engines (CS-E)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
26.	Change to material that retains the physical properties and mechanics of load transfer. For example, a change to trace elements in a metal casting for ease of pouring or to update to a newer or more readily available alloy with similar mechanical properties.	No	No	No	Component-level change.

A.5 Examples of Substantial, Significant, and Not Significant Changes for Propellers (CS-P).

A.5.1 Table A-13 contains an example of a change that is 'substantial' for propellers (CS-P).

Table A-13. Example of a Substantial Change for Propellers (CS-P)

Example	Description of Change	Notes
1.	Change to the number of blades.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

A.5.2 Table A-14 contains examples of changes that are 'significant' for propellers (CS-P).

Table A-14. Examples of Significant Changes for Propellers (CS-P)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Principle of pitch change, such as a change from single acting to dual acting.	Yes	Yes	Yes	Requires extensive modification of the pitch change system with the introduction of backup systems. The inherent control system requires re-evaluation.
2.	Introduction of a different principle of blade retention, such as a single row to a dual row bearing.	Yes	Yes	No	Requires extensive modification of the propeller hub and blade structure. The inherent strength requires re-evaluation.
3.	A hub configuration change, such as a split hub to a one-piece hub.	Yes	Yes	No	Requires extensive modification of the propeller hub structure. The inherent strength requires re-evaluation.

Table A-14. Examples of Significant Changes for Propellers (CS-P)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
4.	Changing the method of mounting the propeller to the engine, such as a spline to a flange mount.	Yes	Yes	No	Requires extensive modification of the propeller hub structure. The inherent strength requires re-evaluation.
5.	Change to hub material from steel to aluminium.	Yes	Yes	No	Requires extensive modification of the propeller hub structure and change to method of blade retention. The inherent strength requires re-evaluation.
6.	Change to blade material from metal to composite.	Yes	Yes	Yes	Requires extensive modification of the propeller blade structure and change to method of blade retention. Composite construction methods required. The inherent strength requires re-evaluation.
7.	Change from hydromechanical to electronic control.	Yes	Yes	Yes	Electronic manufacturing and design methods required. Assumptions used for certification are no longer valid or not addressed in the original certification, i.e. HIRF and lightning protection, fault tolerance, software certification, and other aspects.

A.5.3 Table A-15 contains examples of changes that are ‘not significant’ for propellers (CS-P).

Table A-15. Examples of Not Significant Changes for Propellers (CS-P)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Change to the material of a blade bearing.	No	No	No	Component-level change.
2.	Change to a component in the control system.	No	No	No	Component-level change.
3.	Change to a propeller de-icer boot.	No	No	No	Component-level change.
4.	Changes to the operational design envelope, such as increase in power.	No	No	No	Propeller’s operating characteristics and inherent strength require re-evaluation.

Table A-15. Examples of Not Significant Changes for Propellers (CS-P)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
5.	Change to the intended usage, such as normal to acrobatic category.	No	No	No	Propeller's operating characteristics and inherent strength require re-evaluation.

Appendix B to GM 21.A.101 Application charts for changed product rule

ED Decision 2017/024/R

Table A-16. Application Chart for 21.A.101(a) and (b) and 21.A.19

<table>
<tr><th>Substantial
(21.A.19)</th><th colspan="3">Significant
(21.A.101(a) and (b))</th><th colspan="2">Not Significant
(21.A.101)(b)(1))</th></tr>
<tr><td rowspan="3">Substantially changed product
Compliance with all latest CSs required for product certification.
Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td colspan="3">Affected area
(Changed and/or affected areas)
New demonstration of compliance is required
Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td rowspan="3">Unaffected area
No new demonstration of compliance is required.
Unaffected area continues to comply with the existing certification basis.</td><td rowspan="3">Affected area
(Changed and/or affected areas) New demonstration of compliance is required. The applicant may propose a certification basis using an earlier amendment but not earlier than in the existing TC basis. Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td rowspan="3">Unaffected area
No new demonstration of compliance is required.
Unaffected area continues to comply with the existing certification basis.</td></tr>
<tr><td colspan="2">Compliance with the latest amendment materially contributes to safety</td><td>No material contribution to safety</td></tr>
<tr><td>Practical
—</td><td>Impractical
The applicant may propose a certification basis using earlier CS(s), but not earlier than the existing TC basis.</td><td>The applicant may propose a certification basis using earlier CS(s), but not earlier than the existing TC basis.</td></tr>
<tr><td colspan="6">Certification Basis Proposed by the Applicant</td></tr>
<tr><td colspan="2">New certification basis using latest CSs.</td><td colspan="2">CSs at earlier amendments with supporting rationale.</td><td>Existing certification basis.</td><td>Existing certification basis including ‘elects to comply’.</td><td>Existing certification basis.</td></tr>
<tr><td colspan="6">EASA Resultant Type-Certification Basis</td></tr>
<tr><td colspan="2">New certification basis using the latest CSs, and special conditions if required.</td><td colspan="2">New certification basis using the CSs at earlier approved amendments, and special conditions if required.</td><td>Existing certification basis.</td><td>Existing certification basis (if adequate); if not, first appropriate later amendment(s) and/or special conditions including ‘elects to comply’.</td><td>Existing certification basis.</td></tr>
</table>

Table A-17. Application Chart for 21.A.101(c) Excepted Products

<table>
<tr><td colspan="4">Affected area
(Changed areas and/or unchanged but affected)
New demonstration of compliance is required.
Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td>Unaffected area
No new demonstration of compliance is required.
Unaffected area continues to be compliant with the existing TC basis.</td></tr>
<tr><td colspan="5">Type-Certification Basis Proposed by the Applicant</td></tr>
<tr><td colspan="4">The existing TC basis, including ‘elects to comply’.</td><td>The existing TC basis.</td></tr>
<tr><td colspan="3">Found by EASA to be ‘significant in an area’.</td><td>Not ‘significant in an area’.</td><td rowspan="3"></td></tr>
<tr><td colspan="2">Compliance with a later amendment materially contributes to safety.</td><td rowspan="2">No material contribution to safety.</td><td rowspan="2"></td></tr>
<tr><td>Practical</td><td>Impractical</td></tr>
<tr><td colspan="5">EASA Resultant Type-Certification Basis</td></tr>
<tr><td>The latest amendment designated by EASA including special conditions and including ‘elects to comply’.</td><td colspan="3">The existing TC basis. If inadequate, the first appropriate later amendment. If not appropriate, add special conditions, including ‘elects to comply’.</td><td>The existing TC basis.</td></tr>
</table>

Appendix C to GM 21.A.101 A method to determine the changed and affected areas

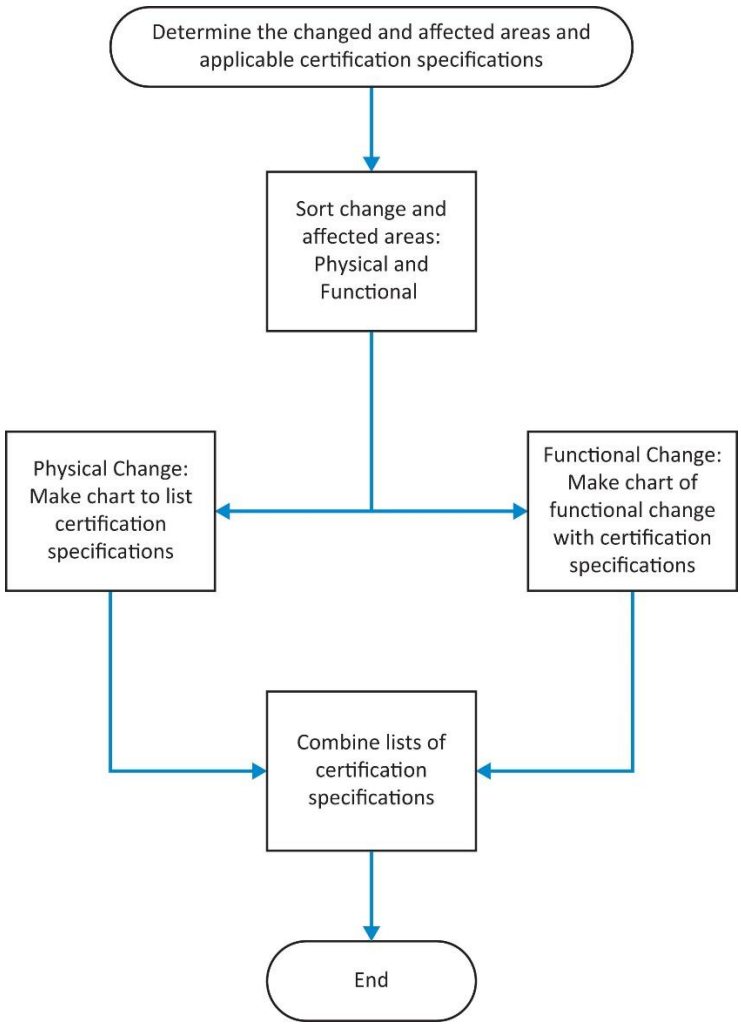
ED Decision 2017/024/R

C.1 Overview.

C.1.1 When a product is changed, some areas may change physically, while others may change functionally. EASA refers to this combination as changed and affected areas. For example, an extension to the wing of a fixed-wing aircraft would physically change the wing tip and likely other wing structure. Some areas of the airframe may have sufficient strength for the increase in load and would change functionally, i.e. they would carry greater load, but they would not change physically. These areas have associated certification specifications, which become part of the certification basis for the change.

C.1.2 Figure C-1 below provides an overview of one method that applicants may use to determine the changed and affected areas and the applicable certification specifications.

Figure C-1. Method to Determine the Changed and Affected Areas



C.2 Physical Changes.

C.2.1 Steps.

- Step 1. Make a list of the physical changes.
- Step 2. List the corresponding certification specifications applicable to the physical changes.
- Step 3. List the amendment level recorded on the existing certification basis of the baseline product and the amendments on the date of application.

C.2.2 Example.

The change is adding a winglet to a fixed-wing aircraft and a change to the leading-edge slats for a performance increase. As part of the change, an electrically driven slat actuator is modified by changing the mounting structure of the actuator used to connect the actuator to the slat. The actuator structure is changed. The electrical system in the actuator is not affected. The applicant would list certification specifications applicable to the actuator. The applicant would not list the certification specifications applicable to the electrical system of the actuator. See Table C-1 below for an example of how to chart a physical change and the associated certification specifications.

Table C-1. Example of Associating a Physical Change with the Applicable Certification Specifications

Physical Change	Applicable Certification Specifications*	Amendment of Existing Certification Basis	Amendment on Application Date
Structural change to slat actuator	25.xxx	25-aaa	25-ddd
	25.yyy	25-bbb	25-eee
	25.zzz	25-ccc	25-fff

* These would be certification specifications related to structural aspects only.

C.3 Functional Changes.

C.3.1 Steps.

- Step 1. Describe each change.
- Step 2. Describe the effects of the change (e.g. structural, performance, electrical, etc.).
- Step 3. List the areas, systems, parts, and appliances that are affected by those effects.
- Step 4. List the certification specifications associated with the effects for each area, system, part, or appliance.
- Step 5. List the amendment level recorded on the existing certification basis of the baseline product and the amendments on the date of application.

C.3.2 Example.

The change is adding a winglet to a fixed-wing aircraft and a change to the leading-edge slats for a performance increase. The wing root bending moment has increased. The loads in the wing box are increased but the wing box has sufficient structural margins to carry the higher loads. Thus, the wing box is not physically changed but its function has changed because it carries greater loads. See Table C-2 below for an example of how to chart a functional change, its effects, and the affected areas (steps 1 through 3 above). See Table C-3 below for an example of how to chart an area affected by a functional change and the associated certification specifications (steps 4 and 5 above).

Table C-2. Example of a Functional Change, Affected Areas, and Associated Effects

Description of Change	Effects	Affected Areas
Installation of winglet	Increased loads in wing structure	Wing spars
		Wing skins
	Effect 2*	Area 1
		Area 2
	Effect 3*	Area 3

* There may be other effects as well.

Table C-3. Example of Associating Affected Areas with the Applicable Certification Specifications

Impacted Area	Applicable Certification Specifications*	Amendment of Existing Certification Basis	Amendment on Application Date
Wing spar	25.xxx	25-aaa	25-ddd
	25.yyy	25-bbb	25-eee
	25.zzz	25-ccc	25-fff

* These would be structural certification specifications only. There could be other certification specifications applicable to the wing box. But since the effect is structural, then only the structural certification specifications are applicable.

C.4 Combine the Lists.

C.4.1 EASA typically presents the certification basis for a product by certification specification and not by area. The next step is to combine these two lists. However, since only a portion of the product is being changed, the changed and affected areas of the new certification basis need to be identified. The unchanged area is not required to comply with the certification specifications in effect at the date of application. (See point 21.A.101(b)(2))

C.4.2 When the change is quite extensive, applicants will save time by listing all the certification specifications applicable to the category of product they are certifying. They can use Table C-4 below in the next step where they will identify any other exceptions that they would like EASA to consider.

C.4.3 Example. If we use the examples above for the combined list for the actuator structural changes and the wing box functional change, then the certification basis would be listed as shown in Table C-4 below.

Table C-4. Example of a Combined List of Physical and Functional Changes with Applicable Certification Specifications

Certification Specification	Amendment Levels		Changed and Affected Area
	Amendment of Existing Certification Basis	Amendment on Application Date	
25.xxx*	25-aaa	25-ddd	- Wing spar - Leading-edge actuator - Wing loads
25.yyy*	25-bbb	25-eee	
25.zzz*	25-ccc	25-fff	

* These represent structural certification specifications.

Appendix D to GM 21.A.101 Other guidance for affected areas

ED Decision 2017/024/R

D.1 Sample Questions in Determining Affected Areas.

Below are sample questions to assist in determining whether an area is affected by the change. If the answer to any of these questions is yes, then the area is considered to be affected.

1. Is the area changed from the identified baseline product?
2. Is the area impacted by a significant product-level change?
3. Is there a functional effect on the unchanged area by a change to the system or system function that it is a part of?
4. Does the unchanged area need to comply with a system or product-level certification specification that is part of the change?
5. Are the product-level characteristics affected by the change?
6. Is the existing compliance for the area invalidated?

D.2 Sub-Areas within an Affected Area.

Within areas affected by a change, there may be 'sub-areas' of the area that are not affected. For those sub-areas, the amendment levels at the existing certification basis remain valid, along with the previous compliance findings. For example, if a passenger seat fitting is changed as part of a significant change, then the structure of the seat is affected. Thus, the amendment level for CS 25.561 and CS 25.562, along with other applicable structural certification specifications, would be at the amendment level on the date of application (unless an exception is granted). However, the seat fabric is not affected, so the amendment level for CS 25.853 (flammability) may remain at the existing certification basis, and a new compliance finding would not be required.

Appendix E to GM 21.A.101 Procedure for evaluating material contribution to safety or impracticality of applying latest certification specifications to a changed product

ED Decision 2019/018/R

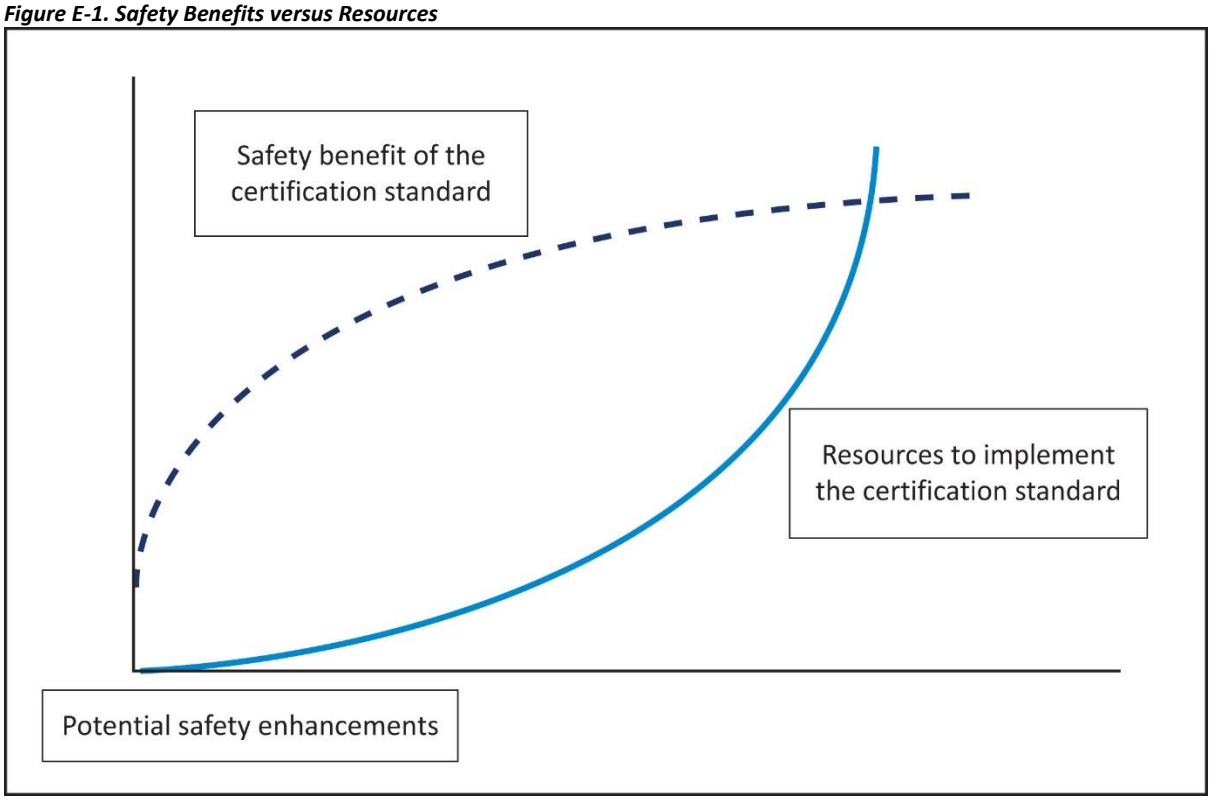
E.1 Introduction.

E.1.1 The basic principle of enhancing the level of safety of changed aeronautical products is to apply the latest certification specifications for significant changes to the greatest extent practical. In certain cases, the cost of complying fully with a later certification specification may not be commensurate with the small safety benefit achieved. These factors form the basis where compliance with the latest standard may be considered impractical, thereby allowing compliance with an earlier certification specification. This Appendix gives one method of determining whether compliance with a later certification specification is impractical; however, it does not preclude the use of other methods for improving the safety of aeronautical products.

E.1.2 EASA recognises that other procedures can be used and have historically been accepted on a case-by-case basis. The acceptance of results through the use of these procedures may vary from state to state. Consequently, they may not be accepted through all bilateral certification processes. Regardless of which method is used, the process must show that a proposed certification basis is able to achieve a positive safety benefit for the overall product.

E.1.3 Regarding impracticality, any method used must encourage the incorporation of safety enhancements that will have the most dramatic impact on the level of safety of the aircraft while considering the effective use of resources. This important point is illustrated graphically in Figure E-1 below. This Figure notionally shows the interrelation between the total resources required for incorporating each potential safety enhancement with the corresponding net increase in safety benefit.

Figure E-1. Safety Benefits versus Resources



E.1.4 Typically, it is found that, for impractical certification basis changes, there are proposals that can achieve a positive safety benefit that are resource-effective. Conversely, there are proposals that may achieve a small safety benefit at the expense of a large amount of resources to implement them. Clearly, there will be a point where a large percentage of the potential safety benefit can be achieved with a reasonable expenditure of resources. The focus of the methods used should be to determine the most appropriate certification standards relative to the respective incremental cost to reach this point.

E.1.5 This Appendix provides procedural guidance for determining the material contribution to the level of safety, or the practicality of applying a certification standard at a particular amendment level to a changed product. The procedure is generic in nature and describes the steps and necessary inputs that may be used on any project to develop a position.

E.1.6 The procedure is intended to be used, along with good engineering judgment, to evaluate the relative merits of a changed product complying with the latest certification standards. It provides a means, but not the only means, for applicants to present their position regarding an exception under point 21.A.101(b)(3).

E.1.7 The certification basis for a change to a product will not be at an amendment level earlier than the existing certification basis.

E.2 Procedure for evaluating the material contribution or impracticality of applying the latest certification specifications to a changed product.

The following are steps to determine the material contribution or impracticality of applying a certification specification at a particular amendment level.

E.2.1 Step 1: Identify the regulatory change being evaluated.

In this step, applicants should document:

E.2.1.1 The specific standard (e.g. CS 25.365),

E.2.1.2 The amendment level of the existing certification basis for the standards, and

E.2.1.3 The latest amendment level of the certification specification.

E.2.2 Step 2: Identify the specific hazard that the certification specification addresses.

E.2.2.1 Each certification specification and its subsequent amendments addresses a hazard or hazards. In this step, the specific hazard(s) is (are) identified. This identification will allow for a comparison of the effectiveness of the amendment levels of the certification specification in addressing the hazard.

E.2.2.2 In many cases, the hazard and the cause of the hazard will be obvious. When the hazard and its related cause are not immediately obvious, it may be necessary to review the explanatory note (EN) and/or the impact assessment (IA) in the ED Decision by which the certification specification or its amendment was adopted. It may also be helpful to discuss the hazard with the responsible EASA team.

E.2.3 Step 3: Review the consequences of the hazard(s).

E.2.3.1 Once the hazard is identified, it is possible to identify the types of consequences that may occur due to the hazard. More than one consequence can be attributed to the same hazard. Typical examples of consequences would include but are not limited to:

— incidents where only injuries occurred,

— accidents where a total hull loss occurred,

— accidents where less than 10 per cent of the passengers died,

— accidents where 10 per cent or more passengers died, and

— engine- and propeller-specific hazards.

E.2.3.2 The explanatory note (EN) and/or the impact assessment (IA) in the ED Decision may provide useful information regarding the consequences of the hazard that the certification specification addresses.

E.2.4 Step 4: Identify the historical and predicted frequency of each consequence.

E.2.4.1 Another source for determining impracticality is the historical record of the consequences of the hazard that led to a certification specification or an amendment to a certification specification. From these data, a frequency of occurrence for the hazard can be determined. It is important to recognise that the frequency of occurrence may be higher or lower in the future. Therefore, it also is necessary to predict the frequency of future occurrences.

E.2.4.2 More than one consequence can be attributed to the same hazard. Therefore, when applicable, the combination of consequences and frequencies of those consequences should be considered together.

E.2.4.3 The explanatory note (EN) and/or the impact assessment (IA) in the ED Decision may provide useful information regarding the frequency of an occurrence.

E.2.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specification would be in addressing the hazard.

E.2.5.1 When each amendment is issued, it is usually expected that compliance with the certification specification would be completely effective in addressing the associated hazard for the designs and technology envisioned at the time. It is expected that the hazard would be eliminated, avoided, or mitigated. However, experience has shown that this may not always be the case. It is also possible that earlier amendment levels may have addressed the hazard but were not completely effective. A product may also contain a design feature(s) that provides a level of safety that approaches that of the latest certification specifications, yet is not fully compliant with the latest certification specifications. Therefore, in comparing the benefits of compliance with the existing certification basis to the latest amendment level, it is useful to estimate the effectiveness of both amendment levels in dealing with the hazard.

E.2.5.2 It is recognised that the determination of levels of effectiveness is normally of a subjective nature. Therefore, prudence should be exercised when making these determinations. In all cases, it is necessary to document the assumptions and data that support the determination.

E.2.5.3 The following five levels of effectiveness are provided as a guideline:

1. Fully effective in all cases. Compliance with the certification specification eliminates the hazard or provides a means to avoid the hazard completely.

2. Considerable potential for eliminating or avoiding the hazard. Compliance with the certification specification eliminates the hazard or provides a means to completely avoid the hazard for all probable or likely cases, but it does not cover all situations or scenarios.

3. Adequately mitigates the hazard. Compliance with the certification specification eliminates the hazard or provides a means to avoid the hazard completely in many cases. However, the hazard is not eliminated or avoided in all probable or likely cases. Usually this action only addresses a significant part of a larger or broader hazard.

4. Hazard only partly addressed. In some cases, compliance with the certification specification partly eliminates the hazard or does not completely avoid the hazard. The hazard is not eliminated or avoided in all probable or likely cases. Usually this action only addresses part of a hazard.

5. Hazard only partly addressed but action has a negative side effect. Compliance with the certification specification does not eliminate or avoid the hazard or may have negative safety side effects. The action is of questionable benefit.

E.2.5.4 If it is determined that compliance with the latest certification specifications does not contribute materially to the product's level of safety, applicants should skip Step 6 of this Appendix and go directly to Step 7 to document the conclusion. If it is determined that complying with the latest amendment of the certification specification contributes materially to the product's level of safety, applicants should continue to Step 6 of this Appendix.

E.2.6 Step 6: Determine the incremental resource costs and cost avoidance.

E.2.6.1 There is always cost associated with complying with a certification specification. This cost may range from minimal administrative efforts to the resource expenditures that support full-scale testing or the redesign of a large portion of an aircraft. However, there are also potential cost savings from compliance with a certification specification. For example, compliance with a certification specification may avoid aircraft damage or accidents and the associated costs to the manufacturer for investigating accidents. Compliance with the latest amendment of a certification specification may also help a foreign authority to certify a product.

E.2.6.2 When determining the impracticality of applying a certification specification at the latest amendment level, only the incremental costs and safety benefits from complying with the existing certification basis should be considered.

E.2.6.3 When evaluating the incremental cost, it may be beneficial for applicants to compare the increase in cost of complying with the latest certification specifications with the cost of incorporating the same design feature in a new aircraft. In many cases, an estimate for the cost of incorporation in a new aircraft is provided by EASA in the regulatory impact assessment, which was presented when the corresponding certification specification was first issued. Incremental costs of retrofit/incorporation on existing designs may be higher than that for production. Examples of costs may include but are not limited to the following:

Costs

The accuracies of fleet size projections, utilisation, etc., may be different from those experienced for derived product designs and must be validated.

— Labour: work carried out in the design, fabrication, inspection, operation, or maintenance of a product for the purpose of incorporating or demonstrating compliance with a proposed action. Non-recurring labour certification specifications, including training, for the applicant supporting development and production of the product, should be considered.

— Capital: construction of new, modified, or temporary facilities for design, production, tooling, training, or maintenance.

— Material: costs associated with product materials, product components, inventory, kits, and spares.

— Operating costs: costs associated with fuel, oil, fees, training, and expendables.

— Revenue/utility loss: costs resulting from earning/usage capability reductions from departure delays, product downtime, and performance loss due to seats, cargo, range, or airport restrictions.

— The cost of changing compliance documentation and/or drawings in itself is not an acceptable reason for an exception.

Cost Avoidance.

— Avoiding costs of accidents, including investigation of accidents, lawsuits, public relations activities, insurance, and lost revenue.

— Foreign certification: conducting a single effort that would demonstrate compliance with the certification specifications of most certifying authorities, thus minimising certification costs.

E.2.7 Step 7: Document the conclusion.

With the information from the previous steps documented and reviewed, the applicant's position and rationale regarding whether complying with the latest certification specifications contributes materially to the product's level of safety or its practicality can be documented. EASA records the determination of whether the conditions for the proposed exception were met. That determination is based on the information and analysis provided by the applicant in the preceding steps. If the determination to grant the exception is based on the product's design features, those features are documented at a high level in the TCDS. Documentation in the TCDS is required so that the features are maintained during subsequent changes to the product, therefore, maintaining the product's agreed level of safety. If the results of this analysis are inconclusive, then further discussions with EASA are warranted.

E.3 Examples of how to certify changed aircraft.

The following examples illustrate the typical process an applicant follows. The process will be the same for all product types.

E.3.1 Example 1: FAR § 25.963, Fuel Tank Access Covers.

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

This example is part of a significant change to a transport aeroplane that increases the passenger payload and gross weight by extending the fuselage by 20 feet (6.1 metres). To accommodate the higher design weights and increased braking requirements and to reduce the runway loading, the applicant will change the landing gear from a two-wheel to four-wheel configuration; this changes the debris scatter on the wing from the landing gear. EASA will require the new model of the aeroplane to comply with the latest applicable certification specifications based on the date of application.

The wing will be strengthened locally at the side of the body and at the attachment points of the engines and the landing gear, but the applicant would not like to alter the wing access panels and the fuel tank access covers. Although the applicant recognises that the scatter pattern and impact loading on the wing from debris thrown from the landing gear will change, the applicant proposes that it would be impractical to redesign the fuel tank access covers.

Note: Points 21.B.107(a)(3) or 21.B.111(a)(3) may be an additional reason why EASA would require compliance with CS 25.963(e), regardless of the 'significant' determination.

E.3.1.1 Step 1: Identify the regulatory change being evaluated.

The existing certification basis of the aeroplane that is being changed is Part 25 prior to Amendment 25-69. Amendment 25-69 added the requirement that fuel tank access covers on transport category aeroplanes be designed to minimise penetration by likely foreign objects, and that they be fire-resistant.

E.3.1.2 Step 2: Identify the specific hazard that the certification specification addresses.

Fuel tank access covers have failed in service due to impact with high-energy objects, such as failed tire tread material and engine debris following engine failures. In one accident, debris from the runway impacted a fuel tank access cover, causing its failure and subsequent fire, which resulted in fatalities and loss of the aeroplane. Amendment 25-69 will ensure that all access covers on all fuel tanks are designed or located to minimise penetration by likely foreign objects, and that they are fire-resistant.

E.3.1.3 Step 3: Review the history of the consequences of the hazard(s).

There have been occurrences with injuries and with more than 10 per cent deaths.

E.3.1.4 Step 4: Identify the historical and predicted frequency of each consequence.

In 200 million departures of large jets, there was:

— 1 occurrence with more than 10 per cent deaths, and

— 1 occurrence with injuries.

There is no reason to believe that the future rate of accidents will be significantly different from the historical record.

E.3.1.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specifications would be in addressing the hazard.

There is considerable potential for eliminating or avoiding the hazard. Compliance with Amendment 25-69 eliminates the hazard or provides a means to avoid the hazard completely for all probable or likely cases. However, it does not cover all situations or scenarios.

E.3.1.6 Step 6: Determine resource costs and cost avoidance.

Costs.

— For a newly developed aeroplane, there would be minor increases in labour resulting from design and fabrication of new fuel tank access covers.

— There would be a negligible increase in costs related to materials, operating costs, and revenue utility loss.

Cost avoidance.

— There were 2 accidents in 200 million departures. The applicant believes that it will manufacture more than 2 000 of these aeroplanes. These aeroplanes would average 5 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding lawsuits, accident investigations, and public relations costs.

— There are cost savings associated with meeting a single certification basis for EASA's and foreign standards.

E.3.1.7 Step 7: Document the conclusion.

It is concluded that compliance with the latest certification specification increases the level of safety at a minimal cost to the applicant. Based on the arguments and information presented by the applicant through the certification review item (CRI) process, EASA determined that meeting the latest amendment would be practical. EASA has also found that fuel tank access covers that are not impact-resistant and fire-resistant, and which are located where a strike is likely, are unsafe features or characteristics which preclude the issue of a type certificate under 21.B.107(a)(3).

E.3.2 Example 2: FAR § 25.365, Pressurized Compartment Loads.

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

This example is a passenger-to-freighter conversion STC. This change affects the floor loads on the aeroplane as well as the decompression venting.

E.3.2.1 Step 1: Identify the regulatory change being evaluated.

The existing certification basis of the aeroplane that is being changed includes § 25.365 at Amendment 25-00. The initial release of § 25.365 required the interior structure of passenger compartments to be designed to withstand the effects of a sudden release of pressure through an opening resulting from the failure or penetration of an external door, window, or windshield panel, or from structural fatigue or penetration of the fuselage, unless shown to be extremely remote.

Amendment 25-54 revised § 25.365 to require the interior structure to be designed for an opening resulting from penetration by a portion of an engine, an opening in any compartment of a size defined by § 25.365(e)(2), or the maximum opening caused by a

failure that was not shown to be extremely improbable. The most significant change is the 'formula hole size' requirement introduced into § 25.365(e)(2) at Amendment 25-54.

Amendment 25-71/72 (Amendments 25-71 and 25-72 are identical) extended the regulation to all pressurised compartments, not just passenger compartments, and to the pressurisation of unpressurised areas. Pressurisation of unpressurised areas had previously been identified as an unsafe feature under § 21.B.111(a)(3).

Amendment 25-87 redefined the pressure differential load factor that applies above an altitude of 45 000 feet. Compliance with Amendment 25-87 is not affected since the aeroplane does not operate above an altitude of 45 000 feet. The applicant proposes to meet the 'pressurisation into unpressurised areas' requirement introduced in Amendment 25-71/72. The applicant does not propose to comply with the 'formula hole size' requirement introduced in § 25.365(e)(2) at Amendment 25-54.

E.3.2.2 Step 2: Identify the specific hazard that the certification specification addresses.

The hazard is a catastrophic structure and/or system failure produced by a sudden release of pressure through an opening in any compartment in flight. This opening could be caused by an uncontained engine failure, an opening of a prescribed size due to the inadvertent opening of an external door in flight, or an opening caused by a failure not shown to be extremely improbable. The opening could be caused by an event that has yet to be identified.

E.3.2.3 Step 3: Review the history of the consequences of the hazard(s).

There have been occurrences with injuries, with less than 10 per cent deaths and with more than 10 per cent deaths.

E.3.2.4 Step 4: Identify the historical and predicted frequency of each consequence.

In 200 million departures of large jets, there were:

— 2 occurrences with more than 10 per cent deaths,

— 1 occurrence with less than 10 per cent deaths, and

— 1 occurrence with injuries.

There is no reason to believe that the future rate of accidents will be significantly different from the historical record.

E.3.2.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specifications would be at addressing the hazard.

Compliance with the latest amendment eliminates the hazard or provides a means to avoid the hazard completely.

Design changes made to the proposed aeroplane bring it closer to full compliance with § 25.365 at Amendment 25-54. The original aeroplane was shown to meet the requirements for a hole size of 1.1 square feet. Amendment 25-54 would require a hole size of 5.74 square feet, and the current reinforcements for the converted aeroplane can sustain a hole size of 3.65 square feet in the forward area and 2.65 square feet at the aft area. This is 3.1 and 2.4 times, respectively, better than the original design condition of Amendment 25-0 and is a significant improvement over the worldwide passenger fleet in service.

E.3.2.6 Step 6: Determine resource costs and cost avoidance.

Costs.

There would be savings in both labour and capital costs if compliance were shown to Amendment 25-0 instead of Amendment 25-54. Major modifications to the floor beams would be necessary to meet the 'formula hole size' requirement in Amendment 25-54.

Cost avoidance.

There were 4 accidents in 200 million departures. The applicant believes that it will manufacture more than 2 000 of these aeroplanes. These aeroplanes would average 2 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding lawsuits, accident investigations, and public relations costs.

There are cost savings associated with meeting a single certification basis for FAA and foreign regulations.

E.3.2.7 Step 7: Document the conclusion regarding practicality.

The design complies with § 25.365 at Amendments 25-0, 25-71/72, and 25-87, and it is nearly in full compliance with Amendment 25-54. The design would adequately address the hazard at an acceptable cost. Therefore, based on arguments of impracticality discussed in an issue paper, the FAA accepts the applicant's proposal to comply with § 25.365 at Amendment 25-0.

E.3.3 Example 3: FAR § 25.981, Fuel Tank Ignition Prevention.

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

This example is part of a significant change to a transport aeroplane that increases passenger payload and gross weight by extending the fuselage by 20 feet (6.1 metres). To accommodate the longer fuselage, the applicant will modify systems wiring installations; this includes changing fuel tank system wiring. The new model of the aeroplane will be required to comply with the latest applicable certification specifications based on the date of application.

E.3.3.1 Step 1: Identify the regulatory change being evaluated.

The existing certification basis of the aeroplane that is being changed is Part 25 prior to Amendment 25-102 but includes Amendment 25-40.

Note: If the original certification basis does not include Amendment 25-40, the certification basis should be considered not adequate for fuel tank ignition prevention.

The 2001 Fuel Tank Safety (FTS) rule adopted Amendment 25-102 to add explicit requirements in § 25.981(a)(3) for demonstrating that the design precludes fuel tank ignition sources. This was required, but had in several cases not been properly applied in demonstrating compliance with §§ 25.901 and 25.1309. Amendment 25-102, § 25.981(b), added a requirement to develop fuel tank system airworthiness limitations to maintain the ignition prevention features of the design. Section H25.4, Amendment 25-102, requires the inclusion of those fuel tank system airworthiness limitations in the Airworthiness Limitations section of the Instructions for Continued Airworthiness (ICA).

Since the FAA policy for performing the failure analysis to demonstrate compliance with §§ 25.901 and 25.1309 at Amendment 25-40 and 25-46 was adopted in the explicit fuel

tank ignition prevention failure analysis requirements of § 25.981(a)(3), the incremental requirement for demonstrating compliance with the ignition prevention requirements of Amendment 25-102 is to develop and implement the fuel tank system airworthiness limitations instead of developing Certification Maintenance Requirements in accordance with § 25.901(b)(2) at Amendments 25-40 through 25-46 and AC 25-19A.

E.3.3.2 Step 2: Identify the specific hazard that the certification specification addresses.

The FAA issued the 2001 FTS rule to preclude fuel tank ignition sources because of a history of fuel tank explosions. The catastrophic TWA Flight 800 in-flight fuel tank explosion on July 17, 1996, caused the death of all 230 people on board.

E.3.3.3 Step 3: Review the history of the consequences of the hazard(s).

There have been occurrences with injuries, with more than 10 per cent deaths, less than 10 per cent deaths, and no deaths.

E.3.3.4 Step 4: Identify the historical and predicted frequency of each consequence.

The 1998 Aviation Rulemaking Advisory Committee Fuel Tank Harmonisation Working Group report documented the number of historical fuel tank explosions as 16, which caused a total of 539 fatalities.

There have been 2 additional fuel tank explosions since that report was issued:

— March 3, 2001: Thai Airways International Flight 114 experienced a fuel tank explosion on the ground that caused 1 fatality and 3 serious injuries. The explosion and subsequent fire destroyed the aeroplane.

— May 4, 2006: A Malaysia Airlines Boeing 727 experienced a wing tank low pressure explosion during ground operations. There was no fire and no injuries. The wing structure suffered significant damage.

There is no reason to believe that the future rate of accidents will be significantly different from the historical record if fuel tank system airworthiness limitations are not included in the ICA as is permitted in earlier amendment levels.

E.3.3.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specifications would be at addressing the hazard.

There is considerable potential for eliminating or avoiding the hazard.

In the 2008 Fuel Tank Flammability Reduction (FTFR) rule, the FAA estimated that compliance with the ignition prevention requirements of Amendment 25-102, together with the fuel tank ignition prevention airworthiness directives issued as a result of the Special Federal Aviation Regulation number 88 reviews, resulted in the range of effectiveness in preventing fuel tank explosions between 25 to 75 per cent with a median value of 50 per cent (73 FR 42449).

E.3.3.6 Step 6: Determine resource costs and cost avoidance.

Costs.

— For newly developed designs, there would be minor increases in costs resulting from the identification and implementation of fuel tank system airworthiness limitations.

— There would be no increase in costs related to materials, operating costs, and revenue utility loss.

Cost avoidance.

There were 18 accidents in 200 million departures. The applicant believes that it will manufacture more than 2 000 of these aeroplanes or derivatives of these aeroplanes. These aeroplanes would average 5 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding fatalities and injuries.

E.3.3.7 Step 7: Document the conclusion.

It is concluded that compliance with the latest certification specification increases the level of safety at a minimal cost to the applicant. Based on the arguments and information presented by the applicant through the issue paper process, the FAA determined that meeting the latest amendment would be practical.

The following is additional background on the specific hazard that the certification specification addresses:

As stated in the 2001 FTS rule under 'Changes to Part 25', § 25.981(a)(3) was adopted because the previous regulations (§§ 25.901 and 25.1309) were not always properly applied.

Section 25.901(b)(2), Amendments 25-40 through 46, requires in part preventative maintenance as necessary to ensure that components of the powerplant installation, which includes the fuel tank system, will safely perform their intended function between inspections and overhauls defined in the maintenance instructions. When demonstrating compliance with the requirements of § 25.901(b) for maintenance of fuel tank ignition prevention features, the policy has been that the applicant identify critical features as critical maintenance requirements using the guidance in AC 25-19A.

Appendix F to GM 21.A.101 The use of service experience in the exception process

ED Decision 2017/024/R

F.1 **Introduction.**

Service experience may support the application of an earlier certification specification pursuant to point 21.A.101(b)(3) if, in conjunction with the applicable service experience and other compliance measures, the earlier certification specification provides a level of safety comparable to that provided by the latest certification specification. The applicant must provide sufficient substantiation to allow EASA to make this determination. A statistical approach may be used, subject to the availability and relevance of data, but sound engineering judgment must be used. For service history to be acceptable, the data must be both sufficient and pertinent. The essentials of the process involve:

— A clear understanding of the certification specification change and the purpose for the change,

— A determination based on detailed knowledge of the proposed design feature,

— The availability of pertinent and sufficient service experience data, and

— A comprehensive review of that service experience data.

F.2 **Guidelines.**

The CRI process (either as a stand-alone CRI or included in the CRI A-01) would be used, and the applicant should provide documentation to support the following:

F.2.1 The identification of the differences between the certification specification in the existing basis and the certification specification as amended, and the effect of the change to the specification.

F.2.2 A description as to what aspect(s) of the latest certification specifications the proposed changed product would not meet.

F.2.3 Evidence showing that the proposed certification basis for the changed product, together with applicable service experience, relative to the hazard, provides a level of safety that approaches the latest certification specification, yet is not fully compliant with the latest certification specifications.

F.2.4 A description of the design feature and its intended function.

F.2.5 Data for the product pertinent to the requirement.

F.2.5.1 Service experience from such data sources, such as:

— Accident reports,

— Incident reports,

— Service bulletins,

— Airworthiness directives,

— Repairs,

— Modifications,

— Flight hours/cycles for fleet leader and total fleet,

— World airline accident summary data,

— Service difficulty reports,

— Accident Investigation Board reports, and

— Warranty, repair, and parts usage data.

F.2.5.2 Show that the data presented represent all relevant service experience for the product, including the results of any operator surveys, and is comprehensive enough to be representative.

F.2.5.3 Show that the service experience is relevant to the hazard.

F.2.5.4 Identification and evaluation of each of the main areas of concern with regard to:

— Recurring and/or common failure modes,

— Cause,

— Probability by qualitative reasoning, and

— Measures already taken and their effects.

F.2.5.5 Relevant data pertaining to aircraft of similar design and construction may be included.

F.2.5.6 Evaluation of failure modes and consequences through analytical processes. The analytical processes should be supported by:

— A review of previous test results,

— Additional detailed testing as required, or

— A review of aircraft functional hazard assessments (FHA) and any applicable system safety assessments (SSA) as required.

F.2.6 A conclusion that draws together the data and the rationale.

F.2.7 These guidelines are not intended to be limiting, either in setting the required minimum elements or in precluding alternative forms of submission. Each case may be different, based on the particulars of the system being examined and the requirement to be addressed.

F.3 **Example: 25.1141(f) for Transport Category Aeroplanes.**

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

F.3.1 The following example, for transport category aeroplanes (§ 25.1141(f), APU Fuel Valve Position Indication System), illustrates the typical process an applicant follows. The process will be the same for all product types.

F.3.2 This example comes from a derived model transport aeroplane where significant changes were made to the main airframe components, engines and systems, and APU. The baseline aeroplane has an extensive service history. The example shows how the use of service experience supports a finding that compliance with the latest certification specifications would not contribute materially to the level of safety and that application of the existing certification basis (or earlier amendment) would be appropriate. The example is for significant derived models of transport aeroplanes with extensive service history. It illustrates the process, following the guidelines in this Appendix, but does not include the level of detail normally required.

F.3.2.1 Determine the differences between the certification specifications applied in the original certification basis and the latest certification specification, and the effect of the change to the certification specifications. The original certification basis of the aeroplane that is being changed is the initial release of Part 25. Amendment 25-40 added requirement

§ 25.1141(f), which mandates that power-assisted valves must have a means to indicate to the flight crew when the valve is in the fully open or closed position, or is moving between these positions. The addressed hazard would be risk of APU fire due to fuel accumulation caused by excessive unsuccessful APU start attempts.

F.3.2.2 What aspect of the proposed changed product would not meet the latest certification specifications? The proposed APU fuel valve position indication system does not provide the flight crew with fuel valve position or transition indication and, therefore, does not comply with the requirements of § 25.1141(f).

F.3.2.3 The applicant provides evidence that the proposed certification basis for the changed product, together with applicable service experience of the existing design, provide a level of safety that approaches, yet is not fully compliant with, the latest certification specifications. The APU fuel shut-off valve and actuator are unchanged from those used on the current family of aeroplanes, and have been found to comply with the earlier Amendment 25-11 of § 25.1141. The existing fleet has achieved approximately (#) flights during which service experience of the existing design has been found to be acceptable. If one assumes a complete APU cycle, i.e. start-up and shutdown for each flight, the number of APU fuel shut-off valve operations would be over 108 cycles, which demonstrates that the valve successfully meets its intended function and complies with the intent of the certification specification.

F.3.2.4 The applicant provides a description of the design feature and its intended function. The fuel shut-off valve, actuator design, and operation is essentially unchanged with the system design ensuring that the valve is monitored for proper cycling from closed to open at start. If the valve is not in the appropriate position (i.e. closed), then the APU start is terminated, an indication is displayed on the flight deck, and any further APU starts are prevented. Design improvements using the capability of the APU electronic control unit (ECU) have been incorporated in this proposed product change. These design changes ensure that the fuel valve indication system will indicate failure of proper valve operation to the flight crew, and these features increase the level of functionality and safety, but the system does not indicate valve position as required by § 25.1141(f).

F.3.2.5 The FAA and the applicant record this in an issue paper. The FAA can use the G-1 or a technical issue paper for this purpose. An issue paper was coordinated, included data, or referenced reports documenting relevant service experience compiled from incident reports, fleet flight hour/cycle data, and maintenance records. The issue paper also discussed existing and proposed design details, failure modes, and analyses showing to what extent the proposed aeroplane complies with the latest amendment of § 25.1141. Information is presented to support the applicant's argument that compliance with the latest amendment would not materially increase the level of safety. Comparative data pertaining to aircraft of similar design and construction are also presented.

F.3.2.6 The conclusion, drawing together the data and rationale, is documented in the G-1 issue paper. The additional features incorporated in the APU fuel shut-off valve will provide a significant increase in safety to an existing design with satisfactory service experience. The applicant proposes that compliance with the latest amendment would not materially increase the level of safety and that compliance with § 25.1141 at Amendment 25-11 would provide an acceptable level of safety for the proposed product change.

Appendix G to GM 21.A.101 Changed product rule (CPR) decision record

ED Decision 2017/024/R

CHANGED PRODUCT RULE (CPR) DECISION RECORD		
TC/STC No: Click here to enter text.	**Project Number:** Click here to enter text.	
Step 1: Identify the proposed type design changes to the aeronautical product. (See paragraph 3.2 of GM 21.A.101)	The proposed type design changes are identified here or in the following document(s): Click here to enter text.	
Note: The CRI process is used to track/document the decisions at Step 2 and Steps 5 through 8 as required.		
Step 2: Is the proposed type design change substantial? (See paragraph 3.3 of GM 21.A.101)	☐ Yes	**New Type Certificate:** Proceed to point 21.A.19. Point 21.A.101 does not apply. A Certification Review Item CRI A-01 will be used to establish and document the certification basis.
	☐ No	**Proceed to Step 3.**
Step 3: Will you use the latest standards? (See paragraph 3.4 of GM 21.A.101)	☐ Yes	**Latest Standards:** Propose a certification basis using the CSs in effect at the date of application. Proceed to Step 8.
	☐ No	**Proceed to Step 4.**
Step 4: Arrange changes into related and unrelated groups. (See paragraph 3.5 of GM 21.A.101)	**Note:** For multiple groupings, continuation of this process should be split into separate decision records. Groupings may be rationalised and recorded in separate documents: Click here to enter text.	
Step 5: Is each related or unrelated group a significant change? (See paragraph 3.6 of GM 21.A.101)	☐ Yes	**Proceed to Step 6.**
	☐ No	Earlier Standards: Propose a certification basis using the CSs in effect before the date of application but not earlier than the existing certification basis. Certification basis to be defined and documented as indicated (below). **Proceed to Step 8.**
Step 6: Prepare your Certification Basis List. (See paragraph 3.9 of GM 21.A.101) **Affected Areas:**	The Affected Area(s) is (are) detailed here or in the following Certification Basis List document number(s): Click here to enter text. Process and propose each applicable certification specification individually. **Proceed to Step 7.**	
Not Affected Areas:	Existing Standards: You may continue using the existing certification basis.	
Step 7: Do the latest standards contribute materially to the level of safety and are they practical? (See paragraph 3.10 of GM 21.A.101)	☐ Yes	Latest Standards: Propose a certification basis using the CSs in effect on the date of application.
	☐ No	Earlier Standards: You may propose a certification basis using the CSs in effect before the date of application but not earlier than the existing certification basis. Certification basis defined or documented as indicated below.
☐ Continuation Sheet(s) Attached	**Note:** Several CSs may apply to each affected area, and the assessment may differ from specifications to specifications. Indicate '**Yes**' if compliance with any latest standard(s) is required. Indicate '**No**' only if earlier standard(s) is (are) proposed.	
Note:	You may submit a proposal for the decision in Step 7; however, EASA will make the final certification basis determination.	
Step 8: Ensure the proposed certification basis is adequate. (See paragraph 3.11 of GM 21.A.101)	If you deem that the certification basis is adequate, submit the proposed certification basis to EASA. If not, consult EASA. CRI A-01 may be needed to document the certification basis.	
Certification Basis:	The certification basis is detailed here or in the following document(s): Click here to enter text.	
Based on the information provided above, I am proposing the certification basis with the following classification for the type design change. (check one)		
☐ Significant, pursuant to point 21.A.101.	☐ Not significant, pursuant to point 21.A.101.	
Click here to enter text. Printed Name/Title	Signature	Click here to enter text. Date

Appendix H to GM 21.A.101 Examples of documenting the proposed certification basis list

ED Decision 2017/024/R

H.1 **Example 1.**

H.1.1 This optional tool may be used to establish the applicable airworthiness and OSD certification specifications that will become part of the type-certification basis for airworthiness or OSD certification basis. For a significant change, the applicant must demonstrate compliance for the change and the area affected by the change with the certification specifications that were in effect at the date of application. However, in some cases earlier or later certification specifications can be used, as allowed in point 21.A.101.

H.1.2 In order to efficiently determine and agree upon a certification basis with EASA, the following information is useful to understand the applicant's position:

H.1.2.1 The scope of the change. This includes a high-level description of the physical and functional changes and performance/functional characteristics, which are changed as a result of the physical or functional change, and the certification specifications for which compliance demonstration is required as a result of the change.

H.1.2.2 The amendment level of all the applicable certification specifications at the date of application.

H.1.2.3 The proposed certification basis, including amendment levels.

H.1.2.4 Applicants who propose a certification basis that includes amendment levels earlier than what was in effect at the date of application should include the exception as outlined in point 21.A.101 and their justification if needed.

H.1.3 Exceptions.

H.1.3.1 Unrelated changes that are not significant (point 21.A.101(b)(1)).

H.1.3.2 Not affected by the change (point 21.A.101(b)(2)).

H.1.3.3 Compliance with the certification specification would not contribute materially to the level of safety (point 21.A.101(b)(3)).

H.1.3.4 Compliance with the certification specification would be impractical (point 21.A.101(b)(3)).

H.1.4 One easy way to document the proposed certification basis is using a tabular form as shown in Table below.

Table H-1. Tabular Form for Documenting a Proposed Certification Basis

CS	Amendment Levels			Applicant Justification for Lower Amendment Level and Comments	Affected Area
	Existing TCDS Amendment	Amendment at Date of Application	Proposed Amendment Level		
Subpart A — General					
Subpart B — Flight					

H.1.5 Best Practices.

H.1.5.1 Account for all certification specifications, even if they are not applicable.

H.1.5.2 Mark certification specifications that are not applicable as ‘N/A’.

H.1.5.3 If more than one amendment level is used depending on the area of the product, list all areas and amendment levels at each area with proper justification.

H.1.5.4 If the justification is long, provide the justification below the table and only place the certification specification reference and note in the comment field.

H.1.5.5 Include airworthiness and OSD standards required by other EU regulations (e.g. Part-26) of affected areas.

H.2 **Example 2.**

Pages 129 through 135 of this Appendix contain another example for documenting a proposed certification basis.

TITLE OF DESIGN CHANGE

Product Name or Change to Type Certificate [XXXX]

Proposed Certification Basis Pursuant to point 21.A.101

1. INTRODUCTION.

1.1 REFERENCE DOCUMENTS.

Reference	Title
[1] Point 21.A.101	Designation of applicable certification specifications and environmental protection requirements
[2] GM 21.A.101-1B	Establishing the Certification Basis of Changed Aeronautical Products
[3] XXXX	Application letter
[4] Type Certificate YYYY	Product type-certification basis
[5] Document ZZZZ	Certification plan
[6]	

<The above-referenced documents are examples. Each applicant should reference documents appropriate to their products and procedures.>

1.2 ACRONYMS.

Acronym	Meaning
AFM	Aircraft Flight Manual
AMC	Acceptable Means of Compliance
CRI	Certification Review Item
ELOS	Equivalent Level of Safety
ESF	Equivalent Safety Finding
GM	Guidance Material
MOC	Means of Compliance
SC	Special Condition
TC	Type Certificate

<This section constitutes a representative list of acronyms. Each applicant should provide an acronym list appropriate for their product and document.>

1.3 PURPOSE OF THE DOCUMENT.

The purpose of this document is to propose the certification basis applicable to [Product Design Change] in accordance with point 21.A.101.

<Note that this optional document is intended to be used for changes to type-certified products for which the change or a portion of the change is significant at the product level pursuant to 21.A.101. Not significant changes being accomplished concurrently with significant changes(s) would also be identified in this document.>

2. DESIGN DEFINITION.

2.1 BASELINE PRODUCT.

The type design to be changed, which is also known as the 'baseline product,' is the Model Series___ (this should be a specific product configuration, such as a specific serial number or line number).

The reference product certification basis is TCDS No. [XXXX], issued on [DATE].

2.2 DESIGN CHANGE AND BASELINE PRODUCT COMPARISON SUMMARY.

<Example table where the product is an aeroplane. This is a representative set of data that may be provided by the applicant.>

Specification	Model Series X	Model Series Y
Max Taxi Weight — MTW (lb)	A1	A2
Max Take-off Weight — MTOW (lb)	B1	B2
Max Landing Weight — MLW (lb)	C1	C2
Max Zero Fuel Weight — MZFW (lb)	D1	D2
Max Length (ft, in)	E1	E2
Max Height (ft, in)	F1	F2
Wing Span (ft, in)	G1	G2
Horizontal Tail Span (ft, in)	H1	H2
Fuel Capacity (gal)	I1	I2
Total Cargo Volume (ft^3)	J1	J2
Max Passenger Limit — one class seating (occupants)	K1	K2
Engine Types	L1 & M1	L2
Maximum Engine Thrust	T1	T2

2.3 DESCRIPTION OF DESIGN CHANGE, GROUPING AND CLASSIFICATION.

2.3.1 SIGNIFICANT CHANGE(S).

<Describe here the stand-alone change(s) and/or change grouping(s) that are part of the proposed changed product and are proposed as significant. Include with each stand-alone change or change grouping the relevant accumulated change(s) and the applicable physical and/or functional effects. Note, the description should be detailed enough to identify why the change or change grouping is proposed as significant.>

The following group of changes is proposed as significant based on [GM 21.A.101-1, Appendix A, '[Description of Change in Appendix A]] or [the general configuration is not retained, principles of construction are not retained, or assumptions for certification of the product to be changed do not remain valid].

Changes Related to [Title of Significant Change X]:

[Title of High-Level Change C1]

The areas of physical change are:

— [design change xx]

— [design change yy]

— [design change zz]

The areas unchanged but affected by the change are:

— [affected area aaa]

— [affected area bbb]

— [affected area ccc]

[Title of High-Level Change C2]…

2.3.2 UNRELATED NOT-SIGNIFICANT CHANGES.

<Describe here the not significant stand-alone changes or change groupings that are part of the modification but are unrelated to any of the significant changes described in paragraph 2.3.1.>

[Title of High-Level Change D1]. [Description].

<The description must be just detailed enough to serve its purpose, which is to identify why each of those changes is not significant and unrelated.>

[Title of High-Level Change D2]. [Description]…

3. IDENTIFICATION OF APPLICABLE CERTIFICATION STANDARDS.

3.1 PROPOSED CERTIFICATION BASIS.

Based on the effective application date, [date], under the provisions of 21.A.101, the applicable certification standards for the [Title of Design Change] are proposed as follows. The proposed certification basis includes exceptions to earlier amendments (reversions), deviations, special conditions, and equivalent (level of) safety findings.

3.1.1 Certification specifications effective at the date of application.

Applicable certification specifications in effect on the date of the application are:

<List the applicable parts and amendment levels here.>

Example for large aeroplanes:

A. Airworthiness:

— CS-25,

— CS-AWO.

B. Operational Suitability Data:

— CS-CCD,

— CS-FCD,

— CS-MCSD (to be published),

— CS-MMEL,

— CS-SIMD.

C. Environmental Protection:

— CS-34,

— CS-36.

3.1.2 Point 21.A.101 exception rationale.

The completed rationale for each does not contribute materially to the level of safety (DCMLS) or impracticality exception is provided in this section.

Exception 1: …

Exception 2: …

3.1.3 Optional certification standards

Applicable certification specifications in effect on the date of the application are:

<List the applicable parts and amendment levels here.>

Example for large aeroplanes:

— CS 25.803, *Emergency evacuation*, Amendment 12,

— CS 25.1810, *Emergency egress assisting means and escape routes*, Amendment 17.

3.1.4 Design-related requirements from other aviation domains.

Applicable certification specifications in effect on the date of the application are:

<List the applicable parts and amendment levels here.>

Example for large aeroplanes:

— CS-ACNS Communications, Navigation and Surveillance

— Initial Issue, dated 17 December 2013, Subpart D Sections 2/3,

— CS-26.

3.1.5 Proposed Special Conditions.

Special Condition (or TBD)	Title	Effective Date (or TBD)

3.1.6 Equivalent Safety Findings.

ELOS Memo No (or TBD)	Title	Applicable Standard

3.1.7 Deviations.

Deviation No (or TBD)	Title	Applicable Standard	Date Issued (or TBD)

3.1.8 Elect to comply

Elect to Comply No (or TBD)	Title	Applicable Standard	Date Issued (or TBD)

Proposed Certification Basis

The certification basis is a complete extract from the applicable FAA 14 CFR part **[A]** and it references the certification basis **[B]**. Column **[C]** identifies the amendment level for the specific requirement on the date of application. The changed product's certification basis is proposed in last column **[D]**. References to FAR sections and amendments are kept.

Example for a Part 25 aeroplane:

[A] Requirement	Title (or subparagraph)	[B] Existing Certification Basis Amendment Level	[C] Amendment Level on Application Date	[D] Proposed Amendment for Changed Product	Applicable Area	Notes
25.25	*Weight limits*					
		25-23	25-63	25-63	Product	
25.33	*Propeller speed and pitch limits*					
		N/A	25-72	N/A	—	Not applicable to Changed Product (Jet Aircraft)
25.1309(a)	*Equipment, systems, and installations*					
		25-41	15-123	25-123	Changed and Affected Areas	
		25-41	25-123	25-41	Exception — Not Affected	See example 1 in section 3.1.2
25.1703	*Function and installation: EWIS*					
		N/A	25-124	N/A	Exception — Product	See example 2 in section 3.2.1

Appendix I to GM 21.A.101 Related documents

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I.1 Related Part 21 requirements.

- 21.A.15, *Application*
- 21.B.70, *Certification specifications*
- 21.B.75, *Special conditions*
- 21.B.80, *Type-certification basis for a type-certificate or restricted type-certificate*
- 21.B.82, *Operational suitability data certification basis for an aircraft type certificate or restricted type-certificate*
- 21.A.19, *Changes requiring a new type certificate*
- 21.B.103, *Issuance of a type-certificate or restricted type-certificate*
- 21.A.31, *Type design*
- 21.A.41, *Type certificate*
- 21.A.91, *Classification of changes to a type certificate*
- 21.A.93, *Application*
- 21.A.97, *Requirements for approval of a major change*

— 21.A.101, *Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate*

— 21.B.107, *Issuance of an approval of a change to a type-certificate*

— 21.A.113, *Application for a supplemental type-certificate*

— 21.A.115, *Requirements for approval of major changes in the form of a supplemental type-certificate*

— 21.B.111, *Issuance of a supplemental type-certificate*

Appendix J to GM 21.A.101 Definitions and terminology

ED Decision 2019/018/R

J.1 Aeronautical product.

The terms 'aeronautical product' or 'product' used in this guidance material include type-certified aircraft, engines, or propellers and, for the purpose of this GM, an ETSOA'd APU.

J.2 Assumptions used for certification.

The assumptions used for certification are the evaluations and decisions that led to the approval of the baseline product's characteristics. Examples of the product's baseline characteristics include but are not limited to the following:

— Design methodologies, methods of compliance, and standards used to achieve compliance with the certification specifications making up the certification basis;

— Structural, mechanical, electrical, propulsion, aerodynamic, performance, operational, and maintenance characteristics;

— Operational and flight envelopes defining the product performance and capabilities at specified weights, speeds, altitudes, load factors, and centres of gravity;

— Crashworthiness;

— Role or mission;

— Airworthiness and operational limitations; or

— Pilot training, if necessary.

J.3 Baseline product.

It is an aeronautical product with a specific, defined approved configuration and certification basis that the applicant proposes to change.

J.4 Certification basis.

The combination of the:

— airworthiness certification specifications as provided for in point 21.B.80;

— OSD certification specifications as provided for in point 21.B.82; and

— environmental protection requirements, as provided for in point 21.B.85,

and as established for the change according to point 21.A.101, as well as the:

— special conditions;

— equivalent safety findings;

— elects to comply; and

— deviations, applicable to the product to be certified.

J.5 Change.

The term 'change' refers to a change to a product type certificate (as defined in point 21.A.41) approved or to be approved under Subpart D or Subpart E (as a supplemental type certificate) of Part 21, including a change to an STC or a change to the ETSOA for auxiliary power units (APUs) under Subpart O. A change may consist of a single stand-alone change to one TC component or several interrelated changes to different TC components (e.g. the type design, operating characteristics, OSD, environmental protection characteristics, etc. (see point 21.A.41 and GM to 21.A.90A)).

J.6 Design change.

The term 'design change' refers to a change to the type design (as defined in point 21.A.31) of an aeronautical product. In the context of this document, the terms 'change to the type design', 'modification', 'design change', and 'type design change' are synonymous.

J.7 Earlier standards.

The certification specifications or previous standards in effect prior to the date of application for the change, but not prior to the existing certification basis.

J.8 Existing certification basis.

The certification specifications or previous standards incorporated by reference in the type certificate of the baseline product to be changed.

J.9 Latest standards.

The certification specifications in effect on the date of application for the change.

J.10 Previous relevant design changes.

Previous design changes, the cumulative effect of which could result in a product significantly or substantially different from the original product or model, when considered from the last time the latest standards were applied.

J.11 Product-level change.

A change or combination of changes that makes the product distinct from other models of the product (e.g. range, payload, speed, design philosophy). Product-level change is defined at the aircraft, aircraft engine, or propeller level of change.

J.12 Secondary change.

A change that is part of a significant physical change that does not contribute materially to the level of safety. Guidance is contained in paragraph 3.10.1.4 of this GM.

J.13 Significant change.

A change to the type certificate to the extent that it changes one or more of the following, but not to the extent to be considered a substantial change: the general configuration, principles of construction, or the assumptions used for certification. The significance of the change is considered in the context of all previous relevant design changes and all related revisions to the applicable standards. Not all product-level changes are significant.

J.14 Significant change to area.

For aircraft excepted under point 21.A.101(c) only: a change to an area is significant if the general configuration or the principles of construction in that area are not retained, or the assumptions used for the certification of that area do not remain valid.

J.15 Substantial change.

A change that is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required, and consequently a new type certificate is required pursuant to point 21.A.19.

GM No 1 to 21.A.101(g) Establishment of the operational suitability data (OSD) certification basis for changes to type certificates (TCs)

ED Decision 2019/018/R

This GM provides guidance on the application of point 21.A.101(g) in order to determine the applicable OSD certification basis in accordance with points 21.A.101(a), (b), (c), (d), (e) and (f) for major changes to the OSD of type-certified aircraft.

1. Minor changes

   Minor changes to the OSD are automatically outside the scope of point 21.A.101. See GM 21.A.95 for their certification basis.

2. Major changes

   a. If the design change that triggered the change to the OSD constituent is classified as non-significant, the change to the OSD constituent is also non-significant.

   b. If the design change that triggered the change to the OSD constituent is classified as significant, the change to the OSD constituent should comply with the latest amendment of the applicable CSs, unless the exceptions of 21.A.101(b)(3) apply or unless the OSD change can be classified as minor as per 21.A.91. The guidance of GM 21.A.101 Section 3.10 regarding the exceptions 'impractical' and 'not contributing materially to the level of safety', can be applied by analogy and as far as it is applicable to OSD changes.

   c. Stand-alone changes to an OSD constituent are considered to be non-significant.

   d. When a new OSD constituent is added or required to be added, it should comply with the latest amendment of the applicable CSs.

   e. Reserved.

   f. Reserved.

   g. Point 21.A.101(c) provides an exception from the requirements of 21.A.101(a) for a change to the OSD of certain aircraft below a specified maximum weight. If an applicant applies for a change to the OSD for an aircraft (other than rotorcraft) of 2 722 kg (6 000 lbs) or less maximum weight, or for a non-turbine-powered rotorcraft of 1 361 kg (3 000 lbs) or less maximum weight, the applicant can demonstrate that the changed OSD complies with the OSD certification basis incorporated by reference in the TC. The applicant can also elect to comply, or may be required to comply, with a later amendment. See also Chapter 4 Section 4.1 (GM 21.A.101) for specific guidance on this requirement.

Note: Refer to GM No 1 to 21.A.15(d) for the applicability of the OSD to other-than-complex motor-powered aircraft.

AMC1 21.A.101(h) Type-certification basis for changes to large aeroplanes subject to point 26.300 of Part-26

ED Decision 2021/007/R

Compliance with point 21.A.101(h) is demonstrated through compliance with Amdt 19 to CS 25.571 or subsequent amendments, or with the following:

(a) For turbine-powered large aeroplanes with a certified maximum take-off weight (MTOW) greater than 34 019 kg (75 000 lbs):

(1) For changes that affect or introduce fatigue critical structures susceptible to widespread fatigue damage (WFD), WFD evaluations should substantiate freedom from WFD up to the existing limit of validity (LOV) or a new reduced LOV approved by EASA;

(2) The extension of an existing LOV is a major change.

(3) The extent of the test evidence required in support of the WFD evaluation should be agreed with EASA;

(4) Inspections and other maintenance actions upon which the LOV is dependent are established and submitted to EASA for approval in accordance with point 21.A.7 of Part 21;

(5) AMC 20-20B paragraph 8 contains additional guidance on this subject.

(b) For turbine-powered large aeroplanes certified to carry 30 passengers or more, or with a payload capacity of 3 402 kg (7 500 lbs) or more:

(1) For changes that affect or introduce fatigue critical structures, damage-tolerance evaluations must be performed according to the certification basis of the aeroplane unless it precedes JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, in which case the certification basis for the change should be:

(i) JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, or later amendments; or

(ii) the specifications used for compliance with the applicable points of Part-26 for the structures affected by the change.

(2) Develop or amend the list of fatigue-critical modified structures (FCMS) as necessary and make it available to aircraft operators as part of the ICA of the change.

(c) For turbine-powered large aeroplanes, the baseline corrosion prevention and control programme is amended or supplemented to address the influence of the change on the effectiveness of the programme, as necessary.

21.A.108 Availability of operational suitability data

Regulation (EU) No 69/2014

In the case of a change affecting the operational suitability data, the holder of the minor change approval shall make available:

(a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known EU operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and

(b) any further change to the affected operational suitability data, to all known EU operators of the changed aircraft; and

(c) on request, the relevant parts of the changes in points (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and

2. any person required to comply with one or more elements of this set of operational suitability data.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

ED Decision 2014/007/R

(a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.

(b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

21.A.109 Obligations and EPA marking

Regulation (EU) 2022/201

The holder of a minor change approval to a type-certificate shall:

(a) undertake the obligations laid down in points 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9 and 21.A.108; and

(b) specify the marking, including EPA (European Part Approval) letters, in accordance with point 21.A.804(a).

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES

21.A.111 Scope

Regulation (EU) 2019/897

This Subpart establishes the procedure for the approval of major changes to the type-certificate under supplemental type-certificate procedures, and establishes the rights and obligations of the applicants for, and holders of, those certificates. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

21.A.112A Eligibility

Regulation (EU) 2019/897

Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with point 21.A.112B may apply for a supplemental type-certificate in accordance with the conditions laid down in this Subpart.

21.A.112B Demonstration of capability

Regulation (EU) 2019/897

(a) An applicant for a supplemental type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Subpart.

(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.93(b).

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

a. Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

b. Format

The FTOM may:

— be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

— be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

c. Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part 21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

a. Exposition (not applicable in the case of APDOA):

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

— for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

— for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

— for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

GM1 21.A.112B Demonstration of capability

ED Decision 2021/001/R

DEMONSTRATION OF CAPABILITY FOR SUPPLEMENTAL TYPE CERTIFICATE (STC) CASES

See also AMC 21.A.14(b) for the details of the alternative procedures.

The following examples of major changes to type design (ref.: 21.A.91) are classified in two groups. Group 1 contains cases where a design organisation approved under Part 21 Subpart J ('Subpart J DOA') should be required, and Group 2 cases where the alternative procedure may be accepted. They are typical examples but each STC case should be addressed on its merits and there would be exceptions in practice. This classification is valid for new STCs, not for evolution of STCs, and may depend upon the nature of the STC (complete design or installation).

Product	Discipline	Kind of STC	Group
All aircraft			
	OSD		
		Major stand-alone change to any OSD constituent	1
Products for which an alternative procedure may be accepted according to 21.A.14(b)	**All disciplines**		2
CS-23 (products where a Subpart J DOA is required for TC)			
Notes: 1) An STC which leads to a reassessment of the loads on large parts of the primary structure should be in Group 1. 2) '2/1' means that an assessment of consequences in terms of handling qualities, performance or complexity of demonstration of compliance may lead to classification in Group 1.			
	Aircraft		
		Conversion to tail wheel configuration	1
		Auxiliary fuel tank installations	2/1
		Glass fibre wing tips	2/1
		Fairings: nacelle, landing gear	2
		Gap seals: aileron, flap, empennage, doors	2
		Vortex generators	2/1
		Spoiler installation	1
		Increase in MTOW	1
	Structures		
		Stretcher installation	2

Product	Discipline	Kind of STC	Group
		Change to seating configuration	2
		Windshield replacement (heated, single piece, etc.)	2
		Lightweight floor panels	2
		Ski installations	2/1
	Propulsion		
		Engine model change	1
		Fixed pitch propeller installation	2
		Constant speed propeller installation	2/1
		Installation of exhaust silencer	2
		Installation of graphic engine monitor	2
		Installation of fuel flow meter	2
		Accessory replacement (alternator, magnetos, etc.)	2
		Inlet modifications: oil cooler; induction air	2
	Equipment		
		Avionics upgrades (EFIS, GPS, etc.)	2/1
		Engine instrument replacements	2
		Carburettor ice detection system	2
		Autopilot system installation	1
		Wing tip landing light; recognition lights	2
		WX radar installation	2
		Aeromedical system installations	2
		De-icing and anti-icing system installations	1
		Emergency power supply installations	2
CS-25			
	Cabin Safety		
Note: Basically, all changes related to cabin configuration should be in Group 2.		Cabin layout (installation of seats (16G), galleys, single class or business / economy class, etc.)	2
		Floor path marking	2
		Crew rest compartment	1
		Change of cargo compartment classification (from class D to class C)	1
	Structure		
Note: An STC which leads to a reassessment of the loads on large parts of the primary structure should be in Group 1.		Cargo door	1
		Change from passenger to freighter configuration	1
	Avionics		
Notes: For CS-25 products, the existence of an ETSO is not taken into account for the classification. The impact on aircraft performance, and influence of aircraft performance are criteria to assess the classification.		CVR	2

Product	Discipline	Kind of STC	Group
Subjective assessment of human factors is considered for determination of the classification.			
		VHF	2
		NAV (ADF, VOR, GPS, BRNAV)	2
		Autopilot, HUD, EFIS, FMS	1
		DFDR	2/1
		Meteo radar	2
		ILS Cat 3	1
		RVSM	1
		TCAS, EGPWS	1
		GPWS	2
	Powerplant		
		Auxiliary fuel tanks	1
		Thrust reverser system	1
		Hushkit	1
		Fire detection	1
		Fuel gauging	1
		Change of engine or propeller	1
CS-27 or CS-29	**All disciplines**		
Note: 2/1 means that an assessment of consequences in terms of handling qualities and performance may lead to classification in Group 1.		Replacement of main rotor or tail rotor blades	1
		Autopilot	1
		Engine type change	1
		GPS installation	2
		Jettisonable overhead raft installation	2
		Utility basket installation	2/1
		Nose or side mount camera installation	2/1
		Passenger access step installation	2/1
		Protection net & handle installation (parachuting)	2
		VIP cabin layout	2
		Navigation system installation	2
		Fuel boost pump automatic switch-on installation	2
		Decrease of maximum seating capacity	2
		Agricultural spray kit installation	2/1
		Long exhaust pipe installation	2
		Flotation gear installation	2/1
		Wipers installation	2
		Engine oil filter installation	2
		Skid gear covering installation	2/1
		Gutter installation (top pilot door)	2
		Cable cutter installation	2
		Auxiliary fuel tank fixed parts installation	2

Product	Discipline	Kind of STC	Group
		Cabin doors windows replacement	2
		Radio altimeter aural warning installation	2
		Standby horizon autonomous power supply	2
		Fire attack system	2/1
		Hoisting system installation	2/1
		External loads hook installation	2
		Emergency flotation gear installation	2/1
		Heating/demisting (P2 supply)	2

21.A.113 Application for a supplemental type-certificate

Regulation (EU) 2019/897

(a) An application for a supplemental type-certificate shall be made in a form and manner established by the Agency.

(b) When applying for a supplemental type-certificate, the applicant shall:

(i) include in the application the information required by point 21.A.93(b);

(ii) specify whether the certification data has been or will be prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.

(c) Point 21.A.93(c) applies to the requirements for the time limits of the application effectivity as well as the requirements related to the need to update the type-certification basis, operational suitability data certification basis and environmental protection requirements, when the change has not been approved or it is evident that it will not be approved within the time limit established.

AMC 21.A.113(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application form for a supplemental type certificate (STC) (FO.CERT.00033)[2], which may be downloaded from the EASA website.

If the form is filled in offline, it should be completed in accordance with the instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[3].

[1] https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

[2] https://www.easa.europa.eu/document-library/application-forms/focert00033 (changes to the link provided may not be reflected in this document).

[3] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

21.A.115 Requirements for approval of major changes in the form of a supplemental type-certificate

Regulation (EU) 2019/897

(a) Supplemental type certificates shall be issued by:

1. the Agency; or
2. an approved design organisation within the scope of its privileges provided for in points (1) and (9) of point 21.A.263(c), as recorded in the terms of approval.

(b) A supplemental type-certificate shall only be issued when:

1. the applicant has demonstrated its capability in accordance with point 21.A.112B;
2. it has been demonstrated that the change to a type-certificate and areas affected by the change comply with the type-certification basis and the environmental protection requirements, as established by the Agency in accordance with point 21.A.101;
3. in the case of a supplemental type-certificate affecting the operational suitability data, it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101;
4. compliance with points (2) and (3) has been demonstrated in accordance with point 21.A.20, as applicable to the change; and
5. in case the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.113(b):
   (i) the type-certificate holder has indicated that it has no technical objection to the information submitted under point 21.A.93; and
   (ii) the type-certificate holder has agreed to collaborate with the supplemental type-certificate holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with points 21.A.44 and 21.A.118A.

(c) By derogation from points (3) and (4) of point (b), at the applicant's request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have a supplemental type-certificate for an aircraft issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(d) A supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.

AMC 21.A.115 Requirements for the approval of major changes in the form of a supplemental type certificate (STC)

ED Decision 2019/018/R

(a) For STCs approved by EASA, the AMC and GM to point 21.A.20 should be followed by the applicant.

(b) For an application under point 21.A.115(c), see GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b).

(c) In accordance with point 21.A.115(d), the compliance demonstration process must always cover the specific configuration(s) in the type certificate (TC) to which the STC under approval is applied. These configurations should be defined by the change to the type certificate considering the type certificate data sheet (TCDS) and the relevant optional installations. The demonstration of compliance should cover these specific applicable configurations. Consequently, the approval of the STC excludes any other configurations, in particular those that already existed, but were not considered in the compliance demonstration process, and those that may be certified in future.

(d) For STCs approved by the design organisation approval (DOA) holder under their privilege as per point 21.A.263(c)(9), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.116 Transferability

Regulation (EU) No 748/2012

A supplemental type-certificate shall only be transferred to a natural or legal person that is able to undertake the obligations of point 21.A.118A and for this purpose has demonstrated its ability to qualify under the criteria of point 21.A.112B except for ELA1 aircraft for which the natural or legal person has sought the Agency agreement for the use of procedures setting out its activities to undertake these obligations.

21.A.117 Changes to that part of a product covered by a supplemental type-certificate

Regulation (EU) No 748/2012

(a) Minor changes to that part of a product covered by a supplemental type-certificate shall be classified and approved in accordance with Subpart D.

(b) Each major change to that part of a product covered by a supplemental type-certificate shall be approved as a separate supplemental type-certificate in accordance with this Subpart.

(c) By way of derogation from point (b), a major change to that part of a product covered by a supplemental type-certificate submitted by the supplemental type-certificate holder itself may be approved as a change to the existing supplemental type-certificate.

21.A.118A Obligations and EPA marking

Regulation (EU) 2022/201

Each holder of a supplemental type-certificate shall:

(a) undertake the obligations:

1. laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9 and 21.A.120B;

2. implicit in the collaboration with the type-certificate holder under point 21.A.115(d)(2);

and for this purpose continue to meet the criteria of point 21.A.112B;

(b) specify the marking, including EPA letters, in accordance with point 21.A.804(a).

21.A.118B Duration and continued validity

Regulation (EU) No 748/2012

(a) A supplemental type-certificate shall be issued for an unlimited duration. It shall remain valid subject to:

1. the holder remaining in compliance with this Annex I (Part 21); and

2. the certificate not being surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the supplemental type-certificate shall be returned to the Agency.

21.A.120B Availability of operational suitability data

Regulation (EU) No 69/2014

In the case of a change affecting the operational suitability data, the holder of the supplemental type-certificate shall make available:

(a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known EU operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and

(b) any further change to the affected operational suitability data, to all known EU operators of the changed aircraft; and

(c) on request, the relevant parts of the changes in points (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and

2. any person required to comply with one or more elements of this set of operational suitability data.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

ED Decision 2014/007/R

(a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.

(b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

21.A.121 Scope

Regulation (EU) No 748/2012

(a) This Subpart establishes the procedure for demonstrating the conformity with the applicable design data of a product, part and appliance that is intended to be manufactured without a production organisation approval under Subpart G.

(b) This Subpart establishes the rules governing the obligations of the manufacturer of a product, part, or appliance being manufactured under this Subpart.

GM No 1 to 21.A.121 Applicability – Individual product, part or appliance

ED Decision 2012/020/R

In this context, 'demonstrating the conformity with the applicable design data of a product, part and appliance' means that conformity with the applicable design data has to be established and shown for each and every product, part or appliance.

GM No 2 to 21.A.121 Applicability – Applicable design data

ED Decision 2019/018/R

Applicable design data is defined as all the necessary drawings, specifications and other technical information provided by the applicant for, or holder of a design organisation approval, TC, STC, approval of repair or minor change design, or ETSO authorisation (or equivalent when Part 21 Section A Subpart F is used for production of products, parts or appliances, the design of which has been approved other than according to Part 21), and released in a controlled manner to the manufacturer that produces under Part 21 Subpart F. This should be sufficient for the development of production data to enable manufacture in conformity with the design data.

Prior to the issue of the TC, STC, approval of repair or minor change design or ETSO authorisation, or equivalent, design data is defined as 'not approved', but parts and appliances may be released with an EASA Form 1 as a certificate of conformity.

After the issue of the TC, STC, approval of repair or minor change or ETSO authorisation, or equivalent, this design data is defined as 'approved' and items manufactured in conformity are eligible for release on an EASA Form 1 for airworthiness purposes.

For the purpose of Subpart F of Part 21, the term 'applicable design data' includes the information related to the applicable engine exhaust emissions and aeroplane CO_2 emissions production cut-off requirements.

21.A.122 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person may apply to show conformity of individual products, parts or appliances under this Subpart, if:

(a) it holds or has applied for an approval covering the design of that product, part or appliance; or

(b) it has ensured satisfactory coordination between production and design, through an appropriate arrangement with the applicant for, or holder of, an approval of such a design.

AMC1 21.A.122 Eligibility

ED Decision 2023/014/R

LINK BETWEEN DESIGN AND PRODUCTION

An 'arrangement' is considered suitable if it is documented and satisfies the competent authority that coordination is satisfactory.

To achieve satisfactory coordination, the documented arrangements must at least define the following aspects, irrespective of whether the design organisation (DO) and the organisation producing or intending to produce under Part 21, Subpart F are separate legal entities or not:

(a) the responsibilities of a DO, which assure correct and timely transfer of up-to-date applicable design data (e.g. drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);

(b) the responsibilities and procedures of the production organisation (PO) for receiving, managing, and using the applicable design data provided by the DO;

(c) the responsibilities and procedures of the PO for developing, where applicable, its own manufacturing data in compliance with the applicable design data package;

(d) the responsibilities of the PO to assist the DO in dealing with continuing airworthiness matters and for required actions (e.g. traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.);

(e) the scope of the arrangements covering Subpart F requirements, in particular, points 21.A.126(a)(4) and 21.A.129(d) and 21.A.3A and any associated GM or AMC;

(f) the responsibilities of the PO, in the case of products prior to type certification to assist a DO in demonstrating compliance with the CS (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);

(g) the procedures to deal adequately with production deviations and non-conforming parts;

(h) the means to achieve adequate configuration control of manufactured parts, to enable the PO to make the final determination and identification for conformity or airworthiness release and eligibility status;

(i) the identification of responsible persons that control the above; and

(j) the acknowledgment by the holder of the TC/STC/repair or change approval/ETSO authorisation that the approved design data that is provided, controlled and modified in accordance with the arrangement is recognised as approved.

In many cases, the person producing or intending to produce under Part 21, Subpart F may receive the approved design data through an intermediate PO. This is acceptable, provided that an effective link between the design approval holder (DAH) and the PO can be maintained to satisfy the intent of point 21.A.122.

When the DO and the PO are two separate legal entities, a direct delivery authorisation should be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

Where there is no general agreement for direct delivery authorisation, specific permissions may be granted (see AMC 21.A.4).

AMC2 21.A.122 Eligibility

ED Decision 2023/014/R

LINK BETWEEN DESIGN AND PRODUCTION

In accordance with AMC1 21.A.122 the person producing or intending to produce under Part 21 Subpart F should demonstrate to the authority that it has entered into an arrangement with the design organisation. The arrangement must be documented irrespective of whether the two organisations are separate legal entities or not.

The documented arrangement must facilitate the person producing or intending to produce under Part 21 Subpart F to demonstrate compliance with the requirement of 21.A.122 by means of written documents agreed.

In the case where the design organisation and the person producing or intending to produce under Part 21 Subpart F are part of the same legal entity these interfaces may be demonstrated by company procedures accepted by the competent authority.

In all other cases to define such a design/production interface the following sample format is offered:

Arrangement Sample Form

<table>
<tr><td colspan="2">ARRANGEMENT
in accordance with 21.A.122</td></tr>
<tr><td>The undersigned agree on the following commitments:</td><td>Relevant interface procedures</td></tr>
<tr><td>The design organisation [NAME] takes responsibility to:
— assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the person producing under Part 21 Subpart F [NAME]
— provide visible statement(s) of approved design data.</td><td></td></tr>
<tr><td>The person producing under Part 21 Subpart F [NAME] takes responsibility to
— assist the design organisation [Name] in dealing with continuing airworthiness matter and for required actions
— assist the design organisation [NAME] in case of products prior to type certification in demonstrating compliance with certification specifications
— develop, where applicable, its own manufacturing data in compliance with the airworthiness data package.</td><td></td></tr>
<tr><td>The design organisation [NAME] and the person producing under Part 21 Subpart F [NAME] take joint responsibility to:
— deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the manufacturer producing under Part 21 Subpart F.
— achieve adequate configuration control of manufactured parts, to enable the manufacturer producing under Part 21 Subpart F to make the final determination and identification for conformity.</td><td></td></tr>
<tr><td colspan="2">The scope of production covered by this arrangement is detailed in [DOCUMENT REFERENCE/ATTACHED LIST]</td></tr>
<tr><td colspan="2">[When the design organisation is not the same legal entity as the manufacturer producing under Part 21 Subpart F]

Transfer of approved design data:
The TC/STC/ETSO authorisation holder [NAME] acknowledges that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved by the competent authority and therefore the parts and appliances manufactured in accordance with these data and found in a condition for safe operation may be released certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation.</td></tr>
<tr><td colspan="2">[When the design organisation is not the same legal entity as the manufacturer producing under Part 21 Subpart F]

Direct Delivery Authorisation:
This acknowledgment includes also [OR does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.</td></tr>
<tr><td>For the [NAME of the design organisation/DOA holder]

Date: xx.xx.xxxx
Signature:
([NAME in block letters])</td><td>For the [NAME of the person producing under Part 21 Subpart F]

Date: xx.xx.xxxx
Signature:
([NAME in block letters])</td></tr>
</table>

Instructions for completion:

Title: The title of the relevant document must clearly indicate that it serves the purpose of a design/production interface arrangement in accordance with 21.A.122.

Commitment: The document must include the basic commitments between the design organisation and the manufacturer producing under Part 21 Subpart F as addressed in AMC 21.A.4 and AMC1 21.A.122.

Relevant Procedures: Identify an entry point into the documentary system of the organisations with respect to the implementation of the arrangement (for example a contract, quality plan, handbooks, common applicable procedures, working plans etc.).

Scope of arrangement: The scope of arrangement must state by means of a list or reference to relevant documents those products, parts or appliances that are covered by the arrangement.

Transfer of approved design data: Identify the relevant procedures for the transfer of the applicable design data required by 21.A.122 and AMC1 21.A.122 from the design organisation to the person producing under Part 21 Subpart F. The means by which the design organisation advises the person producing under Part 21 Subpart F whether such data is approved or not approved must also be identified (ref. 21.A.4 / AMC 21.A.4).

Direct Delivery Authorisation: Where the design organisation and the person producing under Part 21 Subpart F are separate legal entities the arrangement must clearly identify whether authorisation for direct delivery to end users is permitted or not.

Where any intermediate production/design organisation is involved in the chain between the original design organisation and the person producing under Part 21 Subpart F, evidence must be available that this intermediate organisation has received authority from the design organisation to grant Direct Delivery Authorisation.

Signature: AMC1 21.A.122 requests the identification of the responsible persons/offices who control the commitments laid down in the arrangement. Therefore the basic document must be signed mutually by the authorised representatives of the design organisation and the manufacturer producing under Part 21 Subpart F in this regard.

21.A.124 Application

Regulation (EU) No 748/2012

(a) Each application for an agreement to the showing of conformity of individual products, parts and appliances under this Subpart shall be made in a form and manner established by the competent authority.

(b) Such application shall contain:

1. evidence which demonstrates, where applicable, that:

   (i) the issuance of a production organisation approval under Subpart G would be inappropriate; or

   (ii) the certification or approval of a product, part or appliance under this Subpart is needed pending the issuance of a production organisation approval under Subpart G;

2. an outline of the information required in point 21.A.125A(b).

AMC1 21.A.124 Application

ED Decision 2022/021/R

An applicant should submit to the competent authority a fully completed EASA Form 60 (see below):

EASA Form 60 **Application for an agreement of production under Part 21, Subpart F**	
Competent authority ***of an EU Member State or*** ***EASA***	
1. Registered name and address of the applicant:	
2. Trade name (if different)	
3. Location(s) of manufacturing activities:	
4. Description of the manufacturing activities under application:	
(a) identification (TC, P/N, …, as appropriate):	
(b) termination (No. of units, termination date, …):	
5. Evidence supporting the application, as per point 21.A.124(b):	
6. Links/arrangements with design approval holder(s) (DAHs)/ design organisation(s) (DO(s)), where different from Block 1:	
7. Human resources:	
8. Name of the person signing the application:	
_____ Date	_____ Signature

EASA Form 60 Issue 3

Block 1:The name of the applicant should be entered. For legal entities, the name should be as stated in the register of the National Companies Registration Office. In this case, a copy of the entry in the register of the National Companies Registration Office should be provided to the competent authority.

Block 2: State the trade name by which the applicant is known to the public if it is different from the information given in Block 1. The use of a logo may be indicated in this block.

Block 3: State all the locations of the manufacturing activities that are covered by the application. Only those locations should be stated that are directly under the control of the applicant that is stated in Block 1.

Block 4: This block should include further details of the manufacturing activities under approval for the addresses that are indicated in Block 3. The 'Identification' block should indicate the products, parts, or appliances that are intended to be produced, while the 'Termination' block should address any information on the limitation of the activity, e.g. by stating the intended number of units to be manufactured or the expected date of completion of the manufacturing activities.

Block 5: This block should state the evidence that supports the determination of applicability as stated in point 21.A.121. In addition, an outline of the manual that is required by point 21.A.125A(b) should be provided with the application.

Block 6: The information entered here is essential for the evaluation of the eligibility of the application. Therefore, special attention should be given concerning the completion of this block, either directly, or by reference to supporting documentation in relation to the requirements of point 21.A.122 and to AMC1 21.A.122.

Block 7: The information to be entered here should reflect the number of staff or in the case of an initial approval, the intended number of staff for the manufacturing activities under this application, and therefore, it should also include any associated administrative staff.

Block 8: State the name of the person that is authorised to sign the application.

GM 21.A.124(b)(1)(i) Applicability – Inappropriate approval under Subpart G

ED Decision 2012/020/R

The issue of a letter of agreement of production under Part 21 Subpart F may be agreed by the competent authority when:

1. The applicant produces or intends to produce aeronautical products, parts and/or appliances intended for airborne use as part of a type-certificated product (this excludes simulators, ground equipment and tools), and

2. The competent authority determines that Part 21 Section A Subpart G would be inappropriate, and consequently Part 21 Section A Subpart F applies. The main difference between Part 21 Section A Subparts G and F is that Subpart G requires the existence of a Quality System which provides the competent authority with the necessary confidence to grant to the manufacturer the privileges of certifying its own production. There are situations where a Quality System, including independent monitoring and continuous internal evaluation functions, is not justified and /or feasible. In making the determination that Subpart F may apply, the competent authority may take into account one or a combination of parameters such as the following:

    — no flow production (infrequent or low volume of production).

— simple technology (enabling effective inspection phases during the manufacturing process).

— very small organisation.

GM 21.A.124(b)(1)(ii) Certification or approval needed in advance of the issue of a POA

ED Decision 2012/020/R

In cases where Part 21 Section A Subpart G is applicable, but when some time is needed for the organisation to achieve compliance with Subpart G, i.e., to establish the necessary documented quality system, the competent authority may agree to use Part 21 Section A Subpart F for a limited period (transient phase).

In cases where Part 21 Section A Subpart G is applicable, such as to produce ETSO articles, a letter of agreement to produce under Part 21 Subpart F should not be given unless an application has been made for organisation approval under Subpart G, and reasonable progress is being made towards compliance with Subpart G. Long-term production under Part 21 Subpart F will not be permitted.

GM 21.A.124(b)(2) Application – Minimum information to include with the application

ED Decision 2012/020/R

At this early stage, provision of the complete manual is not necessary, but at least the following items should be covered:

1. Table of Contents of the Manual (including list of existing inspection system documents or procedures)
2. Description of items to be manufactured (including intended quantities /deliveries)
3. List of possible suppliers
4. General description of facilities
5. General description of production means
6. Human resources

21.A.124A Means of compliance

Regulation (EU) 2022/201

(a) An organisation may use any alternative means of compliance to establish compliance with this Regulation.

(b) If an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description. The description shall include any revisions to manuals or procedures that may be relevant, as well as an explanation indicating how compliance with this Regulation is achieved.

The organisation may use those alternative means of compliance subject to prior approval from the competent authority.

GM1 21.A.124A and 21.A.134A Means of compliance

ED Decision 2022/021/R

GENERAL

(a) Acceptable means of compliance (AMC), as referred to in Article 76(3) of Regulation (EU) 2018/1139[1], are a tool to standardise the demonstration of compliance with, and facilitate the verification activities of the competent authorities in relation to, that Regulation and its delegated and implementing acts. AMC are published by EASA to achieve those objectives. While competent authorities and regulated entities are not legally bound to use the AMC, applying them is recommended.

(b) If an organisation wishes to use other means to comply with Regulation (EU) 2018/1139 and its delegated and implementing acts, which are different from the AMC that are published by EASA, that organisation may need to demonstrate compliance by using alternative means of compliance (AltMoC) that are established:

(1) by its competent authority (see GM1 21.B.115 and GM1 21.B.215); or

(2) by that organisation and approved by its competent authority (see point (c)).

An AltMoC does not allow deviation from Regulation (EU) 2018/1139 and its delegated or implementing acts.

(c) AltMoC that are established by an organisation and approved by its competent authority

An organisation that wishes to use a different MoC than the one published by EASA can propose an AltMoC to the competent authority and use it only once the competent authority approves it. In that case, the organisation is responsible for demonstrating how that AltMoC establishes compliance with the regulation.

The approval of an AltMoC is granted to the organisation by its competent authority on an individual basis and is restricted to that specific organisation. Other organisations that wish to use the same AltMoC should go through the AltMoC process (i.e. demonstrate how that AltMoC establishes compliance with the regulation) and obtain individual approval from their competent authority.

GM2 21.A.124A and 21.A.134A Means of compliance

ED Decision 2022/021/R

WHEN AN ALTERNATIVE MEANS OF COMPLIANCE IS NEEDED

When there is no EASA AMC to a certain point of a regulation, the means of compliance (MoC) that are proposed by the organisation to that point do not need to go through the AltMoC process. It is the responsibility of the competent authority to verify that compliance with the regulation is achieved. However, in certain cases, the organisation may propose, and the competent authority may agree, to have such MoC go through the AltMoC process.

When there is an EASA AMC, the AltMoC process is needed in the following cases (non-exhaustive list):

[1] Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139).

— an AltMoC to the regulation is technically different to the AMC that is published by EASA; and

— a Form is significantly different from the one that is included in the EASA AMC.

Note: a Form that is required by a delegated or implementing act cannot be modified.

Examples of issues that are not considered to require the AltMoC process include, but are not limited to:

— editorial changes to an EASA AMC, as long as they do not change the intent of the AMC; and

— incorporating an EASA AMC into the organisational structure, organisational processes, or standard operating procedures of an organisation with different wording and terminology that are customised to the organisation's environment if it does not change the intent of the AMC and its associated level of safety.

AMC1 21.A.124A(b) and 21.A.134A(b) Means of compliance

ED Decision 2022/021/R

DESCRIPTION SUPPORTING THE ALTERNATIVE MEANS OF COMPLIANCE

(a) The description of the alternative means of compliance (AltMoC) should include:

(1) a summary of the AltMoC;

(2) the content of the AltMoC;

(3) a statement that compliance with the regulation is achieved; and

(4) in support of that statement, an assessment that demonstrates that the AltMoC reaches an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding EASA AMC.

(b) All these elements that describe the AltMoC are an integral part of the management system records, in accordance with point 21.A.5.

21.A.125A Issuance of a letter of agreement

Regulation (EU) 2022/201

The applicant shall be entitled to have a letter of agreement issued by the competent authority agreeing to the showing of conformity of individual products, parts and appliances under this Subpart, after:

(a) having established a production inspection system that ensures that each product, part or appliance conforms to the applicable design data and is in condition for safe operation;

(b) having provided a manual that contains:

1. a description of the production inspection system required under point (a);

2. a description of the means for making the determination of the production inspection system;

3. a description of the tests required in points 21.A.127 and 21.A.128, and the names of persons authorised for the purpose of point 21.A.130(a);

(c) demonstrating that it is able to provide assistance in accordance with points 21.A.3A and 21.A.129(d).

GM No 1 to 21.A.125A Letter of agreement – Meaning of individual

ED Decision 2012/020/R

'Individual' means that each part number or type of item (i.e., product, part or appliance) to be produced should be specifically referenced, either directly or through a referenced capability list, in the letter of agreement from the competent authority. The letter may also specify any limitation in the production rate.

GM No 1 to 21.A.125A(b) Letter of agreement – Contents of the Manual

ED Decision 2012/020/R

The manual referred in 21.A.125A(b) should include, at least the following information:

1. Declaration by the applicant of undertaking in respect of
   - 1.1 the requirements defined in Part 21 Section A Subpart F
   - 1.2 the procedures contained in the manual and in the documentation mentioned herein
   - 1.3 every legal provision laid down for the carrying on of the business activities (statutory declaration).
2. Declaration by the applicant certifying the conformity of the manual to the requirements defined in Part 21 Section A Subpart F
3. Jobs, power and responsibilities of the accountable personnel
4. Organisation chart, if required by the competent authority
5. Description of the resources, including human resources, with an indication of the personnel qualification criteria
6. Description of location and equipment
7. Description of the scope of work, the production processes and techniques, and reference to the 'capability list'
8. Communications with the competent authority, and specifically those required by 21.A.125A(c)
9. Assistance and communication with the design approval holder, and the means of compliance with 21.A.125A(c)
10. Amendments to the Manual
11. Description of the Inspection System (including test, see GM No 2 to 21.A.125A(b), and 21.A.127 and 21.A.128), and the procedures to meet 21.A.126 and associated GM
12. List of suppliers
13. Issuing of the Statement of Conformity and competent authority inspection for validation

If the information is listed in the Manual in a different order a cross-reference to the above list should be made available in the Manual.

GM No 2 to 21.A.125A(b) Letter of agreement – Production Inspection System: Functional Tests

ED Decision 2012/020/R

All items produced should be subject to inspection to be carried out at suitable phases which permit an effective verification of conformity with the design data.

These inspections may provide for the execution of tests to measure performances as set out in the applicable design data.

Considerations of complexity of the item and/or its integration in the next level of production will largely determine the nature and time for these tests, for example:

— appliances - will require full functional testing to the specifications

— parts - will at least require basic testing to establish conformity, but due allowance may be made for further testing carried out at the next level of production

— material - will require verification of its stated properties.

GM 21.A.125A(c) Letter of agreement – Assistance

ED Decision 2012/020/R

The competent authority should be provided with material which defines the means of providing assistance as required by 21.A.125A(c). Suitable descriptive material should be included in the Manual, as described in GM No 1 to 21.A.125A(b).

21.A.125B Findings and observations

Regulation (EU) 2022/201

(a) After receipt of the notification of findings in accordance with point 21.B.125, the holder of a letter of agreement shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;
2. define a corrective action plan;
3. demonstrate the implementation of the corrective action to the satisfaction of the competent authority.

(b) The actions referred to in point (a) shall be performed within the period agreed with that competent authority in accordance with point 21.B.125.

(c) The observations received in accordance with point 21.B.125(e) shall be given due consideration by the holder of the letter of agreement. The organisation shall record the decisions taken in respect of those observations.

GM No 1 to 21.A.125B(a) Uncontrolled non-compliance with applicable design data

ED Decision 2012/020/R

An uncontrolled non-compliance with applicable design data is a non-compliance:

a) that cannot be discovered through systematic analysis or

b) that prevents identification of affected products, parts, appliances, or material.

GM No 2 to 21.A.125B(a) Examples for level one findings

ED Decision 2012/020/R

Examples for level 1 findings are non-compliances with any of the following points, that could affect the safety of the aircraft:

21.A.126, 21.A.127, 21.A.128, 21.A.129.

It should be anticipated that a non-compliance with these points is only considered a level one finding when objective evidence has been found that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.

GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings and observations

ED Decision 2022/021/R

ROOT CAUSE ANALYSIS

(a) It is important that the analysis does not primarily focus on establishing who or what caused the non-compliance, but on why it was caused. Establishing the root cause(s) of non-compliance often requires an overarching view of the events and circumstances that led to it, to identify all the possible systemic and contributing factors (human factors (HF), regulatory, organisational, technical factors, etc.) in addition to the direct factors.

(b) A narrow focus on single events or failures, or the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the non-compliance, may not properly reflect the complexity of the issue, and therefore, there is a risk that important factors that must be considered to prevent reoccurrence will be ignored.

Such an inappropriate or partial root cause analysis often leads to applying ‘quick fixes’ that only address the symptoms of the non-compliance. A peer review of the results of the root cause analysis may increase its reliability and objectivity.

AMC1 21.A.125B(a)(3), 21.A.158(a)(3) and 21.A.258(a)(3) Findings and observations

ED Decision 2022/021/R

FINDING-RELATED CORRECTIVE-ACTION PLAN AND IMPLEMENTATION

After receipt of notification of findings, the organisation should identify and define the action for all findings, to address the effects of the non-compliance, as well as its root cause(s) and contributing factor(s).

Depending on the issues identified, the organisation may need to take immediate corrective action.

The corrective action plan should:

— include the correction of the issue, corrective and preventive action, as well as the planning to implement them; and

— be timely submitted to the competent authority for acceptance before it is effectively implemented.

After receiving the competent authority’s acceptance of the corrective action plan, the organisation should implement the associated action.

Within the agreed period, the organisation should inform the competent authority that the corrective action plan has been implemented and should send the associated pieces of evidence, on request from the competent authority.

AMC1 21.A.125B(c), 21.A.158(c), 21.A.258(c) Findings and observations

ED Decision 2022/021/R

DUE CONSIDERATION TO OBSERVATIONS

For each observation that is notified by the competent authority, the organisation should analyse the related issues and determine when action is needed.

The handling of the observations may follow a process similar to the handling of the findings by the organisation.

The organisation should record the analysis and the related outputs, such as action taken, or the reasons why no action was taken.

21.A.125C Duration and continued validity

Regulation (EU) 2022/201

(a) The letter of agreement shall be issued for a limited period of time that in any case shall not exceed 1 year. It shall remain valid subject to the organisation's compliance with all the following conditions:

1. the production organisation continues to comply with the applicable requirements of this Annex;
2. the production organisation or any of its partners, suppliers or subcontractors acknowledges that the competent authority may carry out investigations in accordance with point 21.A.9;
3. the production organisation is able to provide the competent authority with evidence showing that it maintains satisfactory control of the manufacture of products, parts and appliances under the letter of agreement;
4. the letter of agreement has not been revoked by the competent authority under point 21.B.65, has not been surrendered by the production organisation, and its duration has not expired.

(b) Upon surrender, revocation or expiry, the letter of agreement shall be returned to the competent authority.

21.A.126 Production inspection system

Regulation (EU) 2022/201

(a) The production inspection system required under point 21.A.125A(a) shall provide a means for determining that:

1. incoming materials, and bought or subcontracted parts, used in the finished product are as specified in the applicable design data;
2. incoming materials, and bought or subcontracted parts, are properly identified;

3. processes, manufacturing techniques and methods of assembly affecting the quality and safety of the finished product are accomplished in accordance with specifications accepted by the competent authority;

4. design changes, including material substitutions, have been approved under Subpart D or E and controlled before being incorporated in the finished product.

(b) The production inspection system required by point 21.A.125A(a), shall also be such as to ensure that:

1. parts in process are inspected for conformity with the applicable design data at points in production where accurate determinations can be made;

2. materials subject to damage and deterioration are suitably stored and adequately protected;

3. current design drawings are readily available to manufacturing and inspection personnel, and used when necessary;

4. rejected materials and parts are segregated and identified in a manner that precludes installation in the finished product;

5. materials and parts that are withheld because of deviations from type design or production specifications, and that are to be considered for installation in the finished product, are subjected to an approved engineering and manufacturing review procedure. Those materials and parts that have been found in that procedure to be serviceable shall be properly identified and reinspected if it is necessary to be reworked or repaired. Materials and parts rejected in that procedure shall be marked and disposed of to ensure that they are not incorporated in the final product.

GM 21.A.126 Production inspection system

ED Decision 2012/020/R

GM 21.A.126(a) and (b) have been developed for persons producing under Part 21 Section A Subpart F on the long term basis as defined in 21.A.124(b)(1)(i).

For those persons producing under Part 21 Section A Subpart F as a transient phase under 21.A.124(b)(1)(ii), compliance with 21.A.126 may also be demonstrated to the satisfaction of the competent authority by using the equivalent Part 21 Section A Subpart G AMC/GM.

GM 21.A.126(a)(1) Production inspection system – Conformity of supplied parts, appliances and material

ED Decision 2012/020/R

1. The person producing under Subpart F is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity, as appropriate, of raw materials, subcontracted works, and supplied products, parts, appliances or material, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.

2. Control may be based upon use of the following techniques, as appropriate:

2.1 first article inspection, including destruction if necessary, to verify that the article conforms to the applicable data for new production line or new supplier,

2.2 incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt,

2.3 identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents,

2.4 any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subject to the checks normally provided by subsequent production or inspection stages.

3. The person producing under Part 21 Subpart F may rely upon an EASA Form 1 issued in accordance with Part 21 if provided as evidence of conformity with applicable design data

For suppliers not holding a POA the inspection system of the person producing under Part 21 Subpart F should establish a system for control of incoming materials and bought or subcontracted items which provides for inspections and tests of such items by the person producing under Part 21 Subpart F at the supplier's facility, if the item cannot or will not be completely inspected upon receipt.

GM 21.A.126(a)(2) Production inspection system – Identification of incoming materials and parts

ED Decision 2012/020/R

All parts and materials coming from external parties should be identified and inspected to ascertain that they have not been damaged during transport or unpacking, that the incoming parts and materials have the appropriate and correct accompanying documentation and that the configuration and condition of the parts or materials is as laid down in that documentation.

Only on completion of these checks and of any incoming further verifications laid down in the procurement specification, may the part or material be accepted for warehousing and used in production.

This acceptance should be certified by an inspection statement.

A suitable recording system should allow reconstruction at any time of the history of every material or part.

The areas where the incoming checks are carried out and the materials or parts are stored pending completion of the checks should be physically segregated from other departments.

GM No 1 to 21.A.126(a)(3) Production inspection system – List of specifications

ED Decision 2012/020/R

It is the responsibility of:

1. The designer, to define all necessary processes, techniques and methods to be followed during manufacture (21.A.31) and this information will be provided as part of the applicable design data.

2. The manufacturer, to ensure that all processes are carried out strictly in accordance with the specifications provided as part of the applicable design data.

GM No 2 to 21.A.126(a)(3) Production inspection system – Means of checking of the production processes

ED Decision 2012/020/R

The Production Inspection System should be provided with appropriate means of checking that production processes, whether performed by the person producing under Part 21 Subpart F or by sub-contractors under its control, are carried out in accordance with applicable data, including:

1. A system for the control and authorised amendment of data provided for the production, inspection and test to ensure that it is complete and up-to-date at the point of use
2. Availability of personnel with suitable qualification, experience, and training for each required production, inspection, and test task. Special attention should be paid to tasks requiring specialised knowledge and skill, e.g., NDT/NDI, welding...
3. A working area where the working conditions and environment are controlled as appropriate in respect of: cleanliness, temperature, humidity, ventilation, lighting, space/access, protection against noise and pollution
4. Equipment and tools sufficient to enable all specified tasks to be accomplished in a safe and effective manner without detrimental effect on the items under production. Calibration control of equipment and tools which affect critical dimensions and values must demonstrate compliance with, and be traceable to, recognised national or international standards.

GM 21.A.126(a)(4) Production inspection system – Applicable design/production data procedures

ED Decision 2012/020/R

1. When a person producing under Part 21 Subpart F is developing its own manufacturing data from the design data package delivered by a Design holder, procedures should demonstrate the correct transcription of the original design data.
2. Procedures should define the manner in which applicable design data is used to issue and update the production/inspection data, which determines the conformity of products, parts, appliances and materials. The procedure should also define the traceability of such data to each individual product, part, appliance or material for the purpose of stating the condition for safe operation and for issuing a Statement of Conformity.
3. During execution, all works should be accompanied by documentation giving either directly or by means of appropriate references, the description of the works as well as the identification of the personnel in charge of inspection and execution tasks for each of the different work phases.

GM 21.A.126(b)(1) Production inspection system – Inspection of parts in process

ED Decision 2012/020/R

The purpose of the Production Inspection System is to check at suitable points during production and provide objective evidence that the correct specifications are used, and that processes are carried out strictly in accordance with the specification.

During the manufacturing process, each article should be inspected in accordance with a plan which identifies the nature of all inspections required and the production stages at which they occur. The

plan should also identify any particular skills or qualification required of person(s) carrying out the inspections (e.g., NDT personnel). A copy of the plan should be included in, or referenced by, the manual required by 21.A.125A(b).

If the parts are such that, if damaged, they could compromise the safety of the aircraft, additional inspections for such damage should be performed at the completion of each production stage.

GM 21.A.126(b)(2) Production inspection system – Suitable storage and protection

ED Decision 2012/020/R

1. Storage areas should be protected from dust, dirt, or debris, and adequate blanking and packaging of stored items should be practised.
2. All parts should be protected from extremes of temperatures and humidity and, where needed, temperature-controlled or full air-conditioned facilities should be provided.
3. Racking and handling equipment should be provided such as to allow storage, handling and movement of parts without damage.
4. Lighting should be such as to allow safe and effective access and handling, but should also cater for items which are sensitive to light e.g., rubber items.
5. Care should be taken to segregate and shield items which can emit fumes (e.g., wet batteries), substances or radiation (e.g., magnetic items) which are potentially damaging to other stored items.
6. Procedures should be in place to maintain and record stored parts identities and batch information.
7. Access to storage areas should be restricted to authorised personnel who are fully trained to understand and maintain the storage control arrangements and procedures.
8. Provisions should be made for segregated storage of non-conforming items pending their disposition (see GM 21.A.126(b)(4)).

GM 21.A.126(b)(3) Production inspection system – Use of derived data instead of original design data

ED Decision 2012/020/R

Where derived data, e.g., worksheets, process sheets, fabrication/inspection instructions, etc., is used instead of original design drawings, documents identification and control procedures should be used to ensure that the documentation in use is always accurate and current.

GM 21.A.126(b)(4) Production inspection system – Segregation of rejected material

ED Decision 2012/020/R

All materials and parts which have been identified at any stage in the manufacturing process as not conforming to the specific working and inspection instructions must be suitably identified by clearly marking or labelling, to indicate their non-conforming status.

All such non-conforming material or parts should be removed from the production area and held in a restricted access segregated area until an appropriate disposition is determined in accordance with 21.A.126(b)(5).

GM1 21.A.126(b)(5) Production inspection system — Engineering and manufacturing review procedure

ED Decision 2022/021/R

(a) The procedure should permit to record the deviation, to present it to the design approval holder (DAH) under the provisions of point 21.A.122, and to record the results of the review and action taken consequently as regards the part/product.

(b) Any unintentional deviation from the manufacturing/inspection data should be recorded and handled in accordance with Part 21, Section A, Subpart D or E as changes to the approved design.

21.A.127 Tests: aircraft

Regulation (EU) No 748/2012

(a) Each manufacturer of an aircraft manufactured under this Subpart shall establish an approved production ground and flight test procedure and check-off forms, and in accordance with those forms, test each aircraft produced, as a means of establishing relevant aspects of compliance with point 21.A.125A(a).

(b) Each production test procedure shall include at least the following:

1. a check on handling qualities;
2. a check on flight performance (using normal aircraft instrumentation);
3. a check on the proper functioning of all aircraft equipment and systems;
4. a determination that all instruments are properly marked, and that all placards and required flight manuals are installed after flight test;
5. a check of the operational characteristics of the aircraft on the ground;
6. a check on any other items peculiar to the aircraft being tested.

GM 21.A.127 Approved production ground and flight tests

ED Decision 2012/020/R

The production ground and flight tests for new aircraft will be specified by the aircraft design organisation.

21.A.128 Tests: engines and propellers

Regulation (EU) No 748/2012

Each manufacturer of engines, or propellers manufactured under this Subpart shall subject each engine, or variable pitch propeller, to an acceptable functional test as specified in the type-certificate holder's documentation, to determine if it operates properly throughout the range of operation for which it is type-certificated, as a means of establishing relevant aspects of compliance with point 21.A.125A(a).

GM No 1 to 21.A.128 Acceptable functional test – Engines

ED Decision 2012/020/R

The functional test required for a new engine will be specified by the engine design organisation and will normally include at least the following:

1. Break-in runs that include a determination of fuel and oil consumption and a determination of power characteristics at rated maximum continuous power or thrust and, if applicable, at rated take-off power or thrust.

2. A period of operation at rated maximum continuous power or thrust. For engines having a rated take-off power or - thrust, part of that period should be at rated take-off power or - thrust.

The test equipment used for the test run should be capable of output determination of accuracy sufficient to assure that the engine output delivered complies with the specified rating and operation limitations.

GM No 2 to 21.A.128 Acceptable functional test – Variable pitch propellers

ED Decision 2012/020/R

The functional tests required for a new propeller will be specified by the propeller design organisation and should normally include a number of complete cycles of control throughout the propeller pitch and rotational speed ranges. In addition, for feathering and/or reversing propellers, several cycles of feathering operation and reversing operation from the lowest normal pitch to the maximum reverse pitch, should normally be required.

GM No 3 to 21.A.128 Acceptable functional test – Engines and Propellers

ED Decision 2012/020/R

After functional test, each engine or propeller should be inspected to determine that the engine or propeller is in condition for safe operation. Such inspection will be specified by the design organisation and should normally include internal inspection and examination. The degree of internal inspections will normally be determined on the basis of the positive results of previous inspections conducted on the first production engines, and on the basis of service experience.

21.A.129 Obligations of the production organisation

Regulation (EU) 2022/201

Each manufacturer of a product, part or appliance being manufactured under this Subpart shall:

(a) make each product, part or appliance available for inspection by the competent authority;

(b) maintain at the place of manufacture the technical data and drawings necessary to determine whether the product conforms to the applicable design data;

(c) maintain the production inspection system that ensures that each product conforms to the applicable design data and is in condition for safe operation;

(d) provide assistance to the holder of the type-certificate, restricted type-certificate or design approval in dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced;

(e) comply with Subpart A of this Section.

GM 21.A.129(a) Availability for inspection by the competent authority

ED Decision 2012/020/R

Each product, part or appliance should be made available for inspection at any time at the request of the competent authority.

It is recommended that a pre-defined plan of inspection points be established and agreed with the competent authority to be used as a basis for such inspections.

The manufacturer should provide such documentation, tools, personnel, access equipment etc. as necessary to enable the competent authority to perform the inspections.

AMC No 1 to 21.A.129(c) Obligations of the manufacturer – Conformity of prototype models and test specimens

ED Decision 2012/020/R

21.A.33 requires determination of conformity of prototype models and test specimens to the applicable design data. For a complete aircraft a 'conformity document', that has to be validated by the competent authority, should be provided as part of the assistance to the design approval applicant. For products other than a complete aircraft, and for parts and appliances, an EASA Form 1 validated by the competent authority may be used as a conformity document as part of the assistance to the design approval applicant.

AMC No 2 to 21.A.129(c) Obligations of the manufacturer – Conformity with Applicable Design Data

ED Decision 2012/020/R

Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type-certificate holder. There are also likely to be unintentional divergences (concessions or non-conformances) during the manufacturing process. All these changes are required to have been approved by the design approval applicant/holder, or when necessary by the Agency.

AMC No 3 to 21.A.129(c) Obligations of the manufacturer – Condition for safe operation

ED Decision 2012/020/R

Before issue of the Statement of Conformity to the competent authority the manufacturer under this Subpart should make an investigation so as to be satisfied in respect to each of the items listed below. The documented results of this investigation should be kept on file by the manufacturer. Certain of these items may be required to be provided (or made available) to the operator or owner of the aircraft, and, for validation of the statement of conformity, to the competent authority.

1. Equipment or modifications which do not meet the requirements of the state of manufacture but have been accepted by the competent authority of the importing country.

2. Identification of products, parts or appliances which:

   2.1 Are not new

   2.2 Are furnished by the buyer or future operator (including those identified in 21.A.801 and 805).

3. Technical records which identify the location and serial numbers of components that have traceability requirements for continued airworthiness purposes including those identified in 21.A.801 and 21.A.805.

4. Log book and a modification record book for the aircraft as required by the Agency.

5. Log books for products identified in 21.A.801 installed as part of the type design as required by the Agency.

6. A weight and balance report for the completed aircraft.

7. A record of missing items or defects which do not affect airworthiness these for example could be furnishing or BFE (Items may be recorded in a technical log or other suitable arrangement such that the operator and Agency are formally aware).

8. Product support information required by other associated implementing rules and CS or GM, such as a Maintenance Manual, a Parts Catalogue, or MMEL all of which are to reflect the actual build standard of the particular aircraft. Also an Electrical load analysis and a wiring diagram.

9. Records which demonstrate completion of maintenance tasks appropriate to the test flight flying hours recorded by the aircraft. These records should show the relationship of the maintenance status of the particular aircraft to the manufacturers recommended maintenance task list and the Maintenance Review Board (MRB) document/report.

10. Details of the serviceability state of the aircraft in respect of, a) the fuel and oil contents, b) provision of operationally required emergency equipment such as life rafts, etc.

11. Details of the approved interior configuration if different from that approved as part of the type design.

12. An approved Flight Manual which conforms to the build standard and modification state of the particular aircraft should be available.

13. Show that inspections for foreign objects at all appropriate stages of manufacture have been satisfactorily performed.

14. The registration has been marked on the exterior of the aircraft as required by national legislation. Where required by national legislation fix a fireproof owners nameplate.

15. Where applicable, there should be a certificate for noise and, for the aircraft radio station.

16. The installed compass and or compass systems have been adjusted and compensated and a deviation card displayed in the aircraft.

17. Software criticality list.

18. A record of rigging and control surface movement measurements.

19. Details of installations which will be removed before starting commercial air transport operations (e.g., ferry kits for fuel, radio or navigation).

20. List of all applicable Service Bulletins and airworthiness directives that have been implemented.

21.A.130 Statement of conformity

Regulation (EU) 2021/1088

(a) Each manufacturer of a product, part or appliance manufactured under this Subpart shall raise a statement of conformity, an EASA Form 52 (see Appendix VIII), for complete aircraft, or EASA Form 1 (see Appendix I), for other products, parts or appliances. This statement shall be signed by an authorised person who holds a responsible position in the manufacturing organisation.

(b) A statement of conformity shall include all of the below:

1. for each product, part or appliance, a statement that the product, part or appliance conforms to the approved design data and is in condition for safe operation;
2. for each aircraft, a statement that the aircraft has been ground- and flight-checked in accordance with point 21.A.127(a);
3. for each engine, or variable pitch propeller, a statement that the engine or variable pitch propeller has been subjected by the manufacturer to a final functional test in accordance with point 21.A.128;
4. additionally, in the case of environmental protection requirements:
   (i) a statement that the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine, and
   (ii) a statement that the completed aeroplane is in compliance with the applicable CO_2 emissions requirements on the date its first certificate of airworthiness is issued.

(c) Each manufacturer of such a product, part or appliance shall:

1. upon the initial transfer by it of the ownership of such a product, part or appliance; or
2. upon application for the original issue of an aircraft certificate of airworthiness; or
3. upon application for the original issue of an airworthiness release document for an engine, a propeller, a part or appliance,

present a current statement of conformity, for validation by the competent authority.

(d) The competent authority shall validate by counter-signature the statement of conformity if it finds after inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation.

GM1 21.A.130, 21.A.163 and 21.A.165 Performance of tasks in real time for the issuance of an 'EASA Form 1' for prototype and new parts, appliances and products other than complete aircraft, using information and communication technologies (ICT)

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote ICT to support the issuance of an 'EASA Form 1' for prototype and newly produced parts, appliances and products other than complete aircraft.

It is the responsibility of the production organisation to assess whether the use of remote ICT constitutes a suitable alternative to the physical inspection of the part, appliance or product in

accordance with the applicable requirements. The production organisation that intends to use the remote ICT for such purposes should first discuss the feasibility aspects with its competent authority.

(a) Terminology

In the context of this GM, the following terminology is used:

— 'issue of an EASA Form 1' means the issuance of an EASA Form 1 under Part 21 Subpart G by a certifying staff, raise an EASA Form 1 under Part 21 Subpart F by an authorised person, and the validation of an EASA Form 1 under Part 21 Subpart F by a competent authority inspector, except in the case of issuance of an EASA Form 1 for the correction of error(s) on a previously issued certificate and for the recertification of an item from 'prototype' to 'new' provided that the design data has not changed;

— 'authorised staff' means certifying staff as defined in Part 21 Subpart G, and 'authorised person' and 'competent authority inspector' as defined in Part 21 Subpart F;

— 'item' means any part, appliance or product other than a complete aircraft;

— 'applicable design data' means non-approved design data for a prototype item and approved design data for a newly produced item;

— 'task' means any inspection, test and/or verification, as described in a documented procedure, which is needed to be performed by an authorised staff before signing an EASA Form 1;

— 'remote ICT' means any real-time video and audio communication tools using information and communication technologies (ICT) whose aim is to enable the performance of the task(s) by the authorised staff from a location different from that where the item is located (on-site).

(b) Regulatory context

The following entities may issue an EASA Form 1 for produced items in order to certify their conformity to the applicable design data and, for new items, their condition for safe operation:

— the holder of a letter of agreement (LoA) that is issued in accordance with Part 21 Subpart F (refer to point 21.A.130(a));

— the competent authority in the context of Part 21 Subpart F (refer to point 21.A.130(d));

— the holder of a production organisation approval (POA) in accordance with Part 21 Subpart G (refer to point 21.A.163(c)).

An EASA Form 1 has to be issued by appropriately qualified authorised staff. Part 21 does not require authorised staff to be on-site when issuing an EASA Form 1, nor how the production organisation and the competent authority shall determine whether the part/appliance/product other than a complete aircraft conforms to the applicable design data and, for a new item, is in a condition for safe operation. These should be detailed in a documented procedure accepted by the competent authority.

Part 21 requires:

— in point 21.A.130(d) that the competent authority validate the EASA Form 1 following inspections performed in accordance with 21.B.135(b) if it finds after the inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation;

— in point 21.A.165(c) that the POA holder has to determine that:

— other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1;

— other products, parts or appliances conform to the applicable data before issuing an EASA Form 1.

Typically, compliance with these requirements is ensured through the on-site presence of the authorised staff in order to guarantee they have appropriate access to the item, as needed.

However, compliance with these requirements may be also ensured in certain circumstances, determined as per the considerations described in point (c) below, by remotely conducting the tasks which are needed before the issuance of an EASA Form 1 by the use of remote ICT. The following considerations should be used as guidelines when the on-site presence of the authorised staff is to be replaced by virtual presence, using remote ICT.

(c) The use of remote ICT to support the issuance of an EASA Form 1

Remote ICT may have limitations that could render it unsuitable for some applications. Accordingly, careful consideration and risk management should be applied when determining when to use remote ICT. These considerations, listed below, are however not exhaustive and should not be treated as a checklist.

(1) General considerations

— As an overarching principle, it needs to be determined whether the nature of the tasks to be performed by the authorised staff allows the use of remote ICT.

— The facility where the item is located:

  — should be referred to in EASA Form 65 or EASA Form 55, directly or indirectly by reference to the corresponding section of the manual or production organisation exposition (POE); or

  — for a POA, should be a facility from where a POE procedure related to point 21.A.139(b)(1)(xv) authorises the issuance of an EASA Form 1.

— The complexity, novelty and safety criticality of the item to be released with the EASA Form 1 should be taken into account.

— The level of competence and experience of the personnel in the use of the particular procedures and equipment that will be used to perform the tasks before issuing EASA Form 1.

— Previous experience of the organisation / confidence in the organisation's inspection system / quality system / management system.

— The appropriateness of the inspection and test instruments and/or equipment, especially if used to evaluate qualitative aspects of a product, part or appliance.

(2) Equipment and set-up considerations

— The suitability of video resolution, fidelity, and field of view for the task being performed.

— The need for multiple cameras, imaging systems or microphones, and whether the person that performs or witnesses the tasks can switch between them, or direct them to be switched, and has the possibility to stop the process, ask a question, move the equipment, etc.

— The controllability of viewing direction, zoom, and lighting.

— The appropriateness of audio fidelity for the evaluation being conducted.

— Whether real-time, uninterrupted communication between the person(s) authorised to remotely witness the activity (authorised staff) and the personnel performing it exists at the location where the item is located.

— The need for unique testing devices or equipment (for example, fast-frame cameras, special lighting conditions, sensitive listening devices, mobile phones with cameras for HD video calls).

— Whether personnel have been adequately trained in the proper set-up, validation and use of the technology, tools and/or equipment to be used.

— The need for the recording of audio and video data, as well for its retention or for the retention of other information.

(3) Cybersecurity considerations

There are cases where the facilities where the tasks have to be performed are subject to strict security limitations. When using remote ICT for the tasks needed before issuing an EASA Form 1, it is the responsibility of the organisation to provide an equivalent level of security, therefore the person that is responsible for IT security within the organisation should concur to the ICT technology before proceeding.

(4) Documenting the use of the remote ICT

The documented processes (procedures) developed by the holder of a letter of agreement (LoA) or a POA should be accepted by the competent authority, and should describe the following:

— the risk assessment process required to determine the appropriateness of the remote ICT taking into account the above-mentioned considerations;

— the tasks to be performed, including preparation activities, inspections, tests, verifications to be done, personnel involved in the remote ICT activities and their level of competence;

— that it is necessary to guarantee that authorised staff have access to all necessary data (e.g. drawings, schematics, datasheets, etc.) they require in order to determine that the item conforms to the applicable design data, and how this can be ensured;

— how remote ICT will be used in real time (not pre-recorded) so that authorised staff may direct the performance of the tasks as if it were conducted in-person, on-site, with the aid of the equipment or the personnel supporting the activity at the remote location;

— the procedures for conducting a reinspection in case the equipment malfunctions or the process fails to yield acceptable results; a reinspection using remote ICT may be accomplished after correcting the malfunction or process, or by an actual on-site inspection;

— how authorised staff should record and communicate any difficulties or concerns regarding the process so that the organisation can improve its programme;

— how the use of the remote ICT will be documented in the required records; and

— how the organisation’s IT security is ensured throughout the remote ICT process (data protection and intellectual property of the organisation also need to be safeguarded).

AMC No 1 to 21.A.130(b) Statement of conformity for complete aircraft

ED Decision 2019/018/R

1. PURPOSE AND SCOPE

The description under this AMC refers only to the use of the aircraft Statement of Conformity issued under Part 21 Section A Subpart F. Statement of Conformity under Part 21 Subpart F for products other than complete aircraft, and for parts and appliances is described in AMC No 2 to 21.A.130(b).

Use of the aircraft Statement of Conformity issued by an approved production organisation is described in 21.A.163(b) under Part 21 Section A Subpart G and the completion instructions are to be found in the Appendices to Part 21.

The purpose of the aircraft Statement of Conformity (EASA Form 52) issued under Part 21 Section A Subpart F is to present to the competent authority a complete aircraft. The competent authority only validates the Statement of Conformity if it finds, as described in 21.A.130 and its associated GM, that the aircraft conforms with the type design and is in condition for safe operation.

2. GENERAL

The Statement of Conformity must comply with the format attached including block numbers and the location of each Block. The size of each Block may however be varied to suit the individual application, but not to the extent that would make the Statement of Conformity unrecognisable. If in doubt consult the competent authority.

The Statement of Conformity must either be pre-printed or computer generated but in either case the printing of lines and characters must be clear and legible. Pre-printed wording is permitted in accordance with the attached model but no other certification statements are permitted.

Statements of Conformity must be issued in one or more of the official language(s) of the issuing competent authority with translations in English shown below, if required. Completion may be either machine/computer printed or hand-written using block letters to permit easy reading.

A copy of the Statement of Conformity and all referenced attachments are to be retained by the manufacturer. A copy of the validated Statement of Conformity is to be retained by the competent authority.

3. COMPLETION OF THE AIRCRAFT STATEMENT OF CONFORMITY BY THE ORIGINATOR

There must be an entry in all Blocks to make the document a valid Statement.

A Statement of Conformity must not be issued for validation by the competent authority, unless the design of the aircraft and its installed products are approved.

The information required in Blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the manufacturer, unless the competent authority agrees otherwise.

This Statement of Conformity is not intended to provide for the complete equipment fit required by the applicable operational rules. However, some of these individual items may be included in Block 10 or in the approved type design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operation.

Block 1 Enter name of the State of manufacture.

Block 2 The competent authority under which authority the Statement of Conformity is issued.

Block 3 A unique serial number should be pre-printed in this Block for Statement control and traceability purposes. Except that in the case of a computer generated document the number need not be pre-printed where the computer is programmed to produce and print a unique number.

Block 4 The full name and location address of the manufacturer issuing the statement. This Block may be pre-printed. Logos, etc., are permitted if the logo can be contained within the Block.

Block 5 The aircraft type in full as defined in the type-certificate and its associated data sheet.

Block 6 The type-certificate reference numbers and issue for the subject aircraft.

Block 7 If the aircraft is registered then this mark will be the registration mark. If the aircraft is not registered then this will be such a mark that is accepted by the competent authority of the Member State and, if applicable, by the competent authority of a third country.

Block 8 The identification number assigned by the manufacturer for control and traceability and product support. This is sometimes referred to as a Manufacturers Serial No or Constructors No.

Block 9 The engine and propeller type(s) in full as defined in the relevant type-certificate and its associated data sheet. Their manufacturer identification No and associated location should also be shown.

Block 10 Approved design changes to the Aircraft Definition.

Block 11 A listing of all applicable airworthiness directives (or equivalent) and a declaration of compliance, together with a description of the method of compliance on the subject individual aircraft including products and installed parts, appliances and equipment. Any future compliance requirement time should be shown.

Block 12 Approved unintentional deviation to the approved type design sometimes referred to as concessions, divergences, or non-conformances.

Block 13 Only agreed exemptions, waivers or derogations may be included here..

Block 14 Remarks: Any statement, information, particular data or limitation which may affect the airworthiness of the aircraft. If there is no such information or data, state: ‘NONE’. If the competent authority has endorsed a CO_2 emissions production cut-off exemption, make the following record: ‘Aeroplane exempted from the applicability of paragraph 2.1.1 [x] as referenced in the 1st Edition of Annex 16, Volume III, Part II, Chapter 2 (July 2017).’

Block 15 Enter ‘Certificate of Airworthiness’ or ‘Restricted Certificate of Airworthiness’ for the Certificate of Airworthiness requested.

Block 16 Additional requirements such as those notified by an importing country should be noted in this Block.

Block 17 Validity of the Statement of Conformity is dependent on full completion of all Blocks on the form. A copy of the flight test report together with any recorded defects and rectification details should be kept on file by the manufacturer. The report should be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g., test pilot or flight test engineer. The flight tests performed are those required by 21.A.127 and GM 21.A.127, to ensure that the aircraft conforms to the applicable design data and is in condition for safe operation.

The listing of items provided (or made available) to satisfy the safe operation aspects of this statement should be kept on file by the manufacturer.

Block 18 The Statement of Conformity may be signed by the person authorised to do so by the manufacturer in accordance with 21.A.130(a). A rubber stamp signature should not be used.

Block 19 The name of the person signing the certificate should be typed or printed in a legible form.

Block 20 The date the Statement of Conformity is signed must be given.

Block 21 For production under Part 21 Subpart F, state 'NOT APPLICABLE'

Additionally, for production under Part 21 Section A Subpart F, this Block must include validation by the competent authority. For this purpose, the validation statement below should be included in the Block 21 itself, and not referred in a separate document. The statement can be pre-printed, computer generated or stamped, and should be followed by the signature of the representative of the competent authority validating the certificate, the name and the position/identification of such representative of the competent authority, and the date of such validation by the competent authority.

VALIDATION STATEMENT:

'After due inspection the *<identify the issuing competent authority>* is satisfied that this document constitutes an accurate and valid Statement of Conformity in accordance with Part 21 Section A Subpart F.'

AMC2 21.A.130(b) Statement of Conformity for Products (other than complete aircraft), parts, appliances and materials — The Authorised Release Certificate (EASA Form 1)

ED Decision 2021/011/R

A. INTRODUCTION

This AMC relates specifically to the use of the EASA Form 1 for manufacturing purposes under Part 21 Subpart F. It can be used as a supplement to the completion instructions in Part 21, Appendix I which covers the use of the EASA Form 1.

1. PURPOSE AND USE

The EASA Form 1 is prepared and signed by the manufacturer. For production under Part 21 Subpart F it is presented for validation by the competent authority.

Under Subpart F the certificate may only be issued by the competent authority.

A mixture of items released under Subpart G and under Subpart F of Part 21 is not permitted on the same certificate.

2. GENERAL FORMAT

Refer to Part 21 Appendix I.

3. COPIES

Refer to Part 21 Appendix I.

The Part 21 Subpart F originator must retain a copy of the certificate in a form that allows verification of original data.

4. ERROR(S) ON THE CERTIFICATE

If an end user finds an error(s) on a certificate, they must identify it/them in writing to the originator. The originator may prepare and sign a new certificate for validation by the competent authority if they can verify and correct the error(s).

The new certificate must have a new tracking number, signature and date.

The request for a new certificate may be honoured without re-verification of the item(s) condition. The new certificate is not a statement of current condition and should refer to the previous certificate in block 12 by the following statement: 'This certificate corrects the error(s) in block(s) [enter block(s) corrected] of the certificate [enter original tracking number] dated [enter original issuance date] and does not cover conformity/condition/release to service.' Both certificates should be retained according to the retention period associated with the first.

5. COMPLETION OF THE CERTIFICATE BY THE ORIGINATOR

Refer to Part 21 Appendix I for completion of the certificate. Specific Part 21 Subpart F instructions that differ from the Part 21 Appendix I are provided below.

Block 1 – Approving competent authority/Country

State the name and country of the competent authority under whose jurisdiction this certificate is issued. When the competent authority is the Agency, 'EASA' must be stated.

Block 12 – Remarks

Examples of conditions which would necessitate statements in Block 12 are:

a) When the certificate is used for prototype purposes, the following statement must be entered at the beginning of Block 12:

'NOT ELIGIBLE FOR INSTALLATION ON IN-SERVICE TYPE-CERTIFICATED AIRCRAFT'.

b) Re-certification of items from 'prototype' (conformity only to non-approved data) to 'new' (conformity to approved data and in a condition for safe operation) once the applicable design data is approved.

The following statement must be entered in Block 12:

RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW':

THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA [insert TC/STC number, revision level], DATED [insert date if necessary for

identification of revision status], TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.

c) When a new certificate is issued to correct error(s), the following statement must be entered in Block 12:

'THIS CERTIFICATE CORRECTS THE ERROR(S) IN BLOCK(S) [enter block(s) corrected] OF THE CERTIFICATE [enter original tracking number] DATED [enter original issuance date] AND DOES NOT COVER CONFORMITY/CONDITION/RELEASE TO SERVICE'.

d) In case of an engine, when the competent authority has granted an exemption from the environmental protection requirements, the following statement must be entered in block 12:

'ENGINE EXEMPTED FROM [*REFERENCE TO THE TYPE OF EMISSION*] EMISSIONS ENVIRONMENTAL PROTECTION REQUIREMENT'

Additionally, for production under Subpart F, this block must include the Statement of Conformity by the manufacturer under 21.A.130. For this purpose, the appropriate Block 13a statement must be included in the block 12 and not referenced in a separate document. The statement may be pre-printed, computer generated or stamped, and must be followed by the signature of the manufacturer's authorised person under 21.A.130(a), the name and the position/identification of such person and the date of the signature.

Block 13b – Authorised Signature

This space shall be completed with the signature of the competent authority representative validating the Block 12 manufacturer Statement of Conformity, under 21.A.130(d). To aid recognition, a unique number identifying the representative may be added.

Block 13c – Approval/Authorisation Number

Enter the authorisation number reference. This number or reference is given by the competent authority to the manufacturer working under Part 21 Subpart F.

AMC1 21.A.130(b)(4)(i) Applicable engine exhaust emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the engine type-certificate holder. It should be noted that the competent authority has the possibility to grant exemptions from these requirements as noted in Chapter 2, paragraph 2.1.1 and Chapter 4, paragraph 4.1.1 of Part III of Volume II of Annex 16 to the Chicago Convention.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted engines that will be produced and their impact on the environment;

— considers imposing a time limit on the production of such engines; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the engine serial number, and makes it publicly available.

ICAO Doc 9501 'Environmental Technical Manual' Volume II provides guidance on the issuing of exemptions.

GM1 21.A.130(b)(4)(i) Definitions of engine type certification date and production date

ED Decision 2021/011/R

Volume II of Annex 16 to the Chicago Convention contains three different references to applicability dates:

1. the 'date of manufacture for the first individual production model', which refers to the date when the type certificate is issued for the engine type or model;
2. the 'date of application for a type certificate', which refers to the application date to the certificating authority of the State of Design of the engine type certification; and
3. the 'date of manufacture for the individual engine', which refers to the production date of a specific engine serial number (date of EASA Form 1).

The third reference refers to the date of the first engine EASA Form 1 issued after the completion of the engine production pass-off test.

The third reference is used in the application of the engine emissions production cut-off requirement, which specifies a date after which all in-production engine models must meet a certain emissions standard.

21.A.130(b)(4)(i) includes the production requirements for engine exhaust emissions.

ICAO Doc 9501 'Environmental Technical Manual' Volume II provides guidance on these applicability dates.

AMC1 21.A.130(b)(4)(ii) Applicable aeroplane CO2 emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the aeroplane type-certificate holder. This data should allow the determination of whether the aeroplane complies with the CO_2 emissions applicability requirements in Chapter 2, paragraph 2.1.1 of Part II of Volume III of Annex 16 to the Chicago Convention.

It should be noted that the competent authority has the possibility to grant exemptions as noted in Chapter 1, paragraph 1.11 and Chapter 2, paragraph 2.1.3 of Part II of Volume III of Annex 16 to the Chicago Convention,.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted aeroplanes that will be produced and their impact on the environment; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the aeroplane serial number, and makes it publicly available.

ICAO Doc 9501 'Environmental Technical Manual' Volume III provides guidance on the issuing of exemptions.

AMC 21.A.130(c) Validation of the Statement of Conformity

ED Decision 2012/020/R

It is the responsibility of the applicant to ensure that each and every product, part and appliance conforms to the applicable design data and is in condition for safe operation before issuing and signing the relevant statement of conformity. During manufacture, the applicant is expected to use such facilities, systems, processes and procedures as are described in the Manual and have been previously agreed with the competent authority.

The competent authority must then make such inspection and investigation of records and product, part or appliance as are necessary to determine that the agreed facilities, systems, processes and procedures have been used, and that the statement of conformity may be regarded as a valid document.

To enable timely inspection and investigation by the competent authority, the statement of conformity must be prepared and submitted to the competent authority immediately upon satisfactory completion of final production inspection and test.

AMC 21.A.130(c)(1) Initial transfer of ownership

ED Decision 2012/020/R

Upon transfer of ownership:

a) For a complete aircraft, whether or not an application for a certificate of airworthiness is to be made, an EASA Form 52 must be completed and submitted to the competent authority for validation.

b) For anything other than a complete aircraft an EASA Form 52 is inappropriate, and an EASA Form 1 must be completed and submitted to the competent authority for validation.

NOTE: If there is any significant delay between the last production task and presentation of the EASA Form 52 or EASA Form 1 to the competent authority, then additional evidence relating to the storage, preservation and maintenance of the item since its production must be presented to the competent authority.

SUBPART G — PRODUCTION ORGANISATION APPROVAL

21.A.131 Scope

Regulation (EU) No 748/2012

This Subpart establishes:

(a) the procedure for the issuance of a production organisation approval for a production organisation showing conformity of products, parts and appliances with the applicable design data;

(b) the rules governing the rights and obligations of the applicant for, and holders of, such approvals.

GM 21.A.131 Scope – Applicable design data

ED Decision 2019/018/R

Applicable design data is defined as all necessary drawings, specifications and other technical information provided by the applicant for, or holder of a design organisation approval, TC, STC, approval of repair or minor change design, or ETSO authorisation and released in a controlled manner to a production organisation approval holder. This should be sufficient for the development of production data to enable repeatable manufacture to take place in conformity with the design data.

Prior to issue of the TC, STC, approval of repair or minor change design or ETSO authorisation, or equivalent, design data is defined as 'not approved' but parts and appliances may be released with an EASA Form 1 as a certificate of conformity.

After issue of the TC, STC, approval of repair or minor change or ETSO authorisation, or equivalent, this design data is defined as 'approved' and items manufactured in conformity are eligible for release on an EASA Form 1 for airworthiness purposes.

For the purpose of Subpart G of Part 21, the term 'applicable design data' includes the information related to the applicable engine exhaust emissions and aeroplane CO_2 emissions production cut-off requirements.

21.A.133 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart. The applicant shall:

(a) justify that, for a defined scope of work, an approval under this Subpart is appropriate for the purpose of showing conformity with a specific design; and

(b) hold or have applied for an approval of that specific design; or

(c) have declared or intends to declare compliance of that specific design in accordance with Subpart C of Section A of Annex Ib (Part 21 Light); or

(d) have ensured satisfactory coordination between production and design, through an appropriate arrangement with:

(1) the applicant for, or holder of, an approval of that specific design issued in accordance with this Regulation; or

(2) the natural or legal person who made a declaration of compliance of that specific design in accordance with Subpart C of Section A of Annex Ib (Part 21 Light).

GM 21.A.133(a) Eligibility – Approval appropriate for showing conformity

ED Decision 2012/020/R

'Appropriate' should be understood as follows:

— The applicant produces or intends to produce aeronautical products, parts and/or appliances intended for airborne use as part of a type-certificated product (this excludes simulators, ground equipment and tools).

— The applicant will be required to show a need for an approval, normally based on one or more of the following criteria:

1. Production of aircraft, engines or propellers (except if the competent authority considers a POA inappropriate)
2. Production of ETSO articles and parts marked EPA
3. Direct delivery to users such as owners or operators maintenance organisations with the need for exercising the privileges of issuing Authorised Release Certificates – EASA Form 1
4. Participation in an international co-operation program where working under an approval is considered necessary by the competent authority
5. Criticality and technology involved in the part or appliance being manufactured. Approval in this case may be found by the competent authority as the best tool to exercise its duty in relation to airworthiness control
6. Where an approval is otherwise determined by the competent authority as being required to satisfy the essential requirements of Annex I to the Regulation (EC) No 216/2008.

— It is not the intent of the competent authority to issue approvals to manufacturing firms that perform only sub-contract work for main manufacturers of products and are consequently placed under their direct surveillance.

— Where standard parts, materials, processes or services are included in the applicable design data (see guidance on applicable design data in GM 21.A.131) their standards should be controlled by the POA holder in a manner which is satisfactory for the final use of the item on the product, part or appliance. Accordingly, the manufacturer or provider of the following will not at present be considered for production organisation approval:

  — consumable materials
  — raw materials
  — standard parts
    — parts identified in the product support documentation as 'industry supply' or 'no hazard'
    — non-destructive testing or inspection
    — processes (heat treatment, surface finishing, shot peening, etc.)

AMC No 1 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations

ED Decision 2012/020/R

An arrangement is considered appropriate if it is documented and satisfies the competent authority that co-ordination is satisfactory.

To achieve satisfactory coordination the documented arrangements must at least define the following aspects irrespective of whether the two organisations are separate legal entities or not:

— The responsibilities of a design organisation which assure correct and timely transfer of up-to-date airworthiness data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);

— The responsibilities and procedures of a POA holder/applicant for developing, where applicable, its own manufacturing data in compliance with the airworthiness data package;

— The responsibilities of a POA holder/applicant to assist the design organisation in dealing with continuing airworthiness matters and for required actions (e.g., traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.);

— The scope of the arrangements must cover Part 21 Subpart G requirements and associated AMC and GM, in particular: 21.A.145(b), 21.A.165(c), (f) and (g);

— The responsibilities of a POA holder/applicant, in case of products prior to type certification to assist a design organisation in demonstrating compliance with CS (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);

— The procedures to deal adequately with production deviations and non-conforming parts;

— The procedures and associated responsibilities to achieve adequate configuration control of manufactured parts, to enable the production organisation to make the final determination and identification for conformity or airworthiness release and eligibility status;

— The identification of the responsible persons/offices who control the above;

— The acknowledgment by the holder of the TC/STC/repair or change approval/ETSO authorisation that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved.

In many cases the production organisation may receive the approved design data through an intermediate production organisation. This is acceptable provided an effective link between the design approval holder and the production organisation can be maintained to satisfy the intent of 21.A.133.

When the design and production organisations are two separate legal entities a Direct Delivery Authorisation must be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

Where there is no general agreement for Direct Delivery Authorisation, specific permissions may be granted (refer to AMC 21.A.4).

AMC No 2 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations

ED Decision 2012/020/R

In accordance with AMC No 1 to 21.A.133(b) and (c) the POA holder must demonstrate to the competent authority that it has entered into an arrangement with the design organisation. The arrangement must be documented irrespective of whether the two organisations are separate legal entities or not.

The documented arrangement must facilitate the POA holder to demonstrate compliance with the requirement of 21.A.133(b) and (c) by means of written documents agreed.

In the case where the design organisation and POA holder are part of the same legal entity these interfaces may be demonstrated by company procedures accepted by the competent authority.

In all other cases to define such a design/production interface the following sample format is offered:

Arrangement Sample Form

<table>
<tr><td colspan="2">ARRANGEMENT
in accordance with 21.A.133(b) and (c)</td></tr>
<tr><td>The undersigned agree on the following commitments:</td><td>Relevant interface procedures</td></tr>
<tr><td>The design organisation [NAME] takes responsibility to
— assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the production organisation approval holder [NAME]
— provide visible statement(s) of approved design data.</td><td></td></tr>
<tr><td>The production organisation approval holder [NAME] takes responsibility to
— assist the design organisation [NAME] in dealing with continuing airworthiness matter and for required actions
— assist the design organisation [NAME] in case of products prior to type certification in demonstrating compliance with certification specifications
— develop, where applicable, its own manufacturing data in compliance with the airworthiness data package.</td><td></td></tr>
<tr><td>The design organisation [NAME] and the POA holder [NAME] take joint responsibility to
— deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the production organisation approval holder
— achieve adequate configuration control of manufactured parts, to enable the POA holder to make the final determination and identification for conformity.</td><td></td></tr>
<tr><td colspan="2">The scope of production covered by this arrangement is detailed in [DOCUMENT REFERENCE/ATTACHED LIST]</td></tr>
<tr><td colspan="2">[When the design organisation is not the same legal entity as the production organisation approval holder]

Transfer of approved design data:
The TC/STC/ETSO holder [NAME] acknowledges that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved by the competent authority and therefore the parts and appliances manufactured in accordance with these data and found in a condition for safe operation may be released certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation..</td></tr>
<tr><td colspan="2">[When the design organisation is not the same legal entity as the production organisation approval holder]

Direct Delivery Authorisation:
This acknowledgment includes also [OR does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.</td></tr>
<tr><td>For the [NAME of the design organisation/DOA holder]

Date: Signature:

xx.xx.xxxx
[NAME in block letters]</td><td>For the [NAME of the POA holder]

Date: Signature:

xx.xx.xxxx
[NAME in block letters]</td></tr>
</table>

Instructions for completion:

Title: The title of the relevant document must clearly indicate that it serves the purpose of a design/production interface arrangement in accordance with 21.A.133(b) and (c).

Commitment: The document must include the basic commitments between the design organisation and the POA holder as addressed in AMC 21.A.4 and AMC No 1 to 21.A.133(b) and (c).

Relevant Procedures: Identify an entry point into the documentary system of the organisations with respect to the implementation of the arrangement (for example a contract, quality plan, handbooks, common applicable procedures, working plans etc.).

Scope of arrangement: The scope of arrangement must state by means of a list or reference to relevant documents those products, parts or appliances that are covered by the arrangement.

Transfer of applicable design data: Identify the relevant procedures for the transfer of the applicable design data required by 21.A.131 and GM 21.A.131 from the design organisation to the POA holder. The means by which the design organisation advises the POA holder whether such data is approved or not approved must also be identified (ref. 21.A.4/AMC 21.A.4).

Direct Delivery Authorisation: Where the design organisation and the POA holder are separate legal entities the arrangement must clearly identify whether authorisation for direct delivery to end users is permitted or not.

Where any intermediate production/design organisations are involved in the chain between the original design organisation and the POA holder evidence must be available that this intermediate organisation has received authority from the design organisation to grant Direct Delivery Authorisation.

Signature: AMC No 1 to 21.A.133(b) and (c) requests the identification of the responsible persons/offices who control the commitments laid down in the arrangement. Therefore the basic document must be signed mutually by the authorised representatives of the design organisation and the POA holder in this regard.

21.A.134 Application

Regulation (EU) No 748/2012

Each application for a production organisation approval shall be made to the competent authority in a form and manner established by that authority, and shall include an outline of the information required by point 21.A.143 and the terms of approval requested to be issued under point 21.A.151.

AMC1 21.A.134 Application

ED Decision 2023/014/R

APPLICATION FORM

An applicant for a POA should complete and submit to the competent authority an EASA Form 50 (see below).

The completed form, an outline of the production organisation exposition, and details of the proposed terms of approval should be forwarded to the competent authority.

EASA Form 50 **Application for a Part 21 production organisation approval**	
Competent authority *of an EU Member State or* *EASA*	
1. Registered name and address of the organisation:	
2. Trade name (if different)	
3. Location(s) for which the approval is applied for:	
4. Brief summary of the proposed activities at the addresses listed in Block 3: a) General: b) Scope of approval: c) Nature of privileges:	
5. Description of organisation:	
6. Links/arrangements with design approval holder(s)/design organisation(s) where different from 1.:	
7. Approximate number of staff engaged or intended to be engaged in the activities:	
8. Position and name of the accountable manager:	
_____ Date	_____ Signature of the accountable manager

EASA Form 50

Block 1: The name of the organisation should be entered as stated in the register of the National Companies Registration Office. For the initial application, a copy of the entry in the register of the National Companies Registration Office should be provided to the competent authority.

Block 2: State the trade name by which the organisation is known to the public if it is different from the information given in Block 1. The logo of the organisation may be used in this block.

Block 3: State all the locations for which the approval is applied for. Only those locations should be stated that are directly under the control of the legal entity stated in Block 1.

Block 4: This block should include further details of the activities under the approval for the addresses indicated in Block 3 The 'General' block must include overall information, while the 'Scope of approval' block should address the scope of work and the products/categories following the principles laid down in GM 21.A.151. The 'Nature of privileges' block should indicate the requested privileges as defined in points 21.A.163(b)-(e). For an application for renewal, state 'not applicable'.

Block 5: This block should provide a summary of the organisation with reference to the outline of the production organisation exposition, including the organisational structure, functions and responsibilities. The nomination of the responsible managers in accordance with point 21.A.145(c)(2) should be included as far as possible. For an application for renewal, state 'not applicable'.

Block 6: The information entered here is essential for the evaluation of the eligibility of the application. Therefore, special attention should be given concerning the completion of this block, either directly or by reference to supporting documentation, in relation to the requirements of points 21.A.133(b) and (c) and the AMC to 21.A.133(b) and (c).

Block 7: The information to be entered here should reflect the number of staff, or in the case of an initial approval, the intended number of staff for the complete set of activities that are to be covered by the approval, and it should also therefore include any associated administrative staff.

Block 8: State the position and name of the accountable manager.

21.A.134A Means of compliance

Regulation (EU) 2022/201

(a) An organisation may use any alternative means of compliance to establish compliance with this Regulation.

(b) If an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description. The description shall include any revisions to manuals or procedures that may be relevant, as well as an explanation indicating how compliance with this Regulation is achieved.

The organisation may use those alternative means of compliance subject to prior approval from the competent authority.

GM1 21.A.124A and 21.A.134A Means of compliance

ED Decision 2022/021/R

GENERAL

(a) Acceptable means of compliance (AMC), as referred to in Article 76(3) of Regulation (EU) 2018/1139[1], are a tool to standardise the demonstration of compliance with, and facilitate the verification activities of the competent authorities in relation to, that Regulation and its delegated and implementing acts. AMC are published by EASA to achieve those objectives. While competent authorities and regulated entities are not legally bound to use the AMC, applying them is recommended.

(b) If an organisation wishes to use other means to comply with Regulation (EU) 2018/1139 and its delegated and implementing acts, which are different from the AMC that are published by EASA, that organisation may need to demonstrate compliance by using alternative means of compliance (AltMoC) that are established:

(1) by its competent authority (see GM1 21.B.115 and GM1 21.B.215); or

(2) by that organisation and approved by its competent authority (see point (c)).

An AltMoC does not allow deviation from Regulation (EU) 2018/1139 and its delegated or implementing acts.

(c) AltMoC that are established by an organisation and approved by its competent authority

An organisation that wishes to use a different MoC than the one published by EASA can propose an AltMoC to the competent authority and use it only once the competent authority approves it. In that case, the organisation is responsible for demonstrating how that AltMoC establishes compliance with the regulation.

The approval of an AltMoC is granted to the organisation by its competent authority on an individual basis and is restricted to that specific organisation. Other organisations that wish to use the same AltMoC should go through the AltMoC process (i.e. demonstrate how that AltMoC establishes compliance with the regulation) and obtain individual approval from their competent authority.

GM2 21.A.124A and 21.A.134A Means of compliance

ED Decision 2022/021/R

WHEN AN ALTERNATIVE MEANS OF COMPLIANCE IS NEEDED

When there is no EASA AMC to a certain point of a regulation, the means of compliance (MoC) that are proposed by the organisation to that point do not need to go through the AltMoC process. It is the responsibility of the competent authority to verify that compliance with the regulation is achieved. However, in certain cases, the organisation may propose, and the competent authority may agree, to have such MoC go through the AltMoC process.

When there is an EASA AMC, the AltMoC process is needed in the following cases (non-exhaustive list):

[1] Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139).

— an AltMoC to the regulation is technically different to the AMC that is published by EASA; and

— a Form is significantly different from the one that is included in the EASA AMC.

Note: a Form that is required by a delegated or implementing act cannot be modified.

Examples of issues that are not considered to require the AltMoC process include, but are not limited to:

— editorial changes to an EASA AMC, as long as they do not change the intent of the AMC; and

— incorporating an EASA AMC into the organisational structure, organisational processes, or standard operating procedures of an organisation with different wording and terminology that are customised to the organisation's environment if it does not change the intent of the AMC and its associated level of safety.

AMC1 21.A.124A(b) and 21.A.134A(b) Means of compliance

ED Decision 2022/021/R

DESCRIPTION SUPPORTING THE ALTERNATIVE MEANS OF COMPLIANCE

(a) The description of the alternative means of compliance (AltMoC) should include:

(1) a summary of the AltMoC;

(2) the content of the AltMoC;

(3) a statement that compliance with the regulation is achieved; and

(4) in support of that statement, an assessment that demonstrates that the AltMoC reaches an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding EASA AMC.

(b) All these elements that describe the AltMoC are an integral part of the management system records, in accordance with point 21.A.5.

21.A.135 Issuance of production organisation approval

Regulation (EU) 2022/201

An organisation shall be entitled to have a production organisation approval issued by the competent authority when it has demonstrated compliance with the applicable requirements under this Subpart.

21.A.139 Production management system

Regulation (EU) 2022/1358

(a) The production organisation shall establish, implement and maintain a production management system that includes a safety management element and a quality management element, with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The production management system shall:

1. correspond to the size of the organisation, and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;

2. be established, implemented and maintained under the direct accountability of a single manager appointed pursuant to point 21.A.145(c)(1).

(c) As part of the safety management element of the production management system, the production organisation shall:

1. establish, implement and maintain a safety policy and the corresponding related safety objectives;

2. appoint key safety personnel in accordance with point 21.A.145(c)(2);

3. establish, implement and maintain a safety risk management process to identify safety hazards entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness;

4. establish, implement and maintain a safety assurance process that includes:

(i) the measurement and monitoring of the organisation's safety performance;

(ii) the management of changes in accordance with point 21.A.147;

(iii) the principles for the continuous improvement of the safety management element;

5. promote safety in the organisation through:

(i) training and education;

(ii) communication;

6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.

(d) as part of the quality management element of the production management system, the production organisation shall:

1. ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in a condition for safe operation, and thus exercise the privileges as defined in point 21.A.163;

2. establish, implement and maintain, as appropriate, within the scope of the approval, control procedures for:

(i) document issue, approval or change;

(ii) vendor and subcontractor assessment audit and control;

(iii) the verification that incoming products, parts, materials and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;

(iv) identification and traceability;

(v) manufacturing processes;

(vi) inspection and testing, including production flight tests;

(vii) the calibration of tools, jigs, and test equipment;

(viii) non-conforming item control;

(ix) airworthiness coordination with:

(A) the applicant for, or holder of, the design approval;

(B) the natural or legal person who made a declaration of design compliance in accordance with Subpart C of Section A of Annex Ib (Part 21 Light);

(x) the completion and retention of records;

(xi) the competence and qualifications of personnel;

(xii) the issue of airworthiness release documents;

(xiii) handling, storage and packing;

(xiv) internal quality audits and the resulting corrective actions;

(xv) work within the terms of approval performed at any location other than the approved facilities;

(xvi) work performed after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;

(xvii) the issue of a permit to fly and approval of the associated flight conditions.

3. include specific provisions in the control procedures for any critical parts.

(e) The production organisation shall establish, as part of the production management system, an independent monitoring function to verify compliance of the organisation with the relevant requirements of this Annex as well as compliance with and adequacy of the production management system. Monitoring shall include feedback to the person or group of persons referred to in point 21.A.145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where necessary, the implementation of corrective action.

(f) If the production organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the production management system may be integrated with that required under the additional certificate(s) held.

GM1 21.A.139, 21.A.239, 21.B.120, 21.B.140, 21.B.220, and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2022/021/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— ‘remote audit’ means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the ‘remote audit’ concept;

— ‘auditing entity’ means the competent authority or organisation that performs the remote audit;

— ‘auditee’ means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

AMC1 21.A.139(c) Production management system

ED Decision 2022/021/R

SAFETY MANAGEMENT ELEMENT

Demonstration of compliance with the international industry standard SM-0001 ‘Implementing a Safety Management System in Design, Manufacturing and Maintenance Organisations’, Issue B, 31 March 2022, is an acceptable means to demonstrate compliance with the safety management element of the production management system.

GM1 21.A.139(c) Production management system

ED Decision 2022/021/R

SAFETY MANAGEMENT ELEMENT

Safety management seeks to proactively identify hazards and mitigate the related safety risks before they result in aviation accidents and incidents. Safety management enables an organisation to manage its activities in a more systematic and focused manner. When an organisation has a clear understanding of its role in, and contribution to, aviation safety, this enables the organisation to prioritise safety risks and more effectively manage its resources for optimal results.

Safety should not be considered the responsibility of a single person or a limited group of people in the organisation. A safety culture should be developed throughout the organisation, which involves all the personnel as active contributors to the safety of the final product, part, or appliance (see AMC1 21.A.139(c)(1)).

The principles of the requirements in points 21.A.3A, 21.A.5, 21.A.139, 21.A.145, and 21.A.147, and the related AMC constitute the EU production management system framework for aviation safety management. This framework addresses the core elements of the International Civil Aviation Organization (ICAO) safety management system (SMS) framework that is defined in ICAO Annex 19, Appendix 2, and facilitates the introduction of the additional safety management element.

This approach is intended to encourage organisations to embed safety management and risk-based decision-making into all their activities, instead of superimposing another system onto their existing management system and governance structure. In addition, if the organisation holds multiple

organisation certificates that are issued under Regulation (EU) 2018/1139, it may choose to implement a single management system to cover all of its activities. An integrated management system may be used not only to capture multiple management system requirements resulting from Regulation (EU) 2018/1139, but also to cover for other regulatory provisions requiring compliance with ICAO Annex 19 or for other business management systems, such as security, occupational health, and environmental management systems. Integration will remove duplication and exploit synergies by managing safety risks across multiple activities. Organisations may determine the best means to structure their management systems to suit their business and organisational needs.

It is important to recognise that safety management will be a continuous activity, as hazards, risks, as well as the effectiveness of safety risk mitigations, will change over time.

The safety management capability of an organisation should be commensurate with the safety risks to be managed, which can be at the product, part, and appliance level or at the organisational level.

The risks that are inherent in a complex structure require a robust safety risk management process (e.g. a complex supply chain may induce hazards that are complex to mitigate, or the rate of production, when stretched to the limit, may require more efficient safety barriers).

As a consequence, scalability and suitability of the safety management element should be a function of the inherent safety risk capability of the organisation. For instance, for organisations with a lower risk level:

(a) the risk assessment model that is used may be very simple in cases in which the identified hazards are easy to mitigate;

(b) expert judgement might be sufficient to measure the efficiency of safety barriers;

(c) the collection of data, safety information, and occurrences might be very limited;

(d) there might be no need for software or tools to manage the SMS; and

(e) the communication policy might be limited.

AMC1 21.A.139(c)(1) Production management system

ED Decision 2022/021/R

SAFETY POLICY & OBJECTIVES

(a) The safety policy should:

(1) reflect organisational commitments regarding safety, and its proactive and systematic management, including the promotion of a positive safety culture;

(2) include internal reporting principles by fostering the reporting of organisational threats as well as events, as defined in AMC3 21.A.3A(a);

(3) be endorsed by the accountable manager (AM);

(4) be communicated, with visible endorsement, throughout the organisation; and

(5) be periodically reviewed to ensure that it remains relevant and appropriate to the organisation.

(b) The safety policy should include the commitment:

(1) to comply with all the applicable legislation, meet all the applicable requirements, and adopt practices to improve safety standards;

(2) to provide the necessary resources for the implementation of the safety policy;

(3) to apply human factors (HF) principles;

(4) to enforce safety as a primary responsibility of all managers; and

(5) to apply 'just culture' principles and, in particular, not to make available or use the information on occurrences:

(i) to attribute blame or liability to personnel for action, omissions, or decisions that are commensurate with their experience and training; or

(ii) for any purpose other than the improvement of aviation safety.

(c) Senior management should continuously promote the safety policy to all personnel, demonstrate their commitment to it, and provide the necessary human and financial resources for its implementation.

(d) Taking due account of its safety policy, the organisation should define safety objectives. The safety objectives should:

(1) form the basis for safety performance monitoring and measurement;

(2) reflect the organisation's commitment to maintaining or continuously improving the overall effectiveness of safety management;

(3) be communicated throughout the organisation; and

(4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.

GM1 21.A.139(c)(1) Production management system

ED Decision 2022/021/R

SAFETY POLICY

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, to improve the safety levels of all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident occurring, as far as reasonably practicable. The safety policy reflects the management's commitment to safety and the organisation's philosophy of safety management. It is the foundation on which the organisation's management system is built and serves as a reminder of 'how we do business here'. The creation of a positive safety culture begins with issuing a clear, unequivocal policy statement.

The commitment to apply 'just culture' principles forms the basis for the organisation's internal rules that describe how 'just culture' principles are guaranteed and implemented.

Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).

AMC1 21.A.139(c)(2) Production management system

ED Decision 2023/014/R

ORGANISATION AND ACCOUNTABILITY

(a) The management system should encompass safety by including a safety manager and a safety review board in the organisational structure. The functions of the safety manager are defined in AMC1 21.A.145(c)(2).

(b) Safety review board

(1) The safety review board (the 'board'), sometimes referred to as 'high-level safety committee', considers matters of strategic safety in support of the safety accountability of the accountable manager.

(2) The board should be normally chaired by the accountable manager and be generally composed of the person or group of persons nominated under point 21.A.145(c)(2). Its composition can be adapted to its needs, considering point 21.A.145(c)(2).

(3) The board should monitor:

(i) the organisation's safety performance against its safety policy and objectives;

(ii) whether any safety action is taken in a timely manner; and

(iii) the effectiveness of the organisation's management system processes.

(4) The board may also be tasked with:

(i) reviewing the results of compliance monitoring; and

(ii) monitoring the implementation of any related corrective and preventive action.

(c) The board should ensure that appropriate resources are allocated to achieve the established safety objectives.

(d) Notwithstanding point (a), if justified by the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment and/or mitigation measures, as well as the competent authority's agreement, the organisation may not need to establish a board. In that case, the tasks that are normally allocated to the board should be allocated to the safety manager.

GM1 21.A.139(c)(2) Production management system

ED Decision 2022/021/R

SAFETY ACTION GROUP

(a) Depending on the size of the organisation and the nature and complexity of its activities, a safety action group may be established as a standing group or as an ad hoc group to assist, or act on behalf of, the safety manager or the safety review board.

(b) More than one safety action group may be established, depending on the scope of the task and the specific expertise that is required.

(c) The safety action group usually reports to, and takes strategic direction from, the safety review board, and may be composed of managers, supervisors, and personnel from operational areas.

(d) The safety action group may be tasked with or assist in the following:

(1) monitoring safety performance;

(2) defining action to control risks to an acceptable level;

(3) assessing the impact of organisational changes on safety;

(4) ensuring that safety action is implemented within the agreed timescales; and

(5) reviewing the effectiveness of previous safety action and safety promotion.

AMC1 21.A.139(c)(3) and (4) Production management system

ED Decision 2022/021/R

SAFETY MANAGEMENT KEY PROCESSES

(a) Hazard identification processes

(1) Hazard identification should be based on a combination of reactive and proactive methods.

(2) The organisation should focus in particular on hazards that may generate nonconformity of a product, part, or appliance that is produced.

(b) Safety risk management processes

(1) The organisation should develop and maintain a safety risk management process that ensures a reactive, proactive, and predictive approach composed of the following elements:

(i) analysis (e.g. in terms of the probability or likelihood as well as severity of the consequences of hazards and occurrences)

(ii) assessment (in terms of tolerability); and

(iii) control (in terms of mitigation) of risks to an acceptable level.

(2) The organisation should specify, within the risk management process, who has the authority to make decisions, considering point (b)(1) of this AMC.

(c) Regardless of the approval status of the subcontracted organisations, the production organisation (PO) is responsible for ensuring that hazard identification and risk management activities are performed on subcontracted activities, as required by point 21.A.139(d)(2)(ii), as well as for the monitoring of their compliance and adequacy, as required by point 21.A.139(e).

(d) Internal investigation

(1) In line with 'just culture' as part of the safety policy, the organisation should define how to investigate events such as errors or near misses, in order to understand not only what happened, but also how it happened, as well as to prevent or reduce the probability and/or the consequences of any future recurrence.

(2) The scope of internal investigations should extend beyond the scope of the occurrences that are required to be reported to the competent authority in accordance with point 21.A.3A.

(e) Safety performance monitoring and measurement

(1) Safety performance monitoring and measurement should be the processes through which the safety performance of the organisation is verified against the safety policy and the safety objectives.

(2) This process may include, as appropriate to the size, nature, and complexity of the organisation, the following elements:

(i) safety reporting that also addresses the status of compliance with the applicable requirements;

(ii) safety reviews, including trend reviews, which should be conducted during the introduction and deployment of new products, parts, or new

equipment/technologies, the implementation of new or changed procedures, or in cases of organisational changes that may have an impact on safety;

(iii) safety audits that focus on the integrity of the organisation's management system, and that periodically assess the status of safety risk controls;

(iv) safety surveys that examine particular elements or procedures of a specific area, such as the following:

(A) the problem areas identified;

(B) bottlenecks in the daily production management activities;

(C) the perceptions and opinions of the production management personnel; and

(D) any areas of dissent or confusion; and

(v) other indicators relevant to safety performance.

(f) Management of change

Changes to the production management system may pose new hazards or decrease the effectiveness of existing safety risk controls. The organisation should manage any safety risks that are related to change in that organisation. The management of change should be a documented process to identify external or internal change that may have an adverse effect on safety. The management of change should use the organisation's existing processes for hazard identification, risk assessment, and risk mitigation.

(g) Continuous improvement

The organisation should continuously seek to improve its safety performance and the effectiveness of its production management system. Continuous improvement may be achieved through review of the following elements:

(1) compliance monitoring and audits;

(2) assessments, including assessments of the effectiveness of the safety culture and of the management system, to assess in particular the effectiveness of the safety risk management processes;

(3) staff surveys, including safety culture surveys, that can provide useful feedback on how engaged the staff are in the production management system;

(4) the monitoring of events and their recurrence;

(5) the evaluation of the safety performance indicators as well as reviews of all the available safety performance information; and

(6) the identification of lessons learned.

AMC1 21.A.139(c)(4)(ii) Production management system

ED Decision 2022/021/R

MANAGEMENT OF CHANGE

This AMC provides a means to consider organisational changes for their potential impact on safety. Organisational changes should also be evaluated for their significance, as required by point 21.A.147. In addition, necessary changes should be introduced into the production organisation exposition (POE), as per point 21.A.143(c). The production management system should be designed such that all the above points are taken into account.

(a) Organisational changes should be proactively considered for their safety implications. The magnitude of a change, its safety criticality, and its potential impact on human performance (HP) should be assessed in any process for the management of change. Certain non-complex organisational changes may not require additional assessment.

(b) Special consideration, including human factors (HF) issues, should be given to the transition period during which the change becomes effective.

(c) During the process for the management of change, relevant previous risk assessments and existing hazards should be reviewed for their possible effects.

GM1 21.A.139(c)(4)(ii) Production management system

ED Decision 2022/021/R

MANAGEMENT OF CHANGE

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. may result in inadvertently creating new hazards, which may expose the organisation to new or greater risks. Effective organisations seek to improve their processes, while being conscious of the fact that changes may expose the organisation to potential hazards and risks if they are not properly and effectively managed.

The process for the management of change typically provides principles and a structured framework for managing all aspects of change. The disciplined implementation of management of change may maximise the effectiveness of change, engage staff, and minimise the risks that are inherent in change.

Change may have the potential to raise new HF issues, or to exacerbate existing ones. For example, changes in computer systems, equipment, technology, personnel changes (including changes in management personnel), procedures, the organisation of work, or work processes are likely to affect performance.

Effective management of change is supported by the following elements:

(a) the implementation of a process for hazard identification/risk analysis and assessment for major operational changes, major organisational changes, changes in key personnel, and changes that may affect the way in which production management is carried out;

(b) the identification of changes that may have a considerable impact on:

  (1) resources (material and human);

  (2) management direction (policies, processes, procedures, training); and

  (3) management control;

(c) safety cases/risk assessments that are aviation-safety-focused; and

(d) the involvement of key stakeholders in the process for the management of change, as appropriate.

AMC1 21.A.139(c)(5) Production management system

ED Decision 2022/021/R

SAFETY COMMUNICATION

(a) The organisation should establish communication to the staff, as appropriate to their safety responsibilities, regarding safety matters, which:

  (1) ensures awareness of safety management activities;

(2) conveys safety-critical information, especially related to assessed risks and analysed hazards;

(3) explains why particular action is taken; and

(4) explains why safety procedures are established or changed.

(b) Regular meetings with staff, during which information, action, and procedures are discussed, may be used to communicate safety matters.

GM1 21.A.139(c)(5) Production management system

ED Decision 2022/021/R

SAFETY PROMOTION

(a) Safety training, combined with safety communication and information sharing, is part of safety promotion.

(b) Safety promotion activities support the following:

(1) the organisation's policies, encouraging a positive safety culture, thus creating an environment that is favourable to the achievement of the organisation's safety objectives;

(2) organisational lessons learned; and

(3) the implementation of an effective safety reporting scheme and the development of a 'just culture'.

(c) Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation action.

AMC1 21.A.139(c)(5)(i) Production management system

ED Decision 2022/021/R

SAFETY TRAINING

(a) The production management staff, as described in points 21.A.145(c)(1) and (2), should receive initial and recurring safety training, as appropriate to their responsibilities, including in safety management principles and the associated safety objectives, to ensure their continued competency.

(b) The organisation should identify the category of other staff to which safety training should be provided, and define the initial and recurrent training programmes, including appropriate timelines.

(c) Adequate records of the safety training that is provided should be kept in accordance with point 21.A.5.

GM1 21.A.139(c)(5)(i) Production management system

ED Decision 2022/021/R

SAFETY TRAINING

(a) The main purpose of the safety training programme is:

(1) to support safety management policies and processes; and

(2) to ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.

(b) Each organisation may adapt its syllabus to its own needs. Typically, depending on the targeted staff, to contribute to a positive safety culture, the following items may be included:

(1) the organisational roles and responsibilities related to safety, including the hazard identification and risk management processes;

(2) the safety objectives and the associated safety performance indicators;

(3) human factors (HF) principles, including human performance (HP) and limitations;

(4) legislation, where applicable;

(5) safety reporting systems and investigations; and

(6) safety issues.

(c) The purpose of the recurrent safety training is:

(1) primarily to ensure that staff are kept abreast notably of changes to safety management system (SMS) principles, processes, and procedures; and

(2) also to share feedback on safety issues that are relevant to the organisation or lessons learned.

(d) The training staff should have sufficient knowledge and experience to teach the topics at the required level, as well as the skills to influence attitudes and behaviours.

AMC1 21.A.139(d) Production management system

ED Decision 2022/021/R

QUALITY SYSTEM ELEMENT

The quality system element is an organisational structure, included in the production management system, with responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles.

The quality system should be documented in such a way that the documentation can be made easily available to personnel who need to use the material for performing their normal duties, in particular:

— procedures, instructions, data to cover the issues of point 21.A.139(d)(2) are available in a written form;

— distribution of relevant procedures to offices/persons is made in a controlled manner,

— procedures which identify persons responsible for the prescribed actions are established; and

— the updating process is clearly described.

The competent authority will verify on the basis of the exposition and by appropriate investigations that the production organisation (PO) has established and can maintain their documented quality system.

GM1 21.A.139(d)(1) Production management system

ED Decision 2022/021/R

CONFORMITY OF SUPPLIED PARTS OR APPLIANCES

The production organisation approval (POA) holder is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of supplied products, parts or appliances, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.

To discharge this responsibility the quality system needs an organisational structure and procedures to adequately control suppliers. Elements of the quality system for the control of suppliers may be performed by other parties provided that the conditions of AMC1 21.A.139(d)(2)(ii) or AMC2 21.A.139(d)(2)(ii) are met.

Control can be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity):

— qualification and auditing of the supplier's quality system;

— evaluation of the supplier's capability in performing all the manufacturing activities, inspections and tests necessary to establish the conformity of parts or appliances to the type design;

— first article inspections, including destruction, if necessary, to verify that the article conforms to the applicable data for a new production line or a new supplier;

— incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt;

— identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents;

— a vendor rating system which gives confidence in the performance and reliability of this supplier; and

— any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subjected to the checks normally provided by subsequent production or inspection stages.

The POA holder may rely on the results of inspections/tests performed by the supplier if it can establish that:

— the personnel responsible for these tasks satisfy the competency standards of the POA quality system;

— quality measurements are clearly identified; and

— the records or reports showing evidence of conformity are available for review and audit.

The POA holder retains direct responsibility for inspections/tests that are performed either at its own facilities or at the supplier's facilities.

The control of suppliers holding a POA for the parts or appliances to be supplied can be reduced to a level at which a satisfactory interface between the two quality systems can be demonstrated. Thus, for the purpose of showing conformity, a POA holder can rely upon documentation for parts or

appliances, which is released in accordance with the supplier's privileges that are defined in point 21.A.163.

A supplier who does not hold a POA is considered to be a subcontractor under the direct control of the POA quality system.

GM2 21.A.139(d)(1) Production management system

ED Decision 2022/021/R

QUALITY SYSTEM ELEMENT — PARTNER AND SUBCONTRACTOR ARRANGEMENTS

When defining the arrangements between the production organisation (PO) and its partners and subcontractors, both elements of the production management system should be taken into account, i.e. the safety management element and the quality system element. The following guidance should therefore be considered applicable to both elements.

(a) When the PO subcontracts activities, the arrangements should consider the safety risk management process that is part of the PO's safety management element (see point 21.A.139(c)(3)). When the subcontractor does not have a safety management element, the subcontractor should be integrated into the safety management element of the PO; when the subcontractor has implemented a safety management system (such as for design organisation approval (DOA) or production organisation approval (POA)), the two safety management systems, i.e. of the PO and of the subcontractor, should be harmonised.

(b) Depending on the complexity and criticality of those arrangements, the following elements within the arrangements should be addressed:

(1) coordination and interfaces between all the parties involved;

(2) applicable procedures;

(3) safety culture, including internal safety reporting schemes (see point 21.A.3A);

(4) communication between all the parties involved, including reporting, regular meetings, and feedback channels;

(5) allocation of tasks, of clear accountability, and of responsibilities; and

(6 the qualifications and competency of key personnel with reference to point 21.A.145.

(c) The safety risk management should focus on the need to exchange safety data and safety information that are deemed significant for the determination of relevant risks in terms of likelihood, severity, impact, and acceptability, such as, wherever appropriate, but not limited to the following:

(1) (at product level) failure, malfunction, defect, or other occurrences, non-conformity or outcome of the compliance monitoring function, quality escape, process failure, foreign object damage (FOD), deviation (e.g. calibration of tools), component failure analysis, in-service event, etc.;

(2) (at documentation level) key processes (e.g. airworthiness directives, production documentation, production processes); and

(3) (at organisational level) organisational changes, disruptive events, resources' issues, human performance (HP) issues.

(d) Regular communication should be ensured between all the parties involved, to discuss work progress, risk mitigation measures, changes to the arrangements, as well as any other significant issues.

AMC1 21.A.139(d)(2) Production management system

ED Decision 2022/021/R

QUALITY SYSTEM — ELEMENTS OF THE QUALITY SYSTEM

(1) The control procedures covering the elements of point 21.A.139(d)(2) should document the standards to which the production organisation intends to work.

(2) An organisation having a quality system designed to meet a recognised Standard such as ISO 9001 (relevant to the scope of approval being requested) should expand it to include at least the following additional topics, as appropriate, in order to demonstrate compliance with the requirements of Part 21:

- mandatory and voluntary occurrence reporting, as required by points 21.A.3A and 21.A.139(c) and continued airworthiness as required by point 21.A.165(e);
- control of work occasionally performed (outside the POA facility by POA personnel);
- coordination with the applicant for, or holder of, an approved design, as required by points 21.A.133(b) and (c) and 21.A.165(g);
- issue of certifications within the scope of approval for the privileges of point 21.A.163;
- incorporation of airworthiness data in production and inspection data, as required in points 21.A.133(b) and (c) and 21.A.145(b)
- when applicable, ground test and/or production flight test of products in accordance with procedures defined by the applicant for, or holder of, the design approval;
- procedures for traceability including a definition of clear criteria of which items need such traceability; traceability is defined as a means of establishing the origin of an article by reference to historical records for the purpose of providing evidence of conformity; and
- personnel training and qualification procedures especially for certifying staff as required in 21.A.145(d).

(3) An organisation having a quality system designed to meet a recognised aerospace quality standard will still need to ensure compliance with all the requirements of Part 21. In all cases, the competent authority will still need to be satisfied that compliance with Part 21 is established.

AMC1 21.A.139(d)(2)(ii) Production management system

ED Decision 2023/014/R

VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT AND CONTROL — PRODUCTION ORGANISATION APPROVAL HOLDER THAT USES DOCUMENTED ARRANGEMENTS WITH OTHER PARTIES FOR THE ASSESSMENT AND SURVEILLANCE OF A SUPPLIER

(1) General

The production organisation is required by point 21.A.139(d) to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation.

To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The use of other parties (OPs), such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the production organisation approval (POA) holder from its obligations under point 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OPs.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of OPs to perform supplier assessments and surveillance should be part of the production organisation quality system and fulfil the conditions of this AMC.

This AMC is applicable to a method whereby a POA holder has a documented arrangement with an OP for the purpose of assessing and/or surveying a POA's supplier.

(2) Reserved

(3) Conditions and criteria for the use of OPs to perform supplier assessment and surveillance

(a) The POA holder should include the use of OPs for supplier assessment and surveillance in the POA holders' quality system to demonstrate compliance with the applicable requirements of Part 21.

(b) The procedures that are required for using OPs for supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.

(c) The procedures of the POA holder that uses OPs to perform supplier assessment and surveillance should include the following:

(1) Identification of the OP that will conduct the supplier assessment and surveillance.

(2) A listing of suppliers under surveillance by the OP. This listing should be maintained by the POA holder and made available to the competent authority upon request.

(3) The method used by the POA holder to evaluate and monitor the OP. The method should include the following as a minimum:

(i) verification that standards and checklists used by the OP are acceptable for the applicable scope;

(ii) verification that the OP is appropriately qualified and has sufficient knowledge, experience, and training to perform its allocated tasks;

(iii) verification that the frequency with which the OP carry out surveillance of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme;

(iv) verification that the assessment and surveillance of the suppliers is including on-site surveillance activities that are conducted by the OP; and

(v) verification that the OP has access to the applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and works in

accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the assessment and surveillance by the other party, items (ii) and (iv) shall be deemed to be complied with.

(4) A definition that states to what extend the OP will conduct surveillance of the suppliers on behalf of the POA holder. If the OP partly replaces surveillance by the POA holder, the POA holder should identify the functions that will continue to be surveyed by the POA holder.

(5) The procedures used by the OP to notify the POA holder of any non-conformity that is discovered at the supplier's facility, and of the corrective action and follow-up.

(d) The POA should make arrangements that allow the competent authority to make investigations in accordance with point 21.A.9 to include OP activities.

AMC2 21.A.139(d)(2)(ii) Production management system

ED Decision 2022/021/R

VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT, AND CONTROL — PRODUCTION ORGANISATION APPROVAL HOLDER THAT USES OTHER PARTIES SUPPLIER CERTIFICATION

(1) General

Other party (OP) supplier certification is a method whereby a supplier contracts an appropriately recognised or accredited OP for the purpose of obtaining a certification from that OP. Certification indicates that the supplier has satisfactorily demonstrated that it meets the applicable standard on a continuing basis. OP certification results in placing the supplier on the OP list of certified organisations, or in the supplier receiving a certificate identifying the requirements that have been met. Periodic follow-up evaluations are conducted by the OP to verify continued compliance with the requirements of the applicable standard.

The production organisation is required by point 21.A.139(d) to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The assessment and surveillance of suppliers by an OP should be deemed to satisfy the requirements of point 21.A.139(b)(1)(ii) when the conditions of this AMC are satisfied. The assessment and surveillance of suppliers by OP as part of supplier certification does not exempt the production organisation approval (POA) holder from its obligations under point 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier’s facilities may be performed by OP.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of suppliers that are certified by OP in accordance with this AMC should be part of a production organisation quality system.

(2) Reserved

(3) Conditions and criteria for using supplier certification for supplier assessment and surveillance

(a) The POA holder should include the use of supplier certification for the supplier assessment and surveillance in the POA holder's quality system to demonstrate compliance with the applicable requirements of Part 21.

(b) The procedures that are required for use of supplier certification for the supplier assessment and surveillance should be consistent the with other procedures of the POA holders' quality system.

(c) The procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:

(1) A listing of the OPs that have certified or will certify suppliers and will conduct supplier assessment and surveillance or the scheme under which the accreditation of the OP is controlled. This listing should be maintained by the POA holder and made available to the competent authority upon request.

(2) A listing of the certified suppliers that are under surveillance by the OP and that are used by the POA holder. This listing should be maintained by the POA holder and made available to the competent authority upon request.

(3) The method used by the POA holder to evaluate and monitor the certification process of any OP certification body or OP certification scheme used. This applies not only to new suppliers, but also to any decision by the POA holder to rely on OP certification of current suppliers. The method should include the following as a minimum:

(i) verification that certification standards and checklists are acceptable and applied to the applicable scope;

(ii) verification that the OP is appropriately qualified and has sufficient knowledge, experience and training to perform its allocated tasks;

(iii) verification that the frequency with which the OP carries out surveillance of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme;

(iv) verification that the surveillance of the suppliers is including on-site surveillance activities that are conducted by the OP;

(v) verification that the surveillance report will be made available to the competent authority upon request;

(vi) verification that the OP continues to be recognised or accredited; and

(vii) verification that the OP has access to the applicable proprietary data to the level of detail necessary to survey the suppliers' functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and works in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes the requirements for the OP certification, items (ii), (iv), and (v) should be deemed to be complied with.

(4) A definition that states to what extend the OP will conduct supplier surveillance on behalf of the POA holder. If the OP partly replaces surveillance by the POA holder, the POA holder should identify the functions that will continue to be surveyed by the POA holder.

(5) the procedures that ensure that the POA is aware of the loss of an existing certification.

(6) the procedures that ensure that the POA holder is aware of any non-conformity and has access to detailed information on any non-conformity.

(7) the procedures to evaluate the consequences of non-conformity and take appropriate actions.

(d) The POA should make arrangements that allow the competent authority to make investigations in accordance with point 21.A.9 to include OP activities.

GM1 21.A.139(d)(2)(ii) Production management system

ED Decision 2022/021/R

ASSESSMENT, AUDIT, AND CONTROL OF VENDOR AND SUBCONTRACTOR

For the purposes of AMC1 21.A.139(d)(2)(ii) and AMC2 21.A.139(d)(2)(ii), vendors and subcontractors are referred to as 'suppliers',whether they hold production organisation approvals (POAs) or not; audit and control are hereinafter referred to as 'surveillance'. Implementing or significantly changing procedures to use an OP for supplier assessment and surveillance is a significant change to the quality system, and it requires approval in accordance with point 21.A.147.

AMC1 21.A.139(e) and 21.A.139(d)(2)(xiv) Production management system

ED Decision 2022/021/R

INDEPENDENT MONITORING FUNCTION

(a) The independent monitoring function should ensure that:

(1) the activities of the production organisation (PO) are monitored for their compliance with the applicable requirements and with any additional requirements as established by the organisation, and that those activities are properly performed under the supervision of the nominated persons that are referred to in point 21.A.145(c)(2); furthermore, compliance with, and the adequacy of, the production management system should be monitored;

(2) all subcontracted production activities are monitored for compliance and adequacy with the applicable arrangements;

(3) an objective review of the complete set of production-management-related activities is provided through independent monitoring activities, such as audits, inspections, reviews;

(4) the independence of the monitoring activities is established by always ensuring that those activities and inspections are performed by staff that are not involved in the

function, procedure, or products that they monitor, and that are independent from the operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring;

(5) a monitoring plan is established to show when and how often the activities that are required by Part 21 will be audited;

(6) the monitoring cycle should not exceed the applicable oversight planning cycle that is established according to point 21.B.222; the determination of the monitoring plan should consider at least the following aspects:

(i) the criticality of the items checked; and

(ii) the safety performance of the organisation, including any previous findings and root causes;

(7) when non-compliance is found, the root cause(s) and contributing factor(s) are identified, and corrective action is defined and followed up;

(8) feedback is provided to the management of the PO; and

(9) the above elements perform the planned continuing and systematic evaluations or audits of the factors that affect the conformity (and, where required, the safe operation) of the products, parts, or appliances to the applicable design; this evaluation should include all the elements of the production management system to demonstrate compliance with Part 21.

(b) The staff performing an independent monitoring function should have access to all the parts of the PO and, as necessary, to any subcontracted organisations.

GM1 21.A.139(f) Production management system

ED Decision 2023/014/R

ADEQUACY OF THE PRODUCTION MANAGEMENT SYSTEM

'Adequacy of the production management sytem' means that the production organisation, through the use of the procedures as defined, is capable of meeting the conformity objectives that are identified in 21.A.139(d)(1).

21.A.139A Information security management system

Regulation (EU) 2022/1645

In addition to the production management system required by point 21.A.139, the production organisation shall establish, implement and maintain an information security management system in accordance with Commission Delegated Regulation (EU) 2022/1645[1] in order to ensure the proper management of information security risks which may have an impact on aviation safety.

[applicable from 16 October 2025 – Regulation (EU) 2022/1645]

[1] Commission Delegated Regulation (EU) 2022/1645 of 14 July 2022 laying down rules for the application of Regulation (EU) 2018/1139 of the European Parliament and of the Council, as regards requirements for the management of information security risks with a potential impact on aviation safety for organisations covered by Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 and amending Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 (OJ L 248, 26.9.2022, p. 18).

21.A.143 Production organisation exposition

Regulation (EU) 2022/201

(a) The production organisation shall establish and maintain a production organisation exposition (POE) that provides directly or by cross reference the following information related to the production management system as described in point 21.A.139:

1. a statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Subpart will be complied with at all times;
2. the title(s) and names of managers accepted by the competent authority in accordance with point 21.A.145(c)(2);
3. the duties and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation;
4. an organisational chart showing associated chains of responsibility of the managers as required by point 21.A.145(c)(1) and (2);
5. a list of certifying staff as referred to in point 21.A.145(d);
6. a general description of man-power resources;
7. a general description of the facilities located at each address specified in the production organisation's certificate of approval;
8. a general description of the production organisation's scope of work relevant to the terms of approval;
9. the procedure for the notification of organisational changes to the competent authority;
10. the amendment procedure for the production organisation exposition;
11. a description of the production management system, the policy, processes and procedures as provided for in point 21.A.139(c);
12. a list of the outside parties referred to in point 21.A.139(d)(1);
13. if flight tests are to be conducted, a flight test operations manual defining the organisation’s policies and procedures in relation to flight test. The flight test operations manual shall include:
    - (i) a description of the organisation’s processes for flight test, including the flight test organisation involvement into the permit to fly issuance process;
    - (ii) crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex I (Part 21), where applicable;
    - (iii) procedures for the carriage of persons other than crew members and for flight test training, when applicable;
    - (iv) a policy for risk and safety management and associated methodologies;
    - (v) procedures to identify the instruments and equipment to be carried;
    - (vi) a list of documents that need to be produced for flight test.

(b) The initial issue of the POE shall be approved by the competent authority.

(c) The POE shall be amended as necessary so that it remains an up-to-date description of the organisation. Copies of any amendments shall be supplied to the competent authority.

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

a. Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

b. Format

The FTOM may:

— be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

— be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

c. Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part 21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

a. Exposition (not applicable in the case of APDOA):

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

  — for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

  — for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

  — for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

GM1 21.A.143 Production organisation exposition

ED Decision 2022/021/R

GENERAL

(a) The purpose of the production organisation exposition (POE) is to state in a concise documented format the organisational relationships, responsibilities, terms of reference, and the associated authority, procedures, means and methods of the organisation.

The information to be provided is specified in point 21.A.143(a). Where this information is documented and integrated in manuals, procedures and instructions, the POE should provide a summary of the information and an appropriate cross-reference.

(b) Point 21.A.143(b) requires that the initial issued of the POE is approved by the competent authority. Revisions of the POE are subject to the process that is described in point (c) below.

(c) When changes to the organisation occur, according to point 21.A.143(c), the POE is required to be kept up to date. This should be done as per a procedure that is laid down in the POE. If the changes are significant, the organisation should not amend the POE before the competent authority approves the change in accordance with point 21.A.147.

AMC1 21.A.143(a)(1) Production organisation exposition

ED Decision 2023/014/R

CONTENT OF THE PRODUCTION ORGANISATION EXPOSITION

(a) All staff should be familiar with those production organisation exposition (POE) parts that are relevant to their tasks.

(b) A paragraph in the POE should provide a description of the organisation, as well as the safety policy and the corresponding objectives, as required by point 21.A.139(c)(1).

(c) The POE should include a statement, signed by the accountable manager (and countersigned by the senior company manager, if different), which confirms that the POE and any associated manuals are complied with at all times.

This statement should read as follows, or embrace the intent of the following text:

'This exposition defines the organisation and the procedures upon which the competent authority's production organisation approval (POA) is based.*

These procedures are approved by the undersigned, and must be complied with, as applicable, to ensure that all production activities are performed on time and to an approved standard.

It is understood that the approval of the production organisation (PO) is based on the organisation's continuous compliance with the applicable requirements of Part 21, and with the organisation's procedures that are described in this exposition. The competent authority is entitled to limit, suspend, or revoke the approval if the organisation fails to fulfil the obligations that are imposed by Part 21, or any conditions according to which the approval was issued.*

Signed .....

Dated .....

Accountable manager and ..... (quote the position of the signatory)

Senior company manager .....

For and on behalf of ..... (quote the organisation's name)'

**Where 'competent authority' is stated, please insert the actual name of the approving competent-authority organisation or administration that grants the POA.*

The statement should be reissued at the earliest opportunity when the accountable manager changes.

(d) The POE should include the description of the internal safety reporting scheme that is required by point 21.A.3A(b)(1).

(e) The POE should include the safety management procedures (including identification of safety hazards, evaluation, and associated risks management), safety assurance procedures, and safety promotion processes.

(f) If the organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, so that the organisation is required to establish another exposition, the organisation may combine the documents by producing a separate manual or supplement that covers the differences between the POE and the other exposition. In that case, the manual or supplement should identify where in the other exposition the remaining information on the production organisation (PO) is covered. That remaining information then formally becomes part of the exposition.

(g) The organisation may document its safety policy, safety objectives, and all the safety management system key processes (as required by point 21.A.139(c)) in a separate manual (e.g. a safety management manual or management system manual) or in its POE. Organisations that hold multiple organisation approvals, which are issued under Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

21.A.145 Resources

Regulation (EU) 2022/1358

The production organisation shall demonstrate that:

(a) the facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and the general organisation are adequate to discharge its obligations under point 21.A.165;

(b) with regard to all the necessary airworthiness and environmental protection data:

1. the production organisation is in receipt of such data from the Agency and from the holder of, or applicant for, the type certificate, restricted type certificate or design approval issued in accordance with this Regulation or a natural or legal person who made a declaration of design compliance under Subpart C of Section A of Annex Ib (Part 21 Light), including any exemption granted against the environmental protection requirements, to determine conformity with the applicable design data;

2. the production organisation has established a procedure to ensure that the airworthiness and environmental protection data are correctly incorporated in its production data;

3. such data is kept up to date and made available to all personnel that need access to such data to perform their duties.

(c) with regard to management and staff:

1. an accountable manager has been appointed by the production organisation with the authority to ensure that, within the organisation, all production is performed to the required standards and that the production organisation is continuously in compliance with the requirements of the production management system referred to in point 21.A.139, and the data and procedures identified in the POE referred to in point 21.A.143;

2. a person or group of persons has/have been nominated by the accountable manager to ensure that the organisation is in compliance with the requirements of this Annex, and are identified, together with the extent of their authority; such person or group of persons shall be responsible to the accountable manager and have direct access to him. The person or group of persons shall have the appropriate knowledge, background and experience to discharge their responsibilities;

3. staff at all levels have been given the appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the production organisation in respect of airworthiness and environmental protection data matters;

(d) with regard to certifying staff authorised by the production organisation to sign the documents issued under point 21.A.163 within the scope of the terms of approval:

1. they have the appropriate knowledge, background (including other functions in the organisation) and experience to discharge their allocated responsibilities;

2. they are provided with evidence of the scope of their authorisation.

AMC1 21.A.145(a) Resources

ED Decision 2022/021/R

EQUIPMENT AND TOOLS

The organisation's equipment and tools should enable all the specified tasks to be accomplished in a repeatable manner without any detrimental effects. The calibration control of the equipment and tools that affect the dimensions and values of products should demonstrate compliance with, and be traceable to, national or international standards.

AMC2 21.A.145(a) Resources

ED Decision 2022/021/R

STAFF NUMBER AND COMPETENCY

(a) Sufficient personnel means that, for each function, according to the nature of the work and the production rate, the organisation has a sufficient number of qualified staff to accomplish all the specified manufacturing tasks and to attest the conformity of such task. The number of staff should be such that the relevant airworthiness considerations may be applied in all areas without any undue pressure.

(b) The organisation should have a system in place to plan the availability of staff to ensure that the organisation has sufficient appropriately qualified staff to plan, perform, supervise, inspect, and monitor the organisation's activities in accordance with the organisation's terms of approval.

(c) The organisation should establish and control the competency of the staff that is involved in activities of the organisation, as detailed in the organisation's terms of approval, in accordance with documented procedures. In addition to the necessary expertise that is related to the job function, the competency of the staff should include an understanding of safety management and human factors (HF) principles, which is appropriate to the staff member's function and responsibilities in the organisation.

(d) The competency evaluation should include verification, where appropriate, that specific qualification standards have been applied, for example, welding for non-destructive testing (NDT), etc.

(e) To assist in the assessment of competency and to perform the analysis of the training needs, job (job family) descriptions are recommended, which should contain sufficient criteria to enable the required competency assessment throughout the duration of the employment/contract.

(f) The organisation should develop a procedure that describes the process for assessing the competency of the staff. The procedure should specify:

(1) the staff that are responsible for that process;

(2) the means and methods for the initial assessment;

(3) the means and methods for the continuous control of the competency of the personnel, including feedback on their performance;

(4) the action to be taken if the assessment is not satisfactory; and

(5) how to record assessment results.

(g) Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. That training should be adapted based on experience that is gained within the organisation (for safety training, refer also to AMC1 21.A.139(c)(5)(i)).

(h) The organisation should record the training that is provided as described in point (g).

GM1 21.A.145(a) Resources

ED Decision 2022/021/R

FACILITIES

A facility is a working area where the working conditions and the environment are controlled as appropriate in respect of: cleanliness, temperature, humidity, ventilation, lighting, space/access, noise, and air pollution.

GM1 21.A.145(b)(2) Resources

ED Decision 2023/014/R

PRODUCTION DATA

When a production organisation approval (POA) holder or an applicant for a POA is developing its own manufacturing data, such as computer-based data, from the design data package that is delivered by a design organisation, procedures are required to demonstrate the correct transcription of the original design data.

Procedures are required to define the manner in which airworthiness and environmental protection data is used to issue and update the production/quality data, which determines the conformity of products, parts, and appliances. The procedure should also define the traceability of such data to each individual product, part, or appliance for the purpose of certifying their condition for safe operation and of issuing a statement of conformity or EASA Form 1.

AMC1 21.A.145(c)(1) Resources

ED Decision 2022/021/R

ACCOUNTABLE MANAGER

(a) The accountable manager (AM) should:

(1) have sufficient knowledge and authority to be able to respond to the competent authority regarding major issues concerning the production organisation approval (POA), and to carry out any necessary improvements;

(2) promote the safety policies and objectives that are specified in AMC1 21.A.139(c)(1); and

(3) demonstrate a Part 21 understanding that is sufficient to discharge the relevant responsibilities.

(b) The production organisation exposition (POE) that is submitted in accordance with point 21.A.143 should show that the AM has the direct or functional responsibility for all the departments of the organisation which are involved in the POA. If any of those departments are functionally linked, the AM still has the ultimate responsibility for compliance of the PO with Part 21.

GM1 21.A.145(c)(1) Resources

ED Decision 2022/021/R

ACCOUNTABLE MANAGER

'Accountable manager' refers to the manager that is responsible and has corporate authority for ensuring that all production work is performed to the required standard. This function may be carried out by the chief executive officer (CEO) or by another person in the organisation, nominated by the CEO to fulfil the function, provided that the position and authority of that person in the organisation allows that person to discharge the associated responsibilities.

The manager is responsible for ensuring that all necessary resources are available and properly used under the production approval in accordance with Part 21, Section A, Subpart G.

AMC1 21.A.145(c)(2) Resources

ED Decision 2023/014/R

NOMINATED MANAGERS

(a) The person or group of persons nominated in accordance with point 21.A.145(c)(2) should represent the management structure of the organisation and be responsible for all the functions as specified in Part 21, Subpart G. Depending on the size of the approved production organisation (PO), the functions may be subdivided under individual managers (and in fact may be further subdivided) or combined in a variety of ways.

(b) The organisation should nominate a person or a group of persons that are responsible for:

(1) the independent monitoring function as defined in point 21.A.139(e); and

(2) ensuring the development, administration, and maintenance of effective safety risk management processes as defined in point 21.A.139(c)(3).

(c) If more than one person is designated for the management of the independent monitoring function, the AM should identify a unique focal point, typically known as the 'quality manager'.

(d) If more than one person is designated for the development, administration, and maintenance of effective safety risk management processes as defined in point 21.A.139(c)(3), the AM should identify a 'safety manager' as the unique focal point.

(e) Each nominated manager should be identified and their credentials submitted to the competent authority as a significant change so that they may be seen to be appropriate in terms of their relevant knowledge and satisfactory experience related to the nature of the production activities as performed by the approved PO.

(f) The responsibilities and the duties of each individual manager should be clearly defined in such a way that all the responsibilities are covered.

(g) Where an approved PO chooses to appoint managers for all or for any combination of functions that are the identified in Part 21 because of the size of the undertaking, those managers should ultimately report to the accountable manager. When a manager does not directly report to the accountable manager, that manager should have a direct access to the accountable manager formally established.

(h) The independent monitoring function should be independent from other functions. As such, the quality manager should not be at the same time one of the other persons that are referred to in point 21.A.145(c)(2), except for the safety manager. If the same person is designated to manage both the independent monitoring function and safety-management-related processes and tasks, the accountable manager, in order to discharge their safety accountability, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation, and the nature and complexity of its activities.

(i) Quality manager

The role of the quality manager should be to ensure that:

(1) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21.A.145(c)(2);

(2) an audit plan is properly implemented, maintained, and continually reviewed and improved; and

(3) corrections and corrective action are requested, as necessary.

(j) Safety manager

The role of the safety manager should be:

(1) to facilitate hazard identification, as well as risk assessment and management;

(2) to monitor the implementation of action taken to mitigate risks, as listed in the safety action plan, unless action follow-up is addressed by the independent monitoring function;

(3) to provide periodic reports on safety performance to the safety review board (the functions of the safety review board are defined in AMC1 21.A.139(c)(2));

(4) to ensure the maintenance of safety management documentation;

(5) to ensure that there is safety training available, and that it meets acceptable standards;

(6) to provide advice on safety matters; and

(7) to ensure the initiation and follow-up of internal investigations of occurrences.

(k) Subject to a risk assessment and the competent authority's agreement, with due regard to the size of the organisation, and the nature and complexity of its activities, the functions of the quality manager and the safety manager may be performed by the accountable manager, provided that the accountable manager has demonstrated the related level of competency.

AMC2 21.A.145(c)(2) Resources

ED Decision 2022/021/R

MANAGEMENT STAFF COMPETENCIES

(a) The organisation should provide initial and recurrent training to the persons or group of persons that are nominated in accordance with point 21.A.145(c)(2), which is adequate to their job function and ensures that their continued competency is maintained throughout the duration of their employment/contract.

(b) All prospective members of the production management staff and staff that is nominated in accordance with point 21.A.145(c)(2) should:

(1) be assessed for their competency, qualifications, and capabilities that are related to their intended duties;

(2) be able to demonstrate their knowledge of, and compliance with, the production management organisation procedures that are applicable to their job function; and

(3) be able to demonstrate an understanding of the safety management principles, as well as human factors (HF) issues and human performance (HP) issues that are related to their tasks.

(c) The quality manager should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the activities of the organisation, including knowledge of, and experience in, independent system monitoring.

(d) The competency of the person that assumes (or the persons that assume) the function of the safety manager should include, but not be limited to, the following:

(1) knowledge of the International Civil Aviation Organization (ICAO) standards and EU requirements for safety management;

(2) an understanding of management systems, including compliance monitoring systems;

(3) an understanding of risk management;

(4) an understanding of safety investigation techniques;

(5) an understanding of HF, including HP and limitations;

(6) an understanding of a positive safety culture and of its promotion; and

(7) operational experience related to the activities of the organisation.

AMC1 21.A.145(d)(1) Resources

ED Decision 2022/021/R

CERTIFYING STAFF

(a) Certifying staff should be nominated by the production organisation to ensure that each of their products, parts, and/or appliances qualifies for a statement of conformity or a release certificate. The position and number of certifying staff should be appropriate to the complexity of the product and the production rate.

(b) The qualifications of certifying staff should be based on their knowledge, background and experience and on specific training (or testing) that is established by the organisation to ensure that it is appropriate to the product, part, or appliance to be released.

(c) Training should be given to certifying staff to develop a satisfactory level of knowledge of product/part specifications, the organisation's procedures, production management systems (including compliance monitoring), aviation legislation, and the associated regulations, AMC and GM, that are relevant to their particular role. Training should include on-the-job training, as relevant.

(d) For that purpose, in addition to the general training policy, the organisation should define its own standards for training, including pre-qualification standards, for personnel to be identified as certifying staff.

(e) A feedback system to ascertain that the required standards are being maintained should be put in place to ensure the continuing compliance of personnel with authorisation requirements.

(f) For the release of products, parts, or appliances, the responsibilities to issue statements of conformity or release certificates (EASA Form 1) or permits to fly, including the approval of flight conditions, are allocated to the certifying staff that is identified in point 21.A.145(d)(2).

AMC1 21.A.145(d)(2) Resources

ED Decision 2022/021/R

EVIDENCE OF AUTHORISATION

(a) The certifying staff should be provided with evidence of their authorisation. This should be done through an internal authorisation document. That document should be in a style that makes its scope clear to the certifying staff and any entitled person that may require to examine the authorisation. It should include the privileges that are granted to the certifying staff and the category of products upon which they may exercise those privileges. Where codes are used to define the scope, an interpretation document should be readily available.

(b) Certifying staff are not required to carry the authorisation document at all times, but they should be able to make it available within a reasonable time following a request from an entitled person, which includes the competent authority.

21.A.147 Changes in the production management system

Regulation (EU) 2022/201

After the issue of a production organisation approval certificate, each change in the production management system that is significant for the demonstration of conformity or the airworthiness and environmental protection characteristics of the product, part or appliance, shall be approved by the competent authority before being implemented. The production organisation shall submit an application for approval to the competent authority demonstrating that it will continue to comply with this Annex.

AMC1 21.A.147 Changes to the production management system

ED Decision 2022/021/R

APPLICATION FOR APPROVAL OF SIGNIFICANT CHANGES OR VARIATIONS IN THE SCOPE OR TERMS OF A PRODUCTION ORGANISATION APPROVAL

(a) An application for approval of significant changes or variations in the scope or terms of a production organisation approval (POA) should be submitted in writing to the competent authority. The production organisation (PO) should demonstrate to the competent authority, on the basis of the submission of any proposed changes to the production organisation

exposition (POE), and before the implementation of the changes, that it will continue to comply with Part 21 after the implementation.

(b) The approved PO should submit to the competent authority an application for any significant change(s), or for a variation in the scope or terms of its POA, using an EASA Form 51 (see below).

EASA Form 51 **Application for significant changes or variation of the scope or terms of a Part 21 POA**	
Competent authority of an EU Member State or EASA	
1. Name and address of the POA holder:	
2. Approval reference number:	
3. Location(s)	
4. Brief summary of the proposed changes to the activities at the Item 3 addresses:	
(a) General:	
(b) Scope of approval:	
(c) Nature of privileges:	
5. Description of organisational changes:	
6. Position and name of the accountable manager or nominee:	
_____ Date	_____ Signature of the accountable manager (or nominee)

EASA Form 51

Block 1: The name should be entered as written on the current approval certificate. If a change in the name is to be announced, state the old name and address here, while using Block 5 for the information about the new name and address. The change of name and/or address should be supported by evidence, e.g. by a copy of the entry in the register of commerce.

Block 2: State the current approval reference number.

Block 3: State the location(s) for which changes in the terms of approval are requested, or state 'not applicable' if no change is anticipated.

Block 4: This block should include further details for the variation of the scope of approval for the addresses indicated in Block 3. The 'General' block should include overall information for the change (including changes e.g. in workforce, facilities, etc.), while the 'Scope of approval' block should address the change in the scope of work and products/categories, following the principles laid down in GM 21.A.151. The 'nature of privileges' block should indicate a change in the privileges as defined in points 21.A.163(b)-(d). State 'not applicable' if no change is anticipated.

Block 5: This block should state the changes to the organisation as it is defined in the current POE, including changes to the organisational structure, functions, and responsibilities. This block should therefore also be used to indicate a change in the accountable manager in accordance with point 21.A.145(c)(1) or a change in the nomination of the responsible managers in accordance with point 21.A.145(c)(2). State 'not applicable' if no change is anticipated.

Block 6: State the position and name of the accountable manager. Where there is a change in the nomination of the accountable manager, the information should refer to the nominee for that position. State 'not applicable' if no change is anticipated.

In case of an application for a change of the accountable manager, EASA Form 51 should be signed by the new nominee for that position. In all other cases, EASA Form 51 should be signed by the accountable manager.

GM1 21.A.147 Changes to the production management system

ED Decision 2023/014/R

SIGNIFICANT CHANGES

Changes to be approved by the competent authority include:

significant changes to the production capacity or methods;

changes in the organisation's structure, especially those parts of the organisation in charge of the safety management element or the quality management element of the organisation's production management system;

a change of the accountable manager or of any other person that is nominated under point 21.A.145(c)(2);

changes in the production management system that may have an important impact on the conformity orairworthiness of any product, part, or appliance, including in the reporting lines between the personnel that is nominated in accordance with point 21.A.145(c)(2) and the accountable manager; and

changes in the placement or control of significant subcontracted work or supplied parts.

To ensure that changes do not result in non-compliance with Part 21, it is in the interest of both the competent authority and the approval holder to establish a relationship and exchange information that will permit the necessary evaluation work to be conducted before the implementation of a change. This relationship should also permit agreement on the need for variation of the terms of approval (refer to point 21.A.143(a)(9)).

Where a change of name or ownership results in the issue of a new approval the investigation will normally take account of the competent authority's knowledge and information from the preceding approval.

Changes of location are addressed in point 21.A.148, changes of ownership in point 21.A.149, and the change of scope of the approval in point 21.A.153.

21.A.148 Changes of location

Regulation (EU) No 748/2012

A change of the location of the manufacturing facilities of the approved production organisation shall be deemed of significance and therefore shall comply with point 21.A.147.

AMC 21.A.148 Changes of location – Management during change of location

ED Decision 2012/020/R

1. The relocation of any work, to an unapproved location, or a location with inappropriate scope of approval, constitutes a change of significance to the organisation and requires approval by the competent authority as prescribed in 21.A.147. An unapproved relocation will invalidate the production organisation approval, and may necessitate re-application for any similar approval required at the new location. However, suitable transitional arrangements may be agreed with the competent authority, in advance of the relocation, which can allow continuation of the approval.
2. When an organisation expands its facility to include a new production location or moves parts of its production to a new location the production organisation approval may continue in force, but the approval does not include the new location until the competent authority has indicated its satisfaction with the arrangements.
3. For a change in location, taking an extended period of time, suitable transitional arrangements would require preparation of a co-ordination plan for the removal. The plan must, at least, identify the following:
   (a) A clearly identified person, or group of persons, responsible for co-ordinating the removal and acting as focal point for communication with all parties, including the competent authority.
   (b) The basis of the co-ordination plan, e.g., whether by product or area.
   (c) Planned timing of each phase of relocation.
   (d) Arrangements for maintaining the standards of the approval up to the point where the production area is closed down.
   (e) Arrangements for verifying continued production quality upon resumption of work at the new location.

(f) Arrangements for check and/or re-calibration of inspection aids or production tools and jigs before resuming production.

(g) Procedures which ensure that goods are not released from the new location until their associated production and quality systems have been verified.

(h) Arrangements for keeping the competent authority informed of progress with the relocation.

4. From the co-ordination plan, the competent authority can determine the points at which it wishes to conduct investigation.

5. If an agreed co-ordination plan is in operation, the competent authority will normally allow the existing approval to remain in force and will, where appropriate, grant an additional approval to cover the new address for the duration of the move.

21.A.149 Transferability

Regulation (EU) No 748/2012

Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.147, a production organisation approval is not transferable.

GM1 21.A.149 and 21.A.249 Transferability

ED Decision 2022/021/R

GENERAL

A transfer of approval to another production or design organisation is, by default, excluded by points 21.A.149 or 21.A.249 respectively. These points only allow it exceptionally if it is a direct consequence of a transfer of ownership in an approved production or design organisation, which is then considered a significant change to the existing approval (to which point 21.A.147 or 21.A.247 applies).

As a consequence, and in order to apply this exception, the production or design organisation has to demonstrate to the competent authority the existence of a change in ownership which resulted in the fact that a different legal entity is now conducting the approved production or design functions while remaining effectively unchanged.

An example of such an exception is a change of ownership that leads to a re-registration of the organisation (supported by the appropriate certificate from the National Companies Registration Office or equivalent). In order to demonstrate that the organisation remains effectively unchanged, the organisation needs to demonstrate that there are no changes affecting the initial demonstration of compliance of the organisation with Subpart G or Subpart J. If, for instance, the change of ownership would, in addition, lead to a change of address, facilities, type of work, staff, accountable manager or persons nominated under points 21.A.145 or 21.A.245, then it is not an acceptable transfer situation; the exception does not apply in this case. A new investigation by the competent authority would be necessary. The new organisation would have to apply for its own approval. In such a case where the organisation applies for a new approval, the demonstration of compliance in accordance with points 21.A.135 or 21.A.235 may be limited to the demonstration that the changes in the organisation comply with the Subpart G or Subpart J requirements, while referring for the rest to the compliance demonstration of the previous approval holder.

A pure name change, where the ownership does not change, does not require a transfer of the approval. In this case, the natural or legal person that holds the approval remains the same. However, as a consequence of the name change, the approval document needs to be amended to reflect the new company name. This is a significant change, to which point 21.A.147 or 21.A.247 applies.

Another example of a transfer of ownership, which may be exceptionally accepted under points 21.A.149 or 21.A.249, may be the event of receivership (bankruptcy, insolvency or another equivalent legal process). In this case, there is no change to the production or design organisation, except that the custodial responsibility for its property, including its tangible and intangible assets and rights, is transferred to a receiver or insolvency administrator. The receivership aims to continue the business of the same organisation.

21.A.151 Terms of approval

Regulation (EU) No 748/2012

The terms of approval shall identify the scope of work, the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise the privileges under point 21.A.163.

Those terms shall be issued as part of a production organisation approval.

GM 21.A.151 Terms of approval – Scope and categories

ED Decision 2012/020/R

Terms of approval document(s) will be issued by the competent authority under 21.A.135 to identify the scope of work, the products, and/or categories for which the holder is entitled to exercise the privileges defined in 21.A.163.

The codes shown against each scope of work item are intended for use by the competent authority for purposes such as managing, administering and filing details of approvals. It may also assist in the production and publication of a list of approval holders.

The scope of work, the Products, Parts, or Appliances for which the POA holder is entitled to exercise the privileges defined in 21.A.163 will be described by the competent authority as follows:

FOR PRODUCTS:

1. General area, similar to the titles of the corresponding certification codes.
2. Type of Product, in accordance with the type-certificate.

FOR PARTS AND APPLIANCES:

1. General area, showing the expertise, e.g., mechanical, metallic structure.
2. Generic type, e.g., wing, landing gear, tyres.

SCOPE OF WORK		PRODUCTS/CATEGORIES
A1	Large Aeroplanes	State types
A2	Small Aeroplanes	‘
A3	Large Helicopters	‘
A4	Small Helicopters	‘
A5	Gyroplanes	‘
A6	Sailplanes	‘
A7	Motor Gliders	‘
A8	Manned Balloons	‘
A9	Airships	‘
A10	Light Sport Aeroplanes	‘
A11	Very Light Aeroplanes	‘
A12	Other	‘

SCOPE OF WORK		PRODUCTS/CATEGORIES
B1 B2 B3 B4	Turbine Engines Piston Engines APU's Propellers	' ' '
C1	Appliances:	State appliance generic types (e.g., Tyres, Altimeter, etc.) Examples include: Avionic, Com/Nav/Pulse Computer System, Aircraft/Engine/Avionic Instruments, Mechanical/Electrical/Gyroscopic/Electronic Mechanical/Hydraulic/Pneumatic
C2	Parts:	State part generic types (e.g., Wing, Landing Gear, etc.) Examples include: Structural, Metallic/non-metallic Mechanical/Hydraulic/Pneumatic Electrical Electronic
D1	Maintenance	State aircraft types
D2	Issue of permit to fly	State aircraft types

21.A.153 Changes to the terms of approval

Regulation (EU) No 748/2012

Each change to the terms of approval shall be approved by the competent authority. An application for a change to the terms of approval shall be made in a form and manner established by the competent authority. The applicant shall comply with the applicable requirements of this Subpart.

AMC 21.A.153 Changes to the terms of approval — Application for a change to the terms of approval

ED Decision 2022/021/R

EASA Form 51 (see AMC1 21.A.147) must be obtained from the competent authority and completed in accordance with the procedures of the production organisation exposition (POE).

The information entered on the form is the minimum required by the competent authority to assess the need for change of the production organisation approval.

The completed form and an outline of the changed POE, and details of the proposed change to POA terms of approval should be forwarded to the competent authority.

21.A.158 Findings and observations

Regulation (EU) 2022/201

(a) After receipt of the notification of findings in accordance with point 21.B.225, the holder of the production organisation approval certificate shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;
2. define a corrective action plan;
3. demonstrate the implementation of the corrective action to the satisfaction of the competent authority.

(b) The actions referred to in point (a) shall be performed within the period agreed with that competent authority in accordance with point 21.B.225.

(c) The observations received in accordance with 21.B.225(e) shall be given due consideration by the holder of the production organisation approval certificate. The organisation shall record the decisions taken in respect of those observations.

GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings and observations

ED Decision 2022/021/R

ROOT CAUSE ANALYSIS

(a) It is important that the analysis does not primarily focus on establishing who or what caused the non-compliance, but on why it was caused. Establishing the root cause(s) of non-compliance often requires an overarching view of the events and circumstances that led to it, to identify all the possible systemic and contributing factors (human factors (HF), regulatory, organisational, technical factors, etc.) in addition to the direct factors.

(b) A narrow focus on single events or failures, or the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the non-compliance, may not properly reflect the complexity of the issue, and therefore, there is a risk that important factors that must be considered to prevent reoccurrence will be ignored.

Such an inappropriate or partial root cause analysis often leads to applying ‘quick fixes’ that only address the symptoms of the non-compliance. A peer review of the results of the root cause analysis may increase its reliability and objectivity.

AMC1 21.A.125B(a)(3), 21.A.158(a)(3) and 21.A.258(a)(3) Findings and observations

ED Decision 2022/021/R

FINDING-RELATED CORRECTIVE-ACTION PLAN AND IMPLEMENTATION

After receipt of notification of findings, the organisation should identify and define the action for all findings, to address the effects of the non-compliance, as well as its root cause(s) and contributing factor(s).

Depending on the issues identified, the organisation may need to take immediate corrective action.

The corrective action plan should:

— include the correction of the issue, corrective and preventive action, as well as the planning to implement them; and

— be timely submitted to the competent authority for acceptance before it is effectively implemented.

After receiving the competent authority’s acceptance of the corrective action plan, the organisation should implement the associated action.

Within the agreed period, the organisation should inform the competent authority that the corrective action plan has been implemented and should send the associated pieces of evidence, on request from the competent authority.

AMC1 21.A.125B(c), 21.A.158(c), 21.A.258(c) Findings and observations

ED Decision 2022/021/R

DUE CONSIDERATION TO OBSERVATIONS

For each observation that is notified by the competent authority, the organisation should analyse the related issues and determine when action is needed.

The handling of the observations may follow a process similar to the handling of the findings by the organisation.

The organisation should record the analysis and the related outputs, such as action taken, or the reasons why no action was taken.

21.A.159 Duration and continued validity

Regulation (EU) 2022/201

(a) A production organisation approval certificate shall be issued for an unlimited period of time. It shall remain valid subject to the production organisation's compliance with all the following conditions:

1. the production organisation continues to comply with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;
2. the competent authority is permitted by the production organisation or by any of its partners, suppliers or subcontractors to perform the investigations in accordance with point 21.A.9;
3. the production organisation is able to provide the competent authority with evidence showing that it maintains satisfactory control of the manufacture of products, parts and appliances under the approval;
4. the production organisation approval certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the production organisation.

(b) Upon surrender or revocation, the production organisation approval certificate shall be returned to the competent authority.

GM1 21.A.159(a)(3) Duration and continued validity

ED Decision 2023/014/R

SATISFACTORY CONTROL OF THE MANUFACTURE

The following are examples of lack of satisfactory control:

1. an uncontrolled non-compliance with type design data affecting the airworthiness of product part or appliance
2. an incident/accident identified as caused by POA holder
3. non-compliance with the POE and its associated procedures which could affect conformity of manufactured items to design data
4. insufficient competency of certifying staff

5. insufficient resources in respect of facilities, tools and equipment

6. insufficient means to ensure good production work standards

7. a lack of effective and timely response to prevent a recurrence of any of point 1 to 6.

21.A.163 Privileges

Regulation (EU) 2022/1358

Pursuant to the terms of approval issued under point 21.A.135, the holder of a production organisation approval may:

(a) perform production activities under this Annex or Annex Ib (Part 21 Light);

(b) in the case of complete type-certified aircraft and upon presentation of a statement of conformity (EASA Form 52) issued under points 21.A.174 and 21.A.204 of this Annex or under points 21L.A.143(c) and 21L.A.163 of Annex Ib (Part 21 Light), obtain an aircraft certificate of airworthiness and a noise certificate without further showing;

(c) in the case of other products, parts or appliances, issue authorised release certificates (EASA Form 1) under this Annex (Part 21) or under Annex Ib (Part 21 Light) without further showing;

(d) in the case of an aircraft that is subject to a declaration of design compliance under point 21L.A.43 of Annex Ib (Part 21 Light) and upon presentation of a statement of conformity (EASA Form 52B) issued under points 21L.A.143(d) and 21L.A.163 of Annex Ib (Part 21 Light), obtain an aircraft restricted certificate of airworthiness and a restricted noise certificate without further showing;

(e) in the case of products or parts to be installed on an aircraft that is subject to a declaration of design compliance under point 21L.A.43 of Annex Ib (Part 21 Light), issue authorised release certificates (EASA Form 1) under Annex Ib (Part 21 Light) without further showing;

(f) maintain a new aircraft that it has produced and issue a certificate of release to service (EASA Form 53) in respect of that maintenance;

(g) under procedures agreed with its competent authority for production, for an aircraft it has produced and when the production organisation itself is controlling under its Production Organisation Approval the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight, to issue a permit to fly in accordance with point 21.A.711(c) including approval of the flight conditions in accordance with point 21.A.710(b).

GM1 21.A.130, 21.A.163 and 21.A.165 Performance of tasks in real time for the issuance of an 'EASA Form 1' for prototype and new parts, appliances and products other than complete aircraft, using information and communication technologies (ICT)

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote ICT to support the issuance of an 'EASA Form 1' for prototype and newly produced parts, appliances and products other than complete aircraft.

It is the responsibility of the production organisation to assess whether the use of remote ICT constitutes a suitable alternative to the physical inspection of the part, appliance or product in accordance with the applicable requirements. The production organisation that intends to use the remote ICT for such purposes should first discuss the feasibility aspects with its competent authority.

(a) Terminology

In the context of this GM, the following terminology is used:

— 'issue of an EASA Form 1' means the issuance of an EASA Form 1 under Part 21 Subpart G by a certifying staff, raise an EASA Form 1 under Part 21 Subpart F by an authorised person, and the validation of an EASA Form 1 under Part 21 Subpart F by a competent authority inspector, except in the case of issuance of an EASA Form 1 for the correction of error(s) on a previously issued certificate and for the recertification of an item from 'prototype' to 'new' provided that the design data has not changed;

— 'authorised staff' means certifying staff as defined in Part 21 Subpart G, and 'authorised person' and 'competent authority inspector' as defined in Part 21 Subpart F;

— 'item' means any part, appliance or product other than a complete aircraft;

— 'applicable design data' means non-approved design data for a prototype item and approved design data for a newly produced item;

— 'task' means any inspection, test and/or verification, as described in a documented procedure, which is needed to be performed by an authorised staff before signing an EASA Form 1;

— 'remote ICT' means any real-time video and audio communication tools using information and communication technologies (ICT) whose aim is to enable the performance of the task(s) by the authorised staff from a location different from that where the item is located (on-site).

(b) Regulatory context

The following entities may issue an EASA Form 1 for produced items in order to certify their conformity to the applicable design data and, for new items, their condition for safe operation:

— the holder of a letter of agreement (LoA) that is issued in accordance with Part 21 Subpart F (refer to point 21.A.130(a));

— the competent authority in the context of Part 21 Subpart F (refer to point 21.A.130(d));

— the holder of a production organisation approval (POA) in accordance with Part 21 Subpart G (refer to point 21.A.163(c)).

An EASA Form 1 has to be issued by appropriately qualified authorised staff. Part 21 does not require authorised staff to be on-site when issuing an EASA Form 1, nor how the production organisation and the competent authority shall determine whether the part/appliance/product other than a complete aircraft conforms to the applicable design data and, for a new item, is in a condition for safe operation. These should be detailed in a documented procedure accepted by the competent authority.

Part 21 requires:

- in point 21.A.130(d) that the competent authority validate the EASA Form 1 following inspections performed in accordance with 21.B.135(b) if it finds after the inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation;
- in point 21.A.165(c) that the POA holder has to determine that:
  - other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1;
  - other products, parts or appliances conform to the applicable data before issuing an EASA Form 1.

Typically, compliance with these requirements is ensured through the on-site presence of the authorised staff in order to guarantee they have appropriate access to the item, as needed.

However, compliance with these requirements may be also ensured in certain circumstances, determined as per the considerations described in point (c) below, by remotely conducting the tasks which are needed before the issuance of an EASA Form 1 by the use of remote ICT. The following considerations should be used as guidelines when the on-site presence of the authorised staff is to be replaced by virtual presence, using remote ICT.

(c) The use of remote ICT to support the issuance of an EASA Form 1

Remote ICT may have limitations that could render it unsuitable for some applications. Accordingly, careful consideration and risk management should be applied when determining when to use remote ICT. These considerations, listed below, are however not exhaustive and should not be treated as a checklist.

(1) General considerations

- As an overarching principle, it needs to be determined whether the nature of the tasks to be performed by the authorised staff allows the use of remote ICT.
- The facility where the item is located:
  - should be referred to in EASA Form 65 or EASA Form 55, directly or indirectly by reference to the corresponding section of the manual or production organisation exposition (POE); or
  - for a POA, should be a facility from where a POE procedure related to point 21.A.139(b)(1)(xv) authorises the issuance of an EASA Form 1.
- The complexity, novelty and safety criticality of the item to be released with the EASA Form 1 should be taken into account.
- The level of competence and experience of the personnel in the use of the particular procedures and equipment that will be used to perform the tasks before issuing EASA Form 1.

— Previous experience of the organisation / confidence in the organisation's inspection system / quality system / management system.

— The appropriateness of the inspection and test instruments and/or equipment, especially if used to evaluate qualitative aspects of a product, part or appliance.

(2) Equipment and set-up considerations

— The suitability of video resolution, fidelity, and field of view for the task being performed.

— The need for multiple cameras, imaging systems or microphones, and whether the person that performs or witnesses the tasks can switch between them, or direct them to be switched, and has the possibility to stop the process, ask a question, move the equipment, etc.

— The controllability of viewing direction, zoom, and lighting.

— The appropriateness of audio fidelity for the evaluation being conducted.

— Whether real-time, uninterrupted communication between the person(s) authorised to remotely witness the activity (authorised staff) and the personnel performing it exists at the location where the item is located.

— The need for unique testing devices or equipment (for example, fast-frame cameras, special lighting conditions, sensitive listening devices, mobile phones with cameras for HD video calls).

— Whether personnel have been adequately trained in the proper set-up, validation and use of the technology, tools and/or equipment to be used.

— The need for the recording of audio and video data, as well for its retention or for the retention of other information.

(3) Cybersecurity considerations

There are cases where the facilities where the tasks have to be performed are subject to strict security limitations. When using remote ICT for the tasks needed before issuing an EASA Form 1, it is the responsibility of the organisation to provide an equivalent level of security, therefore the person that is responsible for IT security within the organisation should concur to the ICT technology before proceeding.

(4) Documenting the use of the remote ICT

The documented processes (procedures) developed by the holder of a letter of agreement (LoA) or a POA should be accepted by the competent authority, and should describe the following:

— the risk assessment process required to determine the appropriateness of the remote ICT taking into account the above-mentioned considerations;

— the tasks to be performed, including preparation activities, inspections, tests, verifications to be done, personnel involved in the remote ICT activities and their level of competence;

— that it is necessary to guarantee that authorised staff have access to all necessary data (e.g. drawings, schematics, datasheets, etc.) they require in order to determine that the item conforms to the applicable design data, and how this can be ensured;

— how remote ICT will be used in real time (not pre-recorded) so that authorised staff may direct the performance of the tasks as if it were conducted in-person, on-site, with the aid of the equipment or the personnel supporting the activity at the remote location;

— the procedures for conducting a reinspection in case the equipment malfunctions or the process fails to yield acceptable results; a reinspection using remote ICT may be accomplished after correcting the malfunction or process, or by an actual on-site inspection;

— how authorised staff should record and communicate any difficulties or concerns regarding the process so that the organisation can improve its programme;

— how the use of the remote ICT will be documented in the required records; and

— how the organisation's IT security is ensured throughout the remote ICT process (data protection and intellectual property of the organisation also need to be safeguarded).

AMC No 1 to 21.A.163(c) Computer generated signature and electronic exchange of the EASA Form 1

ED Decision 2012/020/R

1. Submission to the competent authority

Any POA holder/applicant intending to implement an electronic signature procedure to issue EASA Form 1 and/or to exchange electronically such data contained on the EASA Form 1, should document it and submit it to the competent authority as part of the documents attached with its exposition.

2. Characteristics of the electronic system generating the EASA Form 1

The electronic system should:

— guarantee secure access for each certifying staff;

— ensure integrity and accuracy of the data certified by the signature of the Form and be able to show evidence of the authenticity of the EASA Form 1 (recording and record keeping) with suitable security, safeguards and backups;

— be active only at the location where the part is being released with an EASA Form 1;

— not permit to sign a blank form;

— provide a high degree of assurance that the data has not been modified after signature (if modification is necessary after issuance, i.e. re-certification of a part), a new form with a new number and reference to the initial issuance should be made); and

— provide for a 'personal' electronic signature, identifying the signatory. The signature should be generated only in the presence of the signatory.

An electronic signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication and should meet the following criteria:

— it is uniquely linked to the signatory;

— it is capable of identifying the signatory;

— it is created using means that the signatory can maintain under their sole control.

The electronic signature is defined as an electronically generated value based on a cryptographic algorithm and appended to data in a way to enable the verification of the data's source and integrity.

POA holders/applicants are reminded that additional national and/or European requirements may need to be satisfied when operating electronic systems. 'Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures', as last amended may constitute a reference.

The electronic system should be based on a policy and management structure (confidentiality, integrity and availability), such as:

— administrators, signatories;

— scope of authorisation, rights;

— password and secure access, authentication, protections, confidentiality;

— track changes;

— minimum blocks to be completed, completeness of information;

— archives;

— etc.

The electronic system generating the EASA Form 1 may contain additional data such as:

— manufacturer code;

— customer identification code;

— workshop report;

— inspection results;

— etc.

3. Characteristics of the computer generated signature

To facilitate understanding and acceptance of the EASA Form 1 released with an electronic signature, the following statement should be in Block 13b: 'Electronic Signature on File'.

In addition to this statement, it is accepted to print or display a signature in any form such as a representation of the hand-written signature of the person signing (i.e. scanned signature) or their name.

When printing the electronic form, the EASA Form 1 should meet the general format as specified in Appendix I to Part 21. A watermark-type 'PRINTED FROM ELECTRONIC FILE' should be printed on the document.

When the electronic file contains a hyperlink to data, required to determine the airworthiness of the item(s), the data associated to the hyperlink, when printed, should be in a legible format and be identified as a reference from the EASA Form 1.

Additional information not required by the EASA Form 1 completion instructions may be added to the printed copies of EASA Form 1 as long as the additional data do not prevent a person from filling out, issuing, printing, or reading any portion of the EASA Form 1. This additional data should be provided only in block 12 unless it is necessary to include it in another block to clarify the content of that block.

4. Electronic exchange of the electronic EASA Form 1

The electronic exchange of the electronic EASA Form 1 should be accomplished on a voluntary basis. Both parties (issuer and receiver) should agree on electronic transfer of the EASA Form 1.

For that purpose, the exchange needs to include:

— all data of the EASA Form 1, including data referenced from the EASA Form 1;

— all data required for authentication of the EASA Form 1.

In addition, the exchange may include:

— data necessary for the electronic format;

— additional data not required by the EASA Form 1 completion instructions, such as manufacturer code, customer identification code.

The system used for the exchange of the electronic EASA Form 1 should provide:

— a high level of digital security; the data should be protected, unaltered or uncorrupted;

— traceability of data back to its source should be possible.

Trading partners wishing to exchange EASA Form 1 electronically should do so in accordance with these means of compliance stated in this document. It is recommended that they use an established, common, industry method such as Air Transport Association (ATA) Spec 2000 Chapter 16.

The applicant(s) is/are reminded that additional national and/or European requirements may need to be satisfied when operating the electronic exchange of the electronic EASA Form 1.

The receiver should be capable of regenerating the EASA Form 1 from the received data without alteration; if not the system should revert back to the paper system.

When the receiver needs to print the electronic form, refer to the subparagraph 3 above.

AMC2 21.A.163(c) Completion of EASA Form 1

ED Decision 2021/011/R

EASA Form 1 Block 8 ‘Part Number’

The part number as it appears on the item, is usually defined in the design data; however in the case of a kit of parts, media containing software or any other specific condition of supply may be defined in production data developed from design data. Information about the contents of the kit or media may be given in block 12 or in a separate document cross-referenced from block 12.

EASA Form 1 Block 12 ‘Remarks’

Examples of conditions which would necessitate statements in Block 12 are:

— When the certificate is used for prototype purposes the following statement must be entered at the beginning of block 12:

'NOT ELIGIBLE FOR INSTALLATION ON IN-SERVICE TYPE-CERTIFICATED AIRCRAFT'.

— Re-certification of items from 'prototype' (conformity only to non-approved data) to 'new' (conformity to approved data and in a condition for safe operation) once the applicable design data is approved.

The following statement must be entered in block 12:

RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW':

THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA *[insert TC/STC number, revision level]*, DATED *[insert date if necessary for identification of revision status]*, TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.

— When a new certificate is issued to correct error(s) the following statement must be entered in block 12:

'THIS CERTIFICATE CORRECTS THE ERROR(S) IN BLOCK(S) *[enter block(s) corrected]* OF THE CERTIFICATE *[enter original tracking number]* DATED *[enter original issuance date]* AND DOES NOT COVER CONFORMITY/ CONDITION/RELEASE TO SERVICE'.

Examples of data to be entered in this block as appropriate:

— For complete engines, a statement of compliance with the applicable emissions requirements current on the date of manufacture of the engine.

— For ETSO articles, state the applicable ETSO number.

— Modification standard.

— Compliance or non-compliance with airworthiness directives or service bulletins.

— Details of repair work carried out, or reference to a document where this is stated.

— Shelf-life data, manufacture date, cure date, etc.

— Information needed to support shipment with shortages or reassembly after delivery.

— References to aid traceability, such as batch numbers.

— In the case of an engine, if the competent authority has granted an exemption from the applicable engine environmental protection requirements, the record: 'ENGINE EXEMPTED FROM [*REFERENCE TO THE TYPE OF EMISSION*] EMISSIONS ENVIRONMENTAL PROTECTION REQUIREMENT'.

AMC1 21.A.163(d) Privileges

ED Decision 2021/001/R

MAINTENANCE

The applicant may apply for terms of approval, which cover maintenance of a new aircraft that it has manufactured, as necessary to keep it in an airworthy condition, but not beyond the point at which the applicable operational rules require maintenance to be performed by an approved maintenance organisation. If the production organisation intends to maintain the aircraft beyond that point, it would have to apply for and obtain an appropriate maintenance approval.

When the competent authority is satisfied that the procedures required by 21.A.139 are satisfactory to control maintenance activities so as to ensure that the aircraft is airworthy, this capability will be stated in the terms of approval.

MAINTENANCE OF AIRCRAFT

Examples of such maintenance activities are:

— Preservation, periodic inspection visits, etc.

— Embodiment of a Service Bulletin.

— Application of airworthiness directives.

— Repairs.

— Maintenance tasks resulting from special flights.

— Maintenance tasks to maintain airworthiness during flight training, demo flights and other non-revenue flights.

Any maintenance activities must be recorded in the Aircraft Log Book. It must be signed by certifying staff for attesting the conformity of the work to the applicable airworthiness data.

In some cases the Aircraft Log Book is not available, or the production organisation prefers to use a separate form (for instance for a large work package or for delivery of the aircraft to the customer). In these cases, production organisations must use EASA Form 53 which must subsequently become part of the aircraft maintenance records.

MAINTENANCE OF COMPONENTS OUTSIDE THE POA CAPABILITY

Such a maintenance activity outside the capability of the aircraft POA holder may still be accomplished under the production approval of the original release organisation. In such circumstances, the engine(s), propeller(s), parts and appliances will require re-release in accordance with point 21.A.163(c) (EASA Form 1).

Records relevant to continued airworthiness or retirement lives, such as engine runs, flight hours, landings, etc., which affect part retirement of maintenance schedules must be specified on any re-release.

As an alternative the engine, propeller, part or appliance may be maintained by the holder of an approval in accordance with Part 145, classified and released as ‘used’.

AMC 21.A.163(e) Procedure for the issue of a permit to fly including approval of the flight conditions

ED Decision 2012/020/R

1. INTENT

This acceptable means of compliance provides means to develop a procedure for the issue of a permit to fly including approval of the flight conditions.

Each POA applicant or holder must develop its own internal procedure following this AMC, in order to obtain the privilege of 21.A.163(e) to issue permits to fly for an aircraft under procedures agreed with its competent authority for production, when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight.

2. PROCEDURE FOR THE ISSUE OF A PERMIT TO FLY

2.1 Content

The procedure must address the following points:

— as relevant, in accordance with 21.A.710(b), the approval of flight conditions;

— conformity with approved conditions;

— issue of the permit to fly under the POA privilege;

— authorised signatories;

— interface with the local authority for the flight.

2.2 Approval of the flight conditions (when relevant)

The procedure must include the process to establish and justify the flight conditions, in accordance with 21.A.708 and how compliance with 21.A.710(c) is established, and include the EASA Form 18B as defined in AMC 21.A.709(b) for the approval under the POA privilege.

2.3 Conformity with approved conditions

The procedure must indicate how conformity with approved conditions is made, documented and attested by an authorised person.

2.4 Issue of the permit to fly under the POA privilege

The procedure must describe the process to prepare the EASA Form 20b and how compliance with 21.A.711(c) and (e) is established before signature of the permit to fly.

2.5 Authorised signatories

The person(s) authorised to sign the permit to fly under the privilege of 21.A.163(e) must be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the Production Organisation Exposition.

2.6 Interface with the local authority for the flight

The procedure must include provisions describing the communication with the local authority for compliance with the local requirements which are outside the scope of the conditions of 21.A.708(b) (see 21.A.711(e)).

21.A.165 Obligations of the holder

Regulation (EU) 2022/1358

Pursuant to the terms of approval issued under point 21.A.135, the holder of a production organisation approval shall:

(a) ensure that the production organisation exposition furnished in accordance with point 21.A.143 and the documents to which it refers, are used as basic working documents within the organisation;

(b) maintain the production organisation in conformity with the data and procedures approved for the production organisation approval;

(c) 1. determine that each completed aircraft conforms to the type design and is in condition for safe operation prior to submitting statements of conformity to the competent authority; or

2. determine that other products, parts or appliances are complete and conform to the approved design data or declared design data and are in a condition for safe operation before issuing an EASA Form 1 to certify conformity to approved or declared design data and condition for safe operation;

3. additionally, in the case of environmental requirements determine that:

   (i) the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine; and

   (ii) the completed aeroplane is in compliance with the applicable CO_2 emissions requirements on the date its first certificate of airworthiness is issued.

4. determine that other products, parts or appliances conform to the applicable data before issuing an EASA Form 1 as a conformity certificate;

(d) provide assistance to the holder of the type certificate or other design approval or a natural or legal person who made a declaration of design compliance under Subpart C of Section A of Annex Ib (Part 21 Light) in dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced;

(e) where, under its terms of approval, the holder intends to issue a certificate of release to service, determine that each completed aircraft has been subjected to the necessary maintenance and is in a condition for safe operation, prior to issuing the certificate;

(f) where applicable, under the privilege of point 21.A.163(e), determine the conditions under which a permit to fly can be issued;

(g) where applicable, under the privilege of point 21.A.163(e), establish compliance with points 21.A.711(c) and (e) before issuing an aircraft with a permit to fly;

(h) comply with Subpart A of this Section.

GM1 21.A.130, 21.A.163 and 21.A.165 Performance of tasks in real time for the issuance of an 'EASA Form 1' for prototype and new parts, appliances and products other than complete aircraft, using information and communication technologies (ICT)

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote ICT to support the issuance of an 'EASA Form 1' for prototype and newly produced parts, appliances and products other than complete aircraft.

It is the responsibility of the production organisation to assess whether the use of remote ICT constitutes a suitable alternative to the physical inspection of the part, appliance or product in accordance with the applicable requirements. The production organisation that intends to use the remote ICT for such purposes should first discuss the feasibility aspects with its competent authority.

(a) Terminology

In the context of this GM, the following terminology is used:

— 'issue of an EASA Form 1' means the issuance of an EASA Form 1 under Part 21 Subpart G by a certifying staff, raise an EASA Form 1 under Part 21 Subpart F by an authorised person, and the validation of an EASA Form 1 under Part 21 Subpart F by a competent authority inspector, except in the case of issuance of an EASA Form 1 for the

correction of error(s) on a previously issued certificate and for the recertification of an item from 'prototype' to 'new' provided that the design data has not changed;

— 'authorised staff' means certifying staff as defined in Part 21 Subpart G, and 'authorised person' and 'competent authority inspector' as defined in Part 21 Subpart F;

— 'item' means any part, appliance or product other than a complete aircraft;

— 'applicable design data' means non-approved design data for a prototype item and approved design data for a newly produced item;

— 'task' means any inspection, test and/or verification, as described in a documented procedure, which is needed to be performed by an authorised staff before signing an EASA Form 1;

— 'remote ICT' means any real-time video and audio communication tools using information and communication technologies (ICT) whose aim is to enable the performance of the task(s) by the authorised staff from a location different from that where the item is located (on-site).

(b) Regulatory context

The following entities may issue an EASA Form 1 for produced items in order to certify their conformity to the applicable design data and, for new items, their condition for safe operation:

— the holder of a letter of agreement (LoA) that is issued in accordance with Part 21 Subpart F (refer to point 21.A.130(a));

— the competent authority in the context of Part 21 Subpart F (refer to point 21.A.130(d));

— the holder of a production organisation approval (POA) in accordance with Part 21 Subpart G (refer to point 21.A.163(c)).

An EASA Form 1 has to be issued by appropriately qualified authorised staff. Part 21 does not require authorised staff to be on-site when issuing an EASA Form 1, nor how the production organisation and the competent authority shall determine whether the part/appliance/product other than a complete aircraft conforms to the applicable design data and, for a new item, is in a condition for safe operation. These should be detailed in a documented procedure accepted by the competent authority.

Part 21 requires:

— in point 21.A.130(d) that the competent authority validate the EASA Form 1 following inspections performed in accordance with 21.B.135(b) if it finds after the inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation;

— in point 21.A.165(c) that the POA holder has to determine that:

  — other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1;

  — other products, parts or appliances conform to the applicable data before issuing an EASA Form 1.

Typically, compliance with these requirements is ensured through the on-site presence of the authorised staff in order to guarantee they have appropriate access to the item, as needed.

However, compliance with these requirements may be also ensured in certain circumstances, determined as per the considerations described in point (c) below, by remotely conducting the

tasks which are needed before the issuance of an EASA Form 1 by the use of remote ICT. The following considerations should be used as guidelines when the on-site presence of the authorised staff is to be replaced by virtual presence, using remote ICT.

(c) The use of remote ICT to support the issuance of an EASA Form 1

Remote ICT may have limitations that could render it unsuitable for some applications. Accordingly, careful consideration and risk management should be applied when determining when to use remote ICT. These considerations, listed below, are however not exhaustive and should not be treated as a checklist.

(1) General considerations

— As an overarching principle, it needs to be determined whether the nature of the tasks to be performed by the authorised staff allows the use of remote ICT.

— The facility where the item is located:

  — should be referred to in EASA Form 65 or EASA Form 55, directly or indirectly by reference to the corresponding section of the manual or production organisation exposition (POE); or

  — for a POA, should be a facility from where a POE procedure related to point 21.A.139(b)(1)(xv) authorises the issuance of an EASA Form 1.

— The complexity, novelty and safety criticality of the item to be released with the EASA Form 1 should be taken into account.

— The level of competence and experience of the personnel in the use of the particular procedures and equipment that will be used to perform the tasks before issuing EASA Form 1.

— Previous experience of the organisation / confidence in the organisation's inspection system / quality system / management system.

— The appropriateness of the inspection and test instruments and/or equipment, especially if used to evaluate qualitative aspects of a product, part or appliance.

(2) Equipment and set-up considerations

— The suitability of video resolution, fidelity, and field of view for the task being performed.

— The need for multiple cameras, imaging systems or microphones, and whether the person that performs or witnesses the tasks can switch between them, or direct them to be switched, and has the possibility to stop the process, ask a question, move the equipment, etc.

— The controllability of viewing direction, zoom, and lighting.

— The appropriateness of audio fidelity for the evaluation being conducted.

— Whether real-time, uninterrupted communication between the person(s) authorised to remotely witness the activity (authorised staff) and the personnel performing it exists at the location where the item is located.

— The need for unique testing devices or equipment (for example, fast-frame cameras, special lighting conditions, sensitive listening devices, mobile phones with cameras for HD video calls).

— Whether personnel have been adequately trained in the proper set-up, validation and use of the technology, tools and/or equipment to be used.

— The need for the recording of audio and video data, as well for its retention or for the retention of other information.

(3) Cybersecurity considerations

There are cases where the facilities where the tasks have to be performed are subject to strict security limitations. When using remote ICT for the tasks needed before issuing an EASA Form 1, it is the responsibility of the organisation to provide an equivalent level of security, therefore the person that is responsible for IT security within the organisation should concur to the ICT technology before proceeding.

(4) Documenting the use of the remote ICT

The documented processes (procedures) developed by the holder of a letter of agreement (LoA) or a POA should be accepted by the competent authority, and should describe the following:

— the risk assessment process required to determine the appropriateness of the remote ICT taking into account the above-mentioned considerations;

— the tasks to be performed, including preparation activities, inspections, tests, verifications to be done, personnel involved in the remote ICT activities and their level of competence;

— that it is necessary to guarantee that authorised staff have access to all necessary data (e.g. drawings, schematics, datasheets, etc.) they require in order to determine that the item conforms to the applicable design data, and how this can be ensured;

— how remote ICT will be used in real time (not pre-recorded) so that authorised staff may direct the performance of the tasks as if it were conducted in-person, on-site, with the aid of the equipment or the personnel supporting the activity at the remote location;

— the procedures for conducting a reinspection in case the equipment malfunctions or the process fails to yield acceptable results; a reinspection using remote ICT may be accomplished after correcting the malfunction or process, or by an actual on-site inspection;

— how authorised staff should record and communicate any difficulties or concerns regarding the process so that the organisation can improve its programme;

— how the use of the remote ICT will be documented in the required records; and

— how the organisation’s IT security is ensured throughout the remote ICT process (data protection and intellectual property of the organisation also need to be safeguarded).

GM 21.A.165(a) Obligations of the holder – Basic working document

ED Decision 2012/020/R

Compliance with the production organisation exposition (POE) is a prerequisite for obtaining and retaining a production organisation approval.

The organisation should make the POE available to its personnel where necessary for the performance of their duties. A distribution list should therefore be established. Where the POE mainly refers to separate manuals or procedures, the distribution of the POE could be limited.

The organisation should ensure that personnel have access to and are familiar with that part of the content of the POE or the referenced documents, which covers their activities.

Monitoring of compliance with the POE is normally the responsibility of the quality assurance function.

GM No 1 to 21.A.165(c) Obligations of the holder – Conformity of prototype models and test specimens

ED Decision 2012/020/R

21.A.33 requires determination of conformity of prototype models and test specimens to the applicable design data. The EASA Form 1 may be used as a conformity certificate as part of the assistance a POA holder provides to a design approval holder/applicant.

GM No 2 to 21.A.165(c) Obligations of holder – Conformity with type design

ED Decision 2012/020/R

Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type-certificate holder. There are also likely to be unintentional divergencies (concessions or non-conformances) during the manufacturing process. All these changes should have been approved by the design approval holder, or when necessary by the Agency.

GM No 3 to 21.A.165(c) Obligations of the holder – Condition for safe operation

ED Decision 2012/020/R

Before issue of the Statement of Conformity to the competent authority of the Member State of registry, the holder of a production organisation approval should make an investigation so as to be satisfied in respect of each of the items listed below. The documented results of this investigation should be kept on file by the POA holder. Certain of these items may be required to be provided (or made available) to the operator or owner of the aircraft (and in some cases the competent authority of the Member State of registry):

1. Equipment or modifications which do not meet the requirements of the State of manufacture but have been accepted by the competent authority of the importing country.
2. Identification of products, parts or appliances which:
   a) are not new;
   b) are furnished by the buyer or future operator (including those identified in 21.A.801 and 21.A.805).

3. Technical records which identify the location and serial numbers of components that have special traceability requirements for continued airworthiness purposes including those identified in 21.A.801 and 21.A.805.

4. Log book and a modification record book for the aircraft as required by the Agency.

5. Log books for products identified in 21.A.801 installed as part of the type design as required by the Agency.

6. A weight and balance report for the completed aircraft.

7. A record of missing items or defects which do not affect airworthiness these for example could be furnishing or BFE (Items may be recorded in a technical log or other suitable arrangement such that the operator and Agency are formally aware).

8. Product support information required by other implementing rules and associated CS or GM, such as a Maintenance Manual, a Parts Catalogue, or MMEL all of which are to reflect the actual build standard of the particular aircraft. Also an Electrical load analysis and a wiring diagram.

9. Records which demonstrate completion of maintenance tasks appropriate to the test flight flying hours recorded by the aircraft. These records should show the relationship of the maintenance status of the particular aircraft to the manufacturers recommended maintenance task list and the MRB document/report.

10. Details of the serviceability state of the aircraft in respect of a) the fuel and oil contents, b) provision of operationally required emergency equipment such as life rafts, etc.

11. Details of the approved interior configuration if different from that approved as part of the type design.

12. An approved Flight Manual which conforms to the build standard and modification state of the particular aircraft shall be available.

13. Show that inspections for foreign objects at all appropriate stages of manufacture have been satisfactorily performed.

14. The registration has been marked on the exterior of the aircraft as required by national legislation. Where required by national legislation fix a fireproof owners nameplate.

15. Where applicable there should be a certificate for noise and for the aircraft radio station.

16. The installed compass and or compass systems have been adjusted and compensated and a deviation card displayed in the aircraft.

17. Software criticality list.

18. A record of rigging and control surface movement measurements.

19. Details of installations which will be removed before starting commercial air transport operations (e.g., ferry kits for fuel, radio or navigation).

20. Where maintenance work has been performed under the privilege of 21.A.163(d) issue a release to service that includes a statement that the aircraft is in a condition for safe operation.

21. List of all applicable Service Bulletins and airworthiness directives that have been implemented.

GM No 4 to 21.A.165(c) Airworthiness Release or Conformity Certificate

ED Decision 2012/020/R

The EASA Form 1, when used as a release certificate as addressed in 21.A.165(c)(2) and (3), may be issued in two ways:

— As an airworthiness release, only when by virtue of the arrangement described in 21.A.133(b) and (c), it can be determined that the part conforms to the approved design data and is in a condition for safe operation.

— As a conformity certificate, only when by virtue of the arrangement described in 21.A.133(b) and (c), it can be determined that the part conforms to applicable design data which is not (yet) approved, for a reason that is indicated in Block 12. Parts released with an EASA Form 1 as a conformity certificate are not eligible for installation in a type-certificated aircraft.

The EASA Form 1 should only be used for conformity release purposes when it is possible to indicate the reason that prevents its issue as for airworthiness release purposes.

AMC1 21.A.165(c)(3) Applicable engine exhaust emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the engine type-certificate holder. It should be noted that the competent authority has the possibility to grant exemptions from these requirements as noted in Chapter 2, paragraph 2.1.1 and Chapter 4, paragraph 4.1.1 of Part III of Volume II of Annex 16 to the Chicago Convention.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted engines that will be produced and their impact on the environment;

— considers imposing a time limit on the production of such engines; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the engine serial number, and makes it publicly available.

ICAO Doc 9501 ‘Environmental Technical Manual’ Volume II provides guidance on the issuing of exemptions.

GM1 21.A.165(c)(3) Definitions of engine type certification date and production date

ED Decision 2021/011/R

Volume II of Annex 16 to the Chicago Convention contains three different references to applicability dates:

1. the ‘date of manufacture for the first individual production model’, which refers to the date when the type certificate is issued for the engine type or model;

2. the ‘date of application for a type certificate’, which refers to the application date to the certificating authority of the State of Design of the engine type certification; and

3. the ‘date of manufacture for the individual engine’, which refers to the production date of a specific engine serial number (date of EASA Form 1).

The third reference refers to the date of the first engine EASA Form 1 issued after the completion of the engine production pass-off test.

The third reference is used in the application of engine emissions production cut-off requirement which specifies a date after which all in-production engine models must meet a certain emissions standard.

21.A.165(c)(3) includes the production requirements for engine exhaust emissions.

ICAO Doc 9501 ‘Environmental Technical Manual’ Volume II provides guidance on these applicability dates.

AMC1 21.A.165(c)(4) Applicable aeroplane CO_2 emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the aeroplane type-certificate holder. This data should allow the determination of whether the aeroplane complies with the CO_2 emissions applicability requirements in Chapter 2, paragraph 2.1.1 of Part II of Volume III of Annex 16 to the Chicago Convention.

It should be noted that the competent authority has the possibility to grant exemptions as noted in Chapter 1, paragraph 1.11 and Chapter 2, paragraph 2.1.3 of Part II of Volume III of Annex 16 to the Chicago Convention.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted aeroplanes that will be produced and their impact on the environment; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the aeroplane serial number, and makes it publicly available.

ICAO Doc 9501 ‘Environmental Technical Manual’ Volume III provides guidance on the issuing of exemptions.

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

21.A.171 Scope

Regulation (EU) 2022/1358

This Subpart establishes the procedure for issuing airworthiness certificates to aircraft which conform to a type certificate that has been issued in accordance with this Annex.

21.A.172 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person under whose name an aircraft is registered or will be registered in a Member State ('Member State of registry'), or its representative, shall be eligible as an applicant for an airworthiness certificate for that aircraft under this Subpart.

21.A.173 Classification

Regulation (EU) No 748/2012

Airworthiness certificates shall be classified as follows:

(a) certificates of airworthiness shall be issued to aircraft which conform to a type-certificate that has been issued in accordance with this Annex I (Part 21);

(b) restricted certificates of airworthiness shall be issued to aircraft:

1. which conform to a restricted type-certificate that has been issued in accordance with this Annex I (Part 21); or
2. which have been shown to the Agency to comply with specific airworthiness specifications ensuring adequate safety.

21.A.174 Application

Regulation (EU) 2022/1358

(a) Pursuant to point 21.A.172, an application for an airworthiness certificate shall be made in a form and manner established by the competent authority of the Member State of registry.

(b) each application for a certificate of airworthiness or restricted certificate of airworthiness shall include:

1. the class of airworthiness certificate applied for;
2. with regard to new aircraft:
   (i) a statement of conformity:
   - issued under point 21.A.163(b); or
   - issued under point 21.A.130 and validated by the competent authority; or
   - for an imported aircraft, a statement of conformity issued under point 21.A.163(b) or, in the case of an aircraft imported in accordance with Article 9(4) of this Regulation, a statement signed by the exporting authority that the aircraft conforms to a design approved by the Agency;

(ii) a weight and balance report with a loading schedule and;

(iii) the flight manual, when required by the applicable certification specifications for the particular aircraft.

3. with regard to used aircraft originating from:

(i) a Member State, an airworthiness review certificate issued in accordance with Annex I (Part-M) or Annex Vb (Part-ML) to Commission Regulation (EU) No 1321/2014[1];

(ii) a non-Member State:

— a statement by the competent authority of the State where the aircraft is, or was, registered, reflecting the airworthiness status of the aircraft on its register at the time of transfer;

— a weight and balance report with a loading schedule;

— the flight manual when such a manual is required by the airworthiness code for the aircraft;

— historical records to establish the production, modification and maintenance standard of the aircraft, including all limitations associated with a restricted certificate of airworthiness issued in accordance with point 21.B.327;

— a recommendation for the issuance of a certificate of airworthiness or restricted certificate of airworthiness and for an airworthiness review certificate pursuant to an airworthiness review in accordance with Annex I (Part-M) or Annex Vb (Part-ML) to Regulation (EU) No 1321/2014[2];

— the date on which the first certificate of airworthiness was issued and, if the standards of Volume III of Annex 16 to the Convention on International Civil Aviation apply, the CO_2 metric value data.

(c) Unless otherwise agreed, the statements referred to in points (b)(2)(i) and (b)(3)(ii) shall be issued no more than 60 days before presentation of the aircraft to the competent authority of the Member State of registry.

21.A.175 Language

Regulation (EU) No 748/2012

The manuals, placards, listings, and instrument markings and other necessary information required by applicable certification specifications shall be presented in one or more of the official language(s) of the European Union acceptable to the competent authority of the Member State of registry.

21.A.177 Amendment or modification

Regulation (EU) No 748/2012

An airworthiness certificate may be amended or modified only by the competent authority of the Member State of registry.

[1] Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1).

[2] Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1).

21.A.179 Transferability and re-issuance within Member States

Regulation (EU) 2020/570

(a) Where ownership of an aircraft has changed:

1. if it remains on the same register, the certificate of airworthiness, or the restricted certificate of airworthiness conforming to a restricted type-certificate only, shall be transferred together with the aircraft;

2. if the aircraft is registered in another Member State, the certificate of airworthiness, or the restricted certificate of airworthiness conforming to a restricted type-certificate only, shall be issued:

(i) upon presentation of the former certificate of airworthiness and of a valid airworthiness review certificate issued in accordance with Annex I (Part-M) or Annex Vb (Part-ML) of Regulation (EU) No 1321/2014;

(ii) when satisfying point 21.A.175.

(b) Where ownership of an aircraft has changed, and the aircraft has a restricted certificate of airworthiness not conforming to a restricted type-certificate, the airworthiness certificates shall be transferred together with the aircraft provided the aircraft remains on the same register, or issued only with the formal agreement of the competent authority of the Member State of registry to which it is transferred.

21.A.181 Duration and continued validity

Regulation (EU) 2022/201

(a) An airworthiness certificate shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and

2. the aircraft remaining on the same register; and

3. the type-certificate or restricted type-certificate under which it is issued not being previously invalidated under point 21.A.51;

4. the certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority of the Member State of registry.

21.A.182 Aircraft identification

Regulation (EU) No 748/2012

Each applicant for an airworthiness certificate under this Subpart shall demonstrate that its aircraft is identified in accordance with Subpart Q.

SUBPART I — NOISE CERTIFICATES

21.A.201 Scope

Regulation (EU) 2022/1358

This Subpart establishes the procedure for issuing noise certificates to aircraft which conform to a type certificate that has been issued in accordance with this Annex.

21.A.203 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person under whose name an aircraft is registered or will be registered in a Member State (Member State of registry), or its representative, shall be eligible as an applicant for a noise certificate for that aircraft under this Subpart.

21.A.204 Application

Regulation (EU) 2022/1358

(a) Pursuant to point 21.A.203, an application for a noise certificate shall be made in a form and manner established by the competent authority of the Member State of registry.

(b) each application shall include:

1. with regard to new aircraft:

(i) a statement of conformity:

— issued under point 21.A.163(b); or

— issued under point 21.A.130 and validated by the competent authority; or

— for an imported aircraft, a statement of conformity issued under point 21.A.163(b) or, in the case of an aircraft imported in accordance with Article 9(4) of this Regulation, a statement signed by the exporting authority that the aircraft conforms to a design approved by the Agency; and

(ii) the noise information determined in accordance with the applicable noise requirements;

2. with regard to used aircraft:

(i) the noise information determined in accordance with the applicable noise requirements; and

(ii) historical records to establish the production, modification, and maintenance standard of the aircraft.

(c) Unless otherwise agreed, the statements referred to in point (b)(1) shall be issued no more than 60 days before presentation of the aircraft to the competent authority of the Member State of registry.

21.A.207 Amendment or modification

Regulation (EU) No 748/2012

A noise certificate may be amended or modified only by the competent authority of the Member State of registry.

21.A.209 Transferability and re-issuance within Member States

Regulation (EU) No 748/2012

Where ownership of an aircraft has changed:

(a) if the aircraft remains on the same register, the noise certificate shall be transferred together with the aircraft; or

(b) if the aircraft moves to the register of another Member State, the noise certificate shall be issued upon presentation of the former noise certificate.

21.A.211 Duration and continued validity

Regulation (EU) 2022/201

(a) A noise certificate shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and
2. the aircraft remaining on the same register; and
3. the type-certificate or restricted type-certificate under which it is issued not being previously invalidated under point 21.A.51;
4. the certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority of the Member State of registry.

SUBPART J — DESIGN ORGANISATION APPROVAL

21.A.231 Scope

Regulation (EU) 2019/897

This Subpart establishes the procedure for the approval of design organisations and rules governing the rights and obligations of applicants for, and holders of, such approvals. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

21.A.233 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart:

(a) in order to demonstrate compliance with points 21.A.14, 21.A.112B, 21.A.432B or 21.A.602B of this Annex ; or

(b) in order to demonstrate compliance with points 21L.A.23, 21L.A.83 or 21L.A.204 of Annex Ib (Part 21 Light); or

(c) for the purpose of obtaining privileges under point 21.A.263 regarding approval of minor changes or minor repair design, or issuing declarations of compliance regarding minor changes or minor repair design of aircraft for which design compliance has been declared in accordance with Subpart C of Section A of Annex Ib (Part 21 Light).

21.A.234 Application

Regulation (EU) No 748/2012

Each application for a design organisation approval shall be made in a form and manner established by the Agency and shall include an outline of the information required by point 21.A.243, and the terms of approval requested to be issued under point 21.A.251.

21.A.235 Issue of design organisation approval

Regulation (EU) No 748/2012

An organisation shall be entitled to have a design organisation approval issued by the Agency when it has demonstrated compliance with the applicable requirements under this Subpart.

21.A.239 Design management system

Regulation (EU) 2022/1358

(a) The design organisation shall establish, implement and maintain a design management system that includes a safety management element and a design assurance element with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The design management system shall:

1. correspond to the size of the organisation and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;

2. be established, implemented and maintained under the accountability of a single manager appointed pursuant to point 21.A.245(a).

(c) As part of the safety management element of the design management system, the design organisation shall:

1. establish, implement and maintain a safety policy and the corresponding related safety objectives;

2. appoint key safety personnel in accordance with point 21.A.245(b);

3. establish, implement and maintain a safety risk management process that includes the identification of aviation safety hazards entailed by its activities, their evaluation and the management of the associated risks, including taking actions to mitigate the risks and verify their effectiveness;

4. establish, implement and maintain a safety assurance process that includes:

   (i) the measurement and monitoring of the organisation's safety performance;

   (ii) the management of changes in accordance with points 21.A.243(c) and 21.A.247;

   (iii) the principles for the continuous improvement of the safety management element;

5. promote safety in the organisation through:

   (i) training and education;

   (ii) communication;

6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to continuous improvement of safety.

(d) as part of the design assurance element of the design management system, the design organisation shall:

1. establish, implement and maintain a system for the control and supervision of the design, and of design changes and repairs, of products, parts and appliances covered by the terms of approval; this system shall:

   (i) include an airworthiness function responsible for managing that the design of products, parts and appliances, or the design changes and repairs, comply with the applicable type-certification basis, technical specifications concerning the making of declarations, the applicable operational suitability data certification basis and the environmental protection requirements;

   (ii) ensure that it properly discharges its responsibilities in accordance with this Annex and with the terms of approval issued under point 21.A.251;

2. establish, implement and maintain an independent verification function of the demonstration of compliance on the basis of which the organisation declares compliance with the applicable airworthiness, operational suitability data and environmental protection requirements; and

3. specify the manner in which the design assurance system accounts for the acceptability of the parts or appliances that are designed or the tasks that are performed by its partners or subcontractors according to the methods which are the subjects of written procedures.

(e) The design organisation shall establish, as part of the design management system, an independent monitoring function to verify compliance of the organisation with the relevant requirements of this Annex as well as the compliance with and adequacy of the design management system. Monitoring shall include feedback to the person or the group of persons referred to in point 21.A.245(b) and to the manager referred to in point 21.A.245(a) to ensure, where necessary, the implementation of corrective action.

(f) If the design organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the design management system may be integrated with that required under the additional certificate(s).

GM1 21.A.139, 21.A.239, 21.B.120, 21.B.140, 21.B.220, and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2022/021/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— ‘remote audit’ means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the ‘remote audit’ concept;

— ‘auditing entity’ means the competent authority or organisation that performs the remote audit;

— ‘auditee’ means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

AMC1 21.A.239(c) Design management system

ED Decision 2022/021/R

SAFETY MANAGEMENT ELEMENT

Demonstration of compliance with the international industry standard SM-0001 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organisations', Issue B, 31 March 2022, is an acceptable means to demonstrate compliance with the safety management element of the design management system.

GM1 21.A.239(c) Design management system

ED Decision 2022/021/R

SAFETY MANAGEMENT ELEMENT

Safety management seeks to proactively identify hazards and mitigate the related safety risks before they result in aviation accidents and incidents. Safety management enables an organisation to manage its activities in a more systematic and focused manner. When an organisation has a clear understanding of its role in, and contribution to, aviation safety, this enables the organisation to prioritise safety risks and more effectively manage its resources for optimal results.

Safety should not be considered the responsibility of a single person or a limited group of people in the organisation. A safety culture should be developed throughout the organisation, which involves all the personnel as active contributors to the safety of the final product, part, or appliance, (see AMC1 21.A.239(c)(1)).

The principles of the requirements in points 21.A.3A, 21.A.5, 21.A.239, 21.A.245, and 21.A.247, and the related AMC constitute the EU design management system framework for aviation safety management. This framework addresses the core elements of the International Civil Aviation Organization (ICAO) safety management system (SMS) framework that is defined in ICAO Annex 19, Appendix 2, and facilitates the introduction of the additional safety management element.

This approach is intended to encourage organisations to embed safety management and risk-based decision-making into all their activities, instead of superimposing another system onto their existing management system and governance structure. In addition, if the organisation holds multiple organisation certificates that are issued under Regulation (EU) 2018/1139, it may choose to implement a single management system to cover all of its activities. An integrated management system may be used not only to capture multiple management system requirements resulting from Regulation (EU) 2018/1139, but also to cover for other regulatory provisions requiring compliance with ICAO Annex 19 or for other business management systems, such as security, occupational health, and environmental management systems. Integration will remove duplication and exploit synergies by managing safety risks across multiple activities. Organisations may determine the best means to structure their management systems to suit their business and organisational needs.

It is important to recognise that safety management will be a continuous activity, as hazards, risks, as well as the effectiveness of safety risk mitigations, will change over time.

The safety management capability of an organisation should be commensurate with the safety risks to be managed, which can be at the product, part, and appliance level or at the organisational level.

The risks that are inherent in a complex structure require a robust safety risk management process (e.g. complex interfaces with different partners that participate in the design of a product may pose hazards that are complex to mitigate).

As a consequence, scalability and suitability of the safety management element should be a function of the inherent safety risk capability of the organisation. For instance, for organisations with a lower risk level:

(a) the risk assessment model that is used may be very simple in cases in which the identified hazards are easy to mitigate;

(b) expert judgement might be sufficient to measure the efficiency of safety barriers;

(c) the collection of data, safety information, and occurrences might be very limited;

(d) there might be no need for software or tools to manage the SMS; and

(e) the communication policy might be limited.

AMC1 21.A.239(c)(1) Design management system

ED Decision 2022/021/R

SAFETY POLICY & OBJECTIVES

(a) The safety policy should:

(1) reflect organisational commitments regarding safety, and its proactive and systematic management, including the promotion of a positive safety culture;

(2) include internal reporting principles by fostering the reporting of organisational threats as well as events, as defined in AMC3 21.A.3A(a);

(3) be endorsed by the head of the design organisation (HDO);

(4) be communicated, with visible endorsement, throughout the organisation; and

(5) be periodically reviewed to ensure that it remains relevant and appropriate to the organisation.

(b) The safety policy should include the commitment:

(1) to comply with all the applicable legislation, meet all the applicable requirements, and adopt practices to improve safety standards;

(2) to provide the necessary resources for the implementation of the safety policy;

(3) to apply human factors (HF) principles;

(4) to enforce safety as a primary responsibility of all managers; and

(5) to apply ‘just culture’ principles and, in particular, not to make available or use the information on occurrences:

(i) to attribute blame or liability to personnel for actions, omissions, or decisions that are commensurate with their experience and training; or

(ii) for any purpose other than the improvement of aviation safety.

(c) Senior management should continuously promote the safety policy to all personnel, demonstrate their commitment to it, and provide the necessary human and financial resources for its implementation.

(d) Taking due account of its safety policy, the organisation should define safety objectives. The safety objectives should:

(1) form the basis for safety performance monitoring and measurement;

(2) reflect the organisation's commitment to maintaining and continuously improving the overall effectiveness of safety management;

(3) be communicated throughout the organisation; and

(4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.

GM1 21.A.239(c)(1) Design management system

ED Decision 2022/021/R

SAFETY POLICY

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, to improve the safety levels of all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident occurring, as far as reasonably practicable. The safety policy reflects the management's commitment to safety and the organisation's philosophy of safety management. It is the foundation on which the organisation's management system is built and serves as a reminder of 'how we do business here'. The creation of a positive safety culture begins with issuing a clear, unequivocal policy statement.

The commitment to apply 'just culture' principles forms the basis for the organisation's internal rules that describe how 'just culture' principles are guaranteed and implemented.

Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).

AMC1 21.A.239(c)(2) Design management system

ED Decision 2022/021/R

ORGANISATION AND ACCOUNTABILITY

(a) The management system should encompass safety by including a safety manager and a safety review board in the organisational structure. The functions of the safety manager are defined in AMC1 21.A.245(b).

(b) Safety review board

(1) The safety review board (the 'board'), sometimes referred to as 'high-level safety committee', considers matters of strategic safety in support of the safety accountability of the head of the design organisation (HDO).

(2) The board should be normally chaired by the HDO and be generally composed of the person or group of persons nominated under point 21.A.245(b). Its composition can be adapted to its needs, considering point 21.A.245(b).

(3) The board should monitor:

(i) the organisation's safety performance against its safety policy and objectives;

(ii) whether any safety action is taken in a timely manner; and

(iii) the effectiveness of the organisation's management system processes.

(4) The board may also be tasked with:

(i) reviewing the results of compliance monitoring; and

(ii) monitoring the implementation of related corrective and preventive action.

(c) The board should ensure that appropriate resources are allocated to achieve the established safety objectives.

(d) Notwithstanding point (a), if justified by the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment and/or mitigation measures, as well as the competent authority's agreement, the organisation may not need to establish a board. In that case, the tasks that are normally allocated to the board should be allocated to the safety manager.

GM1 21.A.239(c)(2) Design management system

ED Decision 2022/021/R

SAFETY ACTION GROUP

(a) Depending on the size of the organisation and the nature and complexity of its activities, a safety action group may be established as a standing group or as an ad hoc group to assist, or act on behalf of, the safety manager or the safety review board.

(b) More than one safety action group may be established, depending on the scope of the task and the specific expertise that is required.

(c) The safety action group usually reports to, and takes strategic direction from, the safety review board, and may be composed of managers, supervisors, and personnel from operational areas.

(d) The safety action group may be tasked with or assist in the following:

(1) monitoring safety performance;

(2) defining action to control risks to an acceptable level;

(3) assessing the impact of organisational changes on safety;

(4) ensuring that safety action is implemented within the agreed timescales; and

(5) reviewing the effectiveness of previous safety action and safety promotion.

AMC1 21.A.239(c)(3) and (4) Design management system

ED Decision 2022/021/R

SAFETY MANAGEMENT KEY PROCESSES

(a) Hazard identification processes

(1) Hazard identification should be based on a combination of reactive and proactive methods.

(2) The organisation should focus in particular on hazards that may result from non-compliance or errors in the design of a product, part, or appliance.

(b) Safety risk management processes

(1) The organisation should develop and maintain a safety risk management process that ensures a reactive, proactive, and predictive approach composed of the following elements:

(i) analysis (e.g. in terms of the probability or likelihood as well as severity of the consequences of hazards and occurrences)

(ii) assessment (in terms of tolerability); and

(iii) control (in terms of mitigation) of risks to an acceptable level.

(2) The organisation should specify, within the risk management process, who has the authority to make decisions, considering point (b)(1) of this AMC.

(c) Regardless of the approval status of the subcontracted organisations, the design organisation (DO) is responsible for ensuring that hazard identification and risk management activities are performed on subcontracted activities, as required by point 21.A.239(d)(3), as well as for the monitoring of their compliance and adequacy, as required by point 21.A.239(e).

(d) Internal investigation

(1) In line with 'just culture' as part of the safety policy, the organisation should define how to investigate events such as errors or near misses, in order to understand not only what happened, but also how it happened, as well as to prevent or reduce the probability and/or the consequences of any future recurrence.

(2) The scope of internal investigations should extend beyond the scope of the occurrences that are required to be investigated in accordance with point 21.A.3A.

(e) Safety performance monitoring and measurement

(1) Safety performance monitoring and measurement should be the processes through which the safety performance of the organisation is verified against the safety policy and the safety objectives.

(2) This process may include, as appropriate to the size, nature, and complexity of the organisation, the following elements:

(i) safety reporting that also addresses the status of compliance with the applicable requirements;

(ii) safety reviews, including trend reviews, which should be conducted during the introduction of new technologies, the implementation of new or changed procedures, or in cases of organisational changes that may have an impact on safety;

(iii) safety audits that focus on the integrity of the organisation's management system, and that periodically assess the status of safety risk controls;

(iv) safety surveys that examine particular elements or procedures of a specific area, such as the following:

(A) the problem areas identified;

(B) bottlenecks in the daily design management activities,

(C) the perceptions and opinions of the design management personnel; and

(D) any areas of dissent or confusion; and

(v) other indicators relevant to safety performance.

(f) Management of change

Changes to the design management system may pose new hazards or decrease the effectiveness of existing safety risk controls. The organisation should manage any safety risks that are related to change in that organisation. The management of change should be a documented process to identify external or internal change that may have an adverse effect on safety. The management of change should use of the organisation's existing processes for hazard identification, risk assessment, and risk mitigation.

(g) Continuous improvement

The organisation should continuously seek to improve its safety performance and the effectiveness of its design management system. Continuous improvement may be achieved through review of the following elements:

(1) compliance monitoring and audits;

(2) assessments, including assessments of the effectiveness of the safety culture and of the management system, to assess in particular the effectiveness of the safety risk management processes;

(3) staff surveys, including safety culture surveys, that can provide useful feedback on how engaged the staff are in the design management system;

(4) the monitoring of events and their recurrence;

(5) the evaluation of the safety performance indicators as well as reviews of all the available safety performance information; and

(6) the identification of lessons learned.

AMC1 21.A.239(c)(4)(ii) Design management system

ED Decision 2022/021/R

MANAGEMENT OF CHANGE

This AMC provides a means to consider organisational changes for their potential impact on safety. Organisational changes should also be evaluated for their significance, as required by point 21.A.247. In addition, necessary changes should be introduced into the handbook, as per point 21.A.243(c). The design management system should be designed such that all the above points are taken into account.

(a) Organisational changes should be proactively considered for their safety implications. The magnitude of a change, its safety criticality, and its potential impact on human performance (HP) should be assessed in any process for the management of change. Certain non-complex organisational changes may not require additional assessment.

(b) Special consideration, including human factors (HF) issues, should be given to the transition period during which the change becomes effective.

(c) During the process for the management of change, relevant previous risk assessments and existing hazards should be reviewed for their possible effects.

GM1 21.A.239(c)(4)(ii) Design management system

ED Decision 2022/021/R

MANAGEMENT OF CHANGE

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. may result in inadvertently creating new hazards, which may expose the organisation to new or greater risks. Effective organisations seek to improve their processes, while being conscious of the fact that changes may expose the organisation to potential hazards and risks if they are not properly and effectively managed.

The process for the management of change typically provides principles and a structured framework for managing all aspects of changes. The disciplined implementation of management of change may maximise the effectiveness of change, engage staff, and minimise the risks that are inherent in change.

Change may have the potential to raise new HF issues, or to exacerbate existing ones. For example, changes in computer systems, equipment, technology, personnel changes (including changes in management personnel), procedures, the organisation of work, or work processes are likely to affect performance.

Effective management of change is supported by the following elements:

(a) the implementation of a process for hazard identification/risk analysis and assessment for major operational changes, major organisational changes, changes in key personnel, and changes that may affect the way in which design management is carried out;

(b) the identification of changes that may have a considerable impact on:

  (1) resources (material and human);

  (2) management direction (policies, processes, procedures, training); and

  (3) management control;

(c) safety cases/risk assessments that are aviation-safety focused; and

(d) the involvement of key stakeholders in the process for the management of change, as appropriate.

AMC1 21.A.239(c)(5) Design management system

ED Decision 2022/021/R

SAFETY COMMUNICATION

(a) The organisation should establish communication to the staff, as appropriate to their safety responsibilities, regarding safety matters, which:

  (1) ensures awareness of safety management activities;

  (2) conveys safety-critical information, especially related to assessed risks and analysed hazards;

  (3) explains why particular action is taken; and

  (4) explains why safety procedures are established or changed.

(b) Regular meetings with staff, during which information, action, and procedures are discussed, may be used to communicate safety matters.

GM1 21.A.239(c)(5) Design management system

ED Decision 2022/021/R

SAFETY PROMOTION

(a) Safety training, combined with safety communication and information sharing, is part of safety promotion.

(b) Safety promotion activities support the following:

(1) the organisation's policies, encouraging a positive safety culture, thus creating an environment that is favourable to the achievement of the organisation's safety objectives;

(2) organisational lessons learned; and

(3) the implementation of an effective safety reporting scheme and the development of a 'just culture'.

(c) Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation action.

AMC1 21.A.239(c)(5)(i) Design management system

ED Decision 2022/021/R

SAFETY TRAINING

(a) The design management staff, as described in points 21.A.245(a) and (b), should receive initial and recurring safety training, as appropriate to their responsibilities, including in safety management principles and the associated safety objectives, to ensure their continued competency.

(b) The organisation should identify the category of other staff to which safety training should be provided, and define the initial and recurrent training programmes, including appropriate timelines.

(c) Adequate records of the safety training that is provided should be kept in accordance with point 21.A.5.

GM1 21.A.239(c)(5)(i) Design management system

ED Decision 2022/021/R

SAFETY TRAINING

(a) The main purpose of the safety training programme is:

(1) to support safety management policies and processes; and

(2) to ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.

(b) Each organisation may adapt its syllabus to its own needs. Typically, depending on the targeted staff, to contribute to a positive safety culture, the following items may be included:

(1) the organisational roles and responsibilities related to safety, including the hazard identification and risk management processes;

(2) the safety objectives and the associated safety performance indicators;

(3) human factors (HF) principles, including human performance (HP) and limitations;

(4) legislation, where applicable;

(5) safety reporting systems and investigations; and

(6) safety issues.

(c) The purpose of the recurrent safety training is:

(1) primarily to ensure that staff are kept abreast notably of changes to safety management system (SMS) principles, processes, and procedures; and

(2) also to share feedback on safety issues that are relevant to the organisation or lessons learned.

(d) The training staff should have sufficient knowledge and experience to teach the topics at the required level, as well as the skills to influence attitudes and behaviours.

AMC1 21.A.239(d) Design management system

ED Decision 2022/021/R

DESIGN ASSURANCE ELEMENT

(a) Reserved

(b) Reserved

(c) Design assurance system

The complete design process, starting with the type certification basis, operational sutiability data (OSD) certification basis, as well as environmental protection requirements and product specifications, and culminating with the issuing of a type certificate (TC), is shown in Figure 1, which identifies the relationships between the design, the certification, and the design assurance processes.

Effective design assurance requires a continuing evaluation of all the factors that affect the adequacy of the design for the intended applications. In particular, it should be ensured that the product or part complies with the applicable type certification basis, OSD certification basis, and environmental protection requirements, and that it will continue to comply after any change to the TC or any repair.

Planned and systematic tasks should therefore be defined and performed from the very beginning of the design activities up to the continued-airworthiness activities.

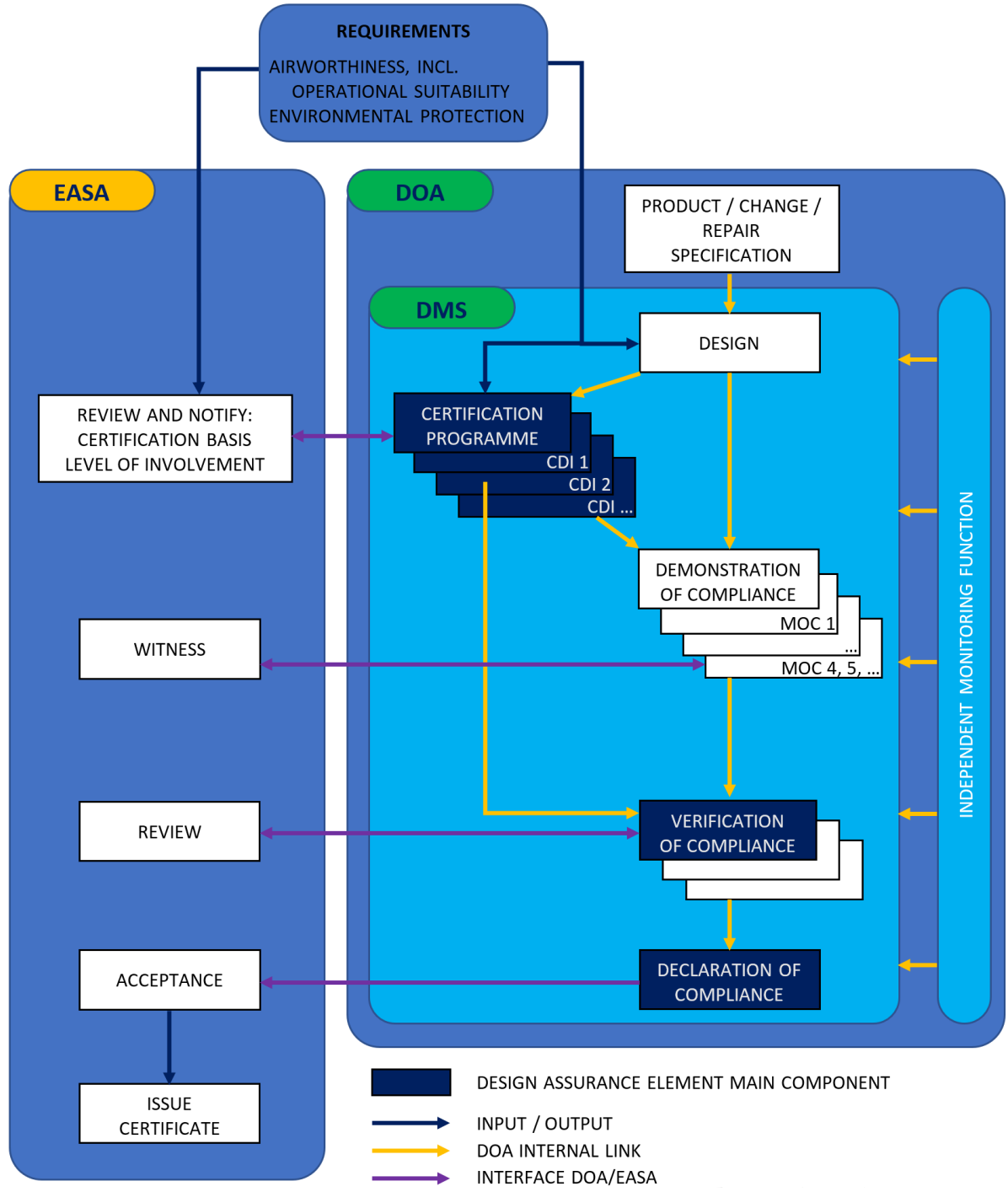


Figure 1 — RELATIONSHIPS' CONCEPT IN DESIGN AND CERTIFICATION

(1) Planned and systematic tasks

For design organisations that carry out the certification process of products, their planned and systematic tasks should cover the following, and the related procedures should be defined accordingly.

(i) General

(A) Issue or, where applicable, supplement, or amend the handbook in accordance with point 21.A.243, in particular to indicate the initiation of design activities on a product.

(B) Assure that all the instructions of the handbook are adhered to.

(C) Conduct the certification process.

(D) Nominate staff as 'compliance verification engineers' that are responsible for approving compliance documents as defined in point (c)(1)(iii).

(E) Nominate staff that belong to the Office of Airworthiness and are responsible as defined in point (c)(1)(iv).

(F) In the case of an applicant for an STC, obtain the agreement of the TC holder for the proposed supplemental type certificate (STC) to the extent that is defined in point 21.A.115.

(G) Ensure that there is full and complete liaison between the design organisation and the related organisations that have responsibility for the products and parts that are manufactured according to the type design.

(H) Provide assurance to EASA that any prototype models and test specimens adequately conform to the type design (see point 21.A.33(c).

(ii) Head of the design organisation (or deputy)

The head of the design organisation (HDO), or an authorised representative, should sign a declaration of compliance (see points 21.A.20(d) and 21.A.97(b)(3)) with the applicable type certification basis, OSD certification basis, and environmental protection requirements after verifying the satisfactory completion of the certification process. In accordance with point 21.A.20(e), the signature of the HDO on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).

(iii) Compliance verification

(A) Approval through the signing of all the compliance documents, including test programmes and data that are necessary for the verification of compliance with the applicable type certification basis, OSD certification basis and environmental protection requirements, as defined in the certification programme.

(B) Approval of the technical content (completeness, technical accuracy, etc.), including any subsequent revisions of the manuals to be approved by EASA (aircraft flight manual (AFM), airworthiness limitations section of the instructions for continued airworthiness (ICA), and certification maintenance requirements (CMRs) document, where applicable).

(iv) Airworthiness function

The airworthiness function is commonly performed by the Office of Airworthiness and should cover the following tasks as relevant*:

(A) liaison between the design organisation (DO) and EASA with respect to all aspects of the certification programme;

(B) ensuring that a handbook and the flight test operations manual, when relevant, are prepared and updated as required by point 21.A.243;

(C) cooperation with EASA in developing procedures to be used for the type certification process;

(D) issuing of guidelines for documenting compliance;

(E) cooperation in issuing guidelines for the preparation of the manuals that are required by the applicable requirements, service bulletins (SBs), drawings, specifications, and standards;

(F) ensuring procurement and distribution of the applicable type certification basis, OSD certification basis, as well as environmental protection requirements and other specifications;

(G) cooperating with EASA in proposing the type certification basis, OSD certification basis, and environmental protection requirements;

(H) the interpretation of the type certification basis, OSD certification basis, and environmental protection requirements, and requesting EASA to take decisions in case of doubt;

(I) advising all the departments of the DO on any question regarding airworthiness, operational suitability, environmental protection approvals, and certification;

(J) the preparation of the certification programme, including a proposal for EASA involvement in the verification of compliance demonstration activities and data, and coordination of all the tasks related to the certification process in agreement with EASA;

(K) regular reporting to EASA about the progress of the certification process, including any difficulty or event that may necessitate a change of the previously notified EASA level of involvement, and announcing scheduled activities (e.g. tests) in due time;

(L) ensuring cooperation in preparing the inspection and test programmes needed for demonstration of compliance;

(M) establishing the compliance checklist and updating it with any changes;

(N) checking that all the compliance documents that are necessary to demonstrate compliance with the type certification basis, OSD certification basis, and environmental protection requirements are prepared and complete, and signing the documents for release;

(O) checking the required type design definition documents that are described in point 21.A.31 and ensuring that they are provided to EASA for approval when required;

(P) preparation, if necessary, of a draft of a type certification data sheet (TCDS) and/or a modification to a TCDS;

(Q) providing verification to the HDO that all the activities that are required for the certification process have been properly completed;

(R) managing the exercise of the DO privileges in accordance with point 21.A.263(c);

(S) monitoring significant events on other aeronautical products, as far as they are relevant, to determine their effect on the airworthiness or operational suitability of the products that are designed by the DO;

(T) ensuring that there is cooperation in preparing SBs and the structural repair manual, and any subsequent revisions, with special attention to the manner in which the contents affect airworthiness and environmental protection, and granting the approval on behalf of EASA;

(U) ensuring the initiation of activities in response to a failure (accident/incident/in-service occurrence) evaluation and to complaints from the operation, and providing information to EASA if airworthiness or operational suitability are impaired (continuing airworthiness and continued operational suitability);

(V) advising EASA on the issuing of airworthiness directives in general based on SBs; and

(W) ensuring that the manuals that are approved by EASA, including any subsequent revisions, (AFM, airworthiness limitations section of the ICA, and CMR document, where applicable) are checked, to determine whether they meet their respective requirements, and that they are provided to EASA for approval.

* Some of the above tasks may be carried out through a different organisational function.

(v) Maintenance and operating instructions

(A) Ensuring the preparation and updating of all the maintenance and operating instructions (including ICA and SBs) that are needed to maintain airworthiness (i.e. continuing airworthiness) in accordance with the relevant certification specifications (CSs). For that purpose, the applicant should:

(a) establish the list of all the documents they produce to comply with CS 2X.1581 (CS 23.2620) and with the Appendix that is referred to in CS 2X.1529, CS-E 20/25, or CS-P 30/40, or CS 23.2625;

(b) establish a system to collect in-service experience to be used for the improvement of the instructions; and

(c) define the procedures and the organisation for producing and issuing those documents, taking into account the obligation of point 21.A.265(h); those procedures should cover the following elements:

(1) preparation, including format and language (available industrial standards can be referred to and used);

(2) proofreading (checking for clarity, readability, typos, etc.);

(3) verification of technical consistency with the corresponding approved change(s), repair(s), or approved data, including effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;

(4) verification of feasibility in practical applications, when relevant and feasible; and

(5) responsibilities and authorised signatories.

Note: Compliance verification, as described in point (c)(1)(iii) of this AMC, applies to the manuals that are approved by EASA (AFM, airworthiness limitations section of the ICA, and CMR document, where applicable); for the other ICA or other maintenance instructions, the procedure that is required by (c)(1)(v) of this AMC provides a sufficient level of verification and does not require specific compliance verification unless, as per point 21.A.90C, additional work to demonstrate compliance is required; in that case, where additional compliance demonstration is required, points 21.A.91 to 21.A.109, as well as the independent checking function of compliance demonstration as per point 21.A.239(b), apply.

(B) In accordance with points 21.A.6 and 21.A.7 and, where applicable, point 21.A.609, ensuring that those documents are made available as per point 21.A.7(b).

(vi) Operational suitability data

(A) Ensuring the preparation and updating of all OSD in accordance with the relevant CSs. For that purpose, the applicant should:

(a) establish the list of all the documents that they produce to comply with CS-MMEL or CS-GEN-MMEL, CS-FCD, CS-CCD, CS-SIMD, and CS-MCSD, as applicable; and

(b) define the procedures and the organisation for producing and issuing those documents, taking into account the obligation of point 21.A.265(h); those procedures should cover the aspects that are described in (c)(1)(v)(A).

(B) In accordance with points 21.A.6, 21.A.62, 21.A.108, and 21.A.120B, ensuring that those documents are provided to all the affected operators and training organisations, as well as to all the authorities involved.

AMC2 21.A.239(d) Design management system

ED Decision 2022/021/R

DESIGN ASSURANCE ELEMENT FOR MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

(a) Purpose

This AMC outlines some basic principles and objectives in order to comply with the design assurance element for organisations designing only minor changes to type design or minor repairs to products.

(b) Design assurance system

— The design assurance system should include the following:

— an organisational structure:

— to control the design;

— to demonstrate compliance with the applicable type certification basis, operational suitability data (OSD) certification basis, and environmental protection requirements;

— to independently check demonstrations of compliance;

— to liaise with EASA;

— to continuously evaluate the design organisation; and

— To control subcontractors; and

— procedures and responsibilities associated with the functions listed above, taking due account of Part 21 requirements applicable to design and approval of minor changes to type design or minor repairs to products.

GM1 21.A.239(d) Design management system

ED Decision 2022/021/R

DESIGN ASSURANCE ELEMENT

(a) Purpose

This GM outlines some basic principles and objectives of the design assurance element.

(b) Definitions

1 The design assurance element includes the organisational structure, responsibilities, procedures, and resources to ensure the proper functioning of the design organisation.

2 'Design assurance' refers to all planned and systematic action necessary to provide adequate confidence that the organisation has the capability to:

— design products or parts in accordance with the applicable type certification basis, the operational suitability data (OSD) certification basis, and the environmental protection requirements;

— demonstrate and verify compliance with the type certification basis, the OSD certification basis, and the environmental protection requirements; and

— demonstrate to EASA that compliance.

3 'Type investigation' refers to the tasks of the organisation in support of the type certificate (TC), supplemental type certificate (STC) or other design approval processes necessary to demonstrate, verify and maintain compliance with the applicable type certification basis, OSD certification basis, and environmental protection requirements.

AMC1 21.A.239(d)(2) Design management system

ED Decision 2022/021/R

INDEPENDENT VERIFICATION FUNCTION OF THE DEMONSTRATION OF COMPLIANCE

(a) The independent verification function of the demonstration of compliance should consist of the verification by a person that did not create the compliance data. Such a person may work in conjunction with the individuals that prepare compliance data.

(b) The verification should be shown by signing compliance documents, including test programmes and data.

(c) For a product, there is normally only one compliance verification engineer that is nominated for each relevant subject. A procedure should cover the non-availability of nominated persons and their replacement, when necessary.

(d) For STC cases, when compliance statement and associated documentation are produced by the TC holder, and when this data is approved under the system of the authority of TC holder, then the STC applicant does not need to provide, within its own DOA, the independent verification function that is required in point 21.A.239(d)(2) for that data.

GM1 21.A.239(d)(3) Design management system

ED Decision 2022/021/R

DESIGN ASSURANCE ELEMENT — PARTNERS AND SUBCONTRACTORS

In meeting the requirements of point 21.A.239(d)(3), the applicant for a design organisation approval under Subpart J may adopt the following policy:

(a) The satisfactory integration of the partner and subcontractor and applicant's design assurance systems is demonstrated for the activities that are covered under the applicant's terms of approval.

(b) In the event that a partner and subcontractor holds a design organisation approval (DOA), then in accordance with point 21.A.239(d)(3), the applicant may take this into account in demonstrating the effectiveness of that integrated system.

(c) When any partner and subcontractor does not hold a DOA, then the applicant will need to establish to its own satisfaction and the satisfaction of EASA, the adequacy of that partner's/subcontractor's design assurance system in accordance with point 21.A.243(b).

GM2 21.A.239(d)(3) Design management system

ED Decision 2022/021/R

DESIGN ASSURANCE ELEMENT — PARTNER AND SUBCONTRACTOR ARRANGEMENTS

When defining the arrangements between the design organisation (DO) and its partners and subcontractors, both elements of the design management system should be taken into account, i.e. the safety management element and the design assurance element. The following guidance should therefore be considered applicable to both elements.

(a) When the DO subcontracts activities, the arrangements should consider the safety risk management process that is part of its safety management element (see point 21.A.239(c)(3)). When the subcontractor does not have a safety management element, the subcontractor should be integrated into the safety management element of the DO; when the subcontractor has implemented a safety management system (such as for design organisation approval (DOA)

or production organisation approval (POA)), the two safety management systems, i.e. of the DO and of the subcontractor, should be harmonised.

(b) Depending on the complexity and criticality of those arrangements, the following elements within the arrangements should be addressed:

(1) coordination and interfaces between all the parties involved;

(2) applicable procedures;

(3) safety culture, including internal safety reporting scheme (see point 21.A.3A).

(4) communication between all the parties involved, including reporting, regular meetings, and feedback channels;

(5) allocation of tasks, of clear accountability, and of responsibilities; and

(6) the qualifications and competency of key personnel with reference to point 21.A.245.

(c) The safety risk management should focus on the needs to exchange safety data and safety information that are deemed significant for the determination of relevant risks in terms of likelihood, severity, impact, and acceptability, such as, wherever appropriate, but not limited to the following:

(1) (at product level) failure, malfunction, defect, or other occurrences, non-conformity or outcome of the compliance monitoring function, component failure analysis, in-service event, etc.;

(2) (at documentation level) key processes (e.g. airworthiness directives, design and certification documentation, design processes); and

(3) (at organisation level) changes, disruptive events, resources' issues, human performance (HP) issues.

(d) Regular communication should be ensured between all the parties involved, to discuss work progress, risk mitigation measures, changes to the arrangements, as well as any other significant issues.

AMC1 21.A.239(e) Design management system

ED Decision 2022/021/R

INDEPENDENT MONITORING FUNCTION

(a) The independent monitoring function should ensure that:

(1) the activities of the design organisation (DO) are monitored for their compliance with the applicable requirements and with any additional requirements as established by the organisation, and that those activities are properly performed under the supervision of the nominated persons that are referred to in point 21.A.245(b); furthermore, compliance with, and the adequacy of, the design management system should be monitored;

(2) all subcontracted design activities are monitored for adequacy and compliance with the applicable arrangements;

(3) an objective review of the complete set of design-management-related activities is provided through independent monitoring activities, such as audits, inspections, reviews;

(4) the independence of the monitoring activities is established by always ensuring that those activities and inspections are performed by staff that are not involved in the function, procedure, or products that they monitor, and that are independent from the operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring;

(5) a monitoring plan is established to show when and how often the activities that are required by Part 21 will be audited;

(6) the monitoring cycle should not exceed the applicable oversight planning cycle that is established according to point 21.B.432; the determination of the monitoring plan should consider at least the following aspects:

— the criticality of the items checked; and

— the safety performance of the organisation, including any previous findings and root causes;

(7) when non-compliance is found, the root cause(s) and contributing factor(s) are identified, and corrective action is defined and followed up; and

(8) feedback is provided to the management of the DO.

(b) The independent monitoring function that is required by point 21.A.239(e) may be undertaken by the existing quality assurance organisation if the DO is part of a larger organisation.

(c) The staff performing an independent monitoring function should have access to all the parts of the DO and, as necessary, to any subcontracted organisations.

21.A.239A Information security management system

Regulation (EU) 2022/1645

In addition to the design management system required by point 21.A.239, the design organisation shall establish, implement and maintain an information security management system in accordance with Commission Delegated Regulation (EU) 2022/1645 in order to ensure the proper management of information security risks which may have an impact on aviation safety.

[applicable from 16 October 2025 – Regulation (EU) 2022/1645]

21.A.243 Handbook

Regulation (EU) 2022/201

(a) As part of the design management system, the design organisation shall create and furnish to the Agency a handbook that describes, directly or by cross reference, the organisation, its relevant policies, processes and procedures, the type of design work, and the categories of products, parts and appliances for which the design organisation holds a design organisation approval, as identified in the terms of approval issued in accordance with point 21.A.251 and, where relevant, the interfaces with and the control of its partners or subcontractors.

If flight tests are to be conducted, a flight test operations manual that defines the organisation's policies and procedures in relation to flight tests shall also be created and furnished to the Agency. The flight test operations manual shall include:

1. a description of the organisation's processes for flight tests, including its involvement in the process for issuing a permit to fly;
2. crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII, where applicable;
3. procedures for the carriage of persons other than the crew members and for flight test training, where applicable;
4. a policy for the risk and safety management and associated methodologies;
5. procedures to identify the instruments and equipment to be carried on board;
6. a list of documents that need to be produced for the flight test.

(b) Where any parts or appliances or any changes to the products are designed by partner organisations or subcontractors, the handbook shall include a statement of how the design organisation is able to demonstrate, for all parts and appliances, the compliance in accordance with point 21.A.239(d)(2), and shall contain, directly or by cross reference, descriptions of and information on the design activities and the organisation of those partner organisations or subcontractors, as necessary to establish the statement.

(c) The handbook shall be amended as necessary to remain an up-to-date description of the organisation, and copies of the amendments shall be provided to the Agency.

(d) The design organisation shall establish and maintain a statement of the qualifications and experience of the management staff and of other persons in the organisation that are responsible for making decisions that affect airworthiness, operational suitability data and environmental protection matters. It shall submit that statement to the competent authority.

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

a. Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

b. Format

The FTOM may:

— be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

— be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

c. Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part 21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

a. Exposition (not applicable in the case of APDOA):

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

— for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

— for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

— for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

AMC1 21.A.243(a) Handbook

ED Decision 2023/014/R

GENERAL

(a) All personnel should be familiar with those parts of the handbook that are relevant to their tasks.

(b) The handbook should provide the following information for each product that is covered by the design organisation approval (DOA).

(1) A description of the tasks that can be performed under the approval, according to the following classification:

(i) general areas, like subsonic turbojet aeroplanes, turboprop aeroplanes, small aeroplanes, rotorcraft, etc.;

(ii) technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.);

(iii) a list of types and models for which the design approval has been granted and for which privileges may be exercised, supported by a brief description for each product; and

(iv) for repair design, classification and (if appropriate) approval activities. it is necessary to specify the scope of activity in terms of structures, systems, engines, etc.

(2) A general description of the organisation, its main departments, their functions and the names of those in charge; a description of the line management and of the functional relationships between the various departments.

(3) A description of the assigned responsibilities and delegated authority of all parts of the organisation, which, taken together, constitute the organisation's design management system, together with a chart indicating the functional and hierarchical relationship of the design management system to the management and to other parts of the organisation; also the chains of responsibilities within the design management system, and the control of the work of all partners and subcontractors.

(4) A general description of the way in which the organisation performs all the design functions in relation to airworthiness, operational suitability and environmental protection approvals, including:

(i) the procedures followed and forms used in the certification process to ensure that the design of, or the change to the design of, the product as applicable, is identified and documented, and complies with the applicable type certification basis, operational suitability data (OSD) certification basis, and the environmental protection requirements, including specific requirements for import by importing authorities;

(ii) the procedures for classifying design changes as 'major' or 'minor' and for the approval of minor changes;

(iii) the procedures for classifying and approving unintentional deviations from the applicable design data occurring in production (concessions or non-conformity); and

(iv) the procedure for classifying and obtaining approval for repairs.

(5) A general description of the way in which the organisation performs its functions in relation to the continuing airworthiness and continued operational suitability of the product it designs, including cooperation with the production organisation when dealing with any continuing airworthiness action that is related to the production of the product, part, or appliance, as applicable.

(6) A description of the human resources, facilities, and equipment, which constitutes the means for design and, where appropriate, for ground and flight testing.

(7) An outline of a system for controlling and informing the personnel of the organisation of current changes in engineering drawings, specifications, and design management procedures.

(8) A description of the recording system for:

(i) the type design, including relevant design information, drawings and test reports, including inspection records of test specimens;

(ii) the means of compliance; and

(iii) the compliance documentation (compliance checklist, reports, etc.).

(9) A description of the record-keeping system to comply with point 21.A.5.

(10) A description of the means by which the organisation collects, monitors, analyses and responds to reports of problems that cause or might cause an adverse effect on the airworthiness or operational suitability of its product, part, or appliance during design, production, and in service, in particular to comply with point 21.A.3A (see also AMC3 21.A.3A(a) and AMC1 21.A.239(d)).

(11) The names of the design organisation (DO)-authorised signatories. Nominated persons with specific responsibilities such as those mentioned in points 21.A.33 and 21.A.35 should be listed as well.

(12) (Reserved).

(13) A clear definition of the tasks, competency, and areas of responsibility of the Office of Airworthiness.

(14) A description of the procedures for the establishment and the control of the manuals and instructions for continued airworthiness (ICA) (see points 21.A.6, 21.A.7 and, where applicable, 21.A.609).

(15) A description of the means by which the continuing evaluation (system monitoring) of the design management system will be performed in order to ensure that it remains effective.

(16) A description of the procedures for the establishment and control of the OSD (see points 21.A.5, 21.A.62, 21.A.108, and 21.A.120B).

(17) A description of the organisation's safety policy and objectives, as required by point 21.A.239(c)(1).

(18) A description of the internal safety reporting scheme, as required by point 21.A.3A(a)(1).

(19) A description of the safety management procedures (including identification of safety hazards, evaluation, and associated risks management), safety assurance procedures, and safety promotion processes.

(20) A statement, signed by the head of the design organisation (HDO) (and countersigned by the senior company manager, if different), which confirms that the design management handbook and any associated manuals are complied with at all times.

This statement should read as follows, or embrace the intent of the following text:

'This handbook defines the organisation and procedures upon which EASA's DOA is based.

These procedures are approved by the undersigned, and must be complied with, as applicable, to ensure that all design activities are performed on time and to an approved standard.

It is understood that the approval of the DO is based on the organisation's continuous compliance with the applicable requirements of Part 21, and with the organisation's procedures that are described in this handbook. EASA is entitled to limit, suspend, or revoke the approval if the organisation fails to fulfil the obligations that are imposed by Part 21, or any conditions according to which the approval was issued.

Signed .....

Dated .....

HDO and ..... (quote the position of the signatory)

Senior company manager

For and on behalf of ..... (quote the organisation's name)'

The statement should be reissued at the earliest opportunity when the HDO changes.

(c) The organisation may document its safety policy, safety objectives, and all the safety management system key processes (as required by point 21.A.239(c)) in a separate manual (e.g. a safety management manual or management system manual) or in its handbook. Organisations that hold multiple organisation approvals, which are issued under Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

AMC2 21.A.243(a) Handbook

ED Decision 2022/021/R

TYPICAL CONTENT OF HANDBOOK FOR ORGANISATIONS THAT DESIGN MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

The following is a typical table of contents for the handbook:

Part 1. Organisation

1.1 Objective of the handbook and binding statement

1.2 Responsible person for the administration of the handbook

1.3 Amendment procedure

1.4 List of effective pages

1.5 Distribution list

1.6 Presentation of the design organisation (DO) (including locations)

1.7 Scope of work (with identification of type and models of products)

1.8 Organisation charts

1.9 Human resources

1.10 Management staff

1.11 Certifying personnel (see GM2 21.A.243(d), point 2)

1.12 Independent system monitoring

1.13 Safety management system

Part 2. Procedures

2.1 Management of changes to type design and design of repairs:

- configuration control,
- classification, and
- approval of minor changes to type design and minor repairs

2.2 Control of design subcontractors

2.3 Collecting/Investigating of failures, malfunctions, and defects

2.4 Coordination with production

2.5 Documentation control

- in relation to the changes and repairs, and
- in relation to failures/malfunctions and defects (i.e. services bulletins)

2.6 Record-keeping

AMC1 21.A.243(d) Handbook

ED Decision 2022/021/R

STATEMENT OF QUALIFICATIONS AND EXPERIENCE

(a) The following statements should be provided:

(1) Other management staff as defined in GM1 21.A.243(d)

For each nominated manager, the organisation should provide this data to EASA to show that the nominated managers are suitable in terms of their relevant knowledge and satisfactory experience related to the nature of the design activities that are performed by the organisation.

(2) The staff that make decisions that affect airworthiness, operational suitability, and environmental protection

For that staff, no individual statements are required. The organisation should demonstrate that there is an internal authorisation system that allows it to select, train, maintain, and identify them for all the tasks for which they are needed.

(b) The staff that is defined in point (a) should be identified in the handbook or linked to it. This, together with the corresponding procedures, should enable that staff to carry out the assigned tasks and to properly discharge the associated responsibilities.

AMC2 21.A.243(d) Handbook

ED Decision 2022/021/R

STATEMENT OF THE QUALIFICATION AND EXPERIENCE — ORGANISATIONS THAT DESIGN MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

For organisations that design minor changes to type design or minor repairs to products, the statement of the qualifications and experience that is required by point 21.A.243(d) should be addressed as follows:

(a) The nominated managers should be identified and their relevant knowledge and satisfactory experience related to the nature of the design activities that they perform should be demonstrated. For each nominated manager, the organisation should provide evidence of competency so that they may be considered to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.

(b) The persons responsible for:

- classifying changes to type design or repairs (point 21.A.263(c)(1));
- verifying compliance (point 21.A.239(d)(2));
- approving minor changes to type design and minor repairs (point 21.A.263(c)(2));
- issuing information or instructions (point 21.A.265(h)),

should be selected by the organisation in accordance with a procedure and criteria agreed by EASA.

GM1 21.A.243(d) Handbook

ED Decision 2023/014/R

STATEMENT OF QUALIFICATIONS AND EXPERIENCE

Three different types of functions are named or implicitly identified in the requirements of Part 21, Subpart J or in the associated AMC and GM, when using qualified and experienced personnel:

the senior company manager (see AMC1 21.A.245(a), GM1 21.A.249, GM 21.A.265(b));

the other management staff:

- the head of the design organisation (HDO) (see points 21.A.239(b)(2) and 21.A.245(a));
- the chief of the airworthiness function (see point 21.A.245(b)(1));
- the chief of the independent monitoring function (see point 21.A.245(b)(2));
- the safety manager (see GM1 21.A.239(c)(2), AMC1 21.A.239(c)(2) and AMC1 21.A.245(b), point (g)); and
- when a safety review board is established, the chairperson of that board, if different from the HDO (see AMC1 21.A.239(c)(2)); and

the staff making decisions affecting airworthiness, operational suitability, and environmental protection:

— compliance verification engineers (see AMC1 21.A.239(d), point (c)(1)(iii) and AMC1 21.A.239(c)(2));and

— staff of the Office of Airworthiness making decisions affecting airworthiness, operational suitability, and environmental protection, especially those that are linked with the 21.A.263 privileges (signing documents for release, approving classification of changes and repairs, and granting the approval of minor/major changes, supplemental type certificates (STCs) and minor/major repairs, granting the approval of service bulletins (SBs), and minor revisions to the aircraft flight manual) (see AMC1 21.A.239(d), point (c)(1)(iv)).

A statement of the qualifications and experience of the senior company manager is not required. For the other two categories that are identified above, a statement of qualifications and experience should be provided (see AMC1 21.A.243(d) and AMC2 21.A.243(d) respectively).

21.A.245 Resources

Regulation (EU) 2022/201

(a) The organisation shall appoint a head of the design organisation with the authority to ensure that, within the organisation, all design activities are performed to the required standards and that the design organisation is continuously in compliance with the requirements of the design management system referred to in point 21.A.239 and the procedures specified in the handbook referred to in point 21.A.243.

(b) The head of the design organisation shall nominate and specify the extent of authority of:

1. a chief of the airworthiness function;
2. a chief of the independent monitoring function;
3. depending on the size of the organisation and the nature and complexity of its activities, any other person or group of persons that are required to ensure that the organisation complies with the requirements of this Annex.

(c) By way of derogation from point 21.A.245(b)(1), the airworthiness function referred to in point 21.A.239(d)(1)(i) may be performed under the direct supervision of the head of the design organisation in either of the following cases:

1. where the scope of activities of/of work of the design organisation, as identified in the terms of approval issued under point 21.A.251, is limited to minor changes and/or minor repairs;
2. for a limited period of time when the design organisation does not have a nominated chief of the airworthiness function and the exercise of that function under the direct supervision of the head of the design organisation is commensurate with the scope and level of the organisation's activities.

(d) The person or group of persons nominated pursuant to point (b) shall:

1. be answerable to the head of the design organisation and have direct access to them;
2. have the appropriate knowledge, background and experience to discharge their responsibilities.

(e) The design organisation shall ensure that:

1. the staff in all technical departments are of sufficient numbers and experience and have been given the appropriate authority to be able to discharge their allocated responsibilities and the facilities, equipment and accommodation that are adequate to enable the staff to fulfil the airworthiness, operational suitability data and environmental protection requirements as regards the product;

2. there is full and efficient coordination between the departments and within the departments in respect of airworthiness, operational suitability data and environmental protection matters.

AMC1 21.A.245(a) Resources

ED Decision 2023/014/R

HEAD OF THE DESIGN ORGANISATION

(a) The head of the design organisation (HDO) should:

(1) have sufficient knowledge and authority to be able to respond to the competent authority regarding major issues concerning the design organisation (DO) and the product design approval, and to carry out any necessary improvements;

(2) promote the safety policy that is specified in AMC1 21.A.239(c)(1); and

(3) demonstrate a Part 21 understanding that is sufficient to discharge the relevant responsibilities.

(b) The handbook that is submitted in accordance with point 21.A.243 should show that the HDO has the direct or functional responsibility for all the departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the HDO still has the ultimate responsibility for compliance of the DO with Part 21.

NOTE: When the HDO has no direct control on the resources necessary for the proper functioning of the design organisation, then a senior company manager should provide these resources. To confirm such commitment, the senior company manager should sign, along with the HDO, the binding statement (see AMC1 21.A.243(a), point (b)(20) and GM 21.A.265(b)).

AMC1 21.A.245(b) Resources

ED Decision 2022/021/R

NOMINATED MANAGERS

(a) The person or group of persons nominated in accordance with point 21.A.245(b) should represent the management structure of the organisation and be responsible for all the functions as specified in Part 21, Subpart J.

(b) The nominated managers should be identified (see GM1 21.A.243(d)).

(c) The responsibilities and the duties of each individual manager should be defined.

(d) The independent monitoring function should be independent from the design and airworthiness functions. As such, the chief of the independent monitoring function should not be at the same time one of the other persons that are referred to in point 21.A.245(b)(1) or (b)(3), except for the safety manager. If the same person is designated to manage both the independent monitoring function and safety-management-related processes and tasks, the

head of the design organisation (HDO), in order to discharge their safety accountability, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation, and the nature and complexity of its activities.

(e) Chief of the airworthiness function

If more than one team, including their management, are designated for the airworthiness function as defined in point 21.A.239(d)(1)(i), the HDO should identify the person that acts as the unique focal point for the entire design organisation (DO), i.e. the 'chief of the airworthiness function'.

The need to designate more than one team may be triggered by the specific scope and volume of activity of the DO. For example:

— managing several lines of products (separate airworthiness representative per line of product); and

— division between initial and continued airworthiness activities.

The tasks for which the chief of the airworthiness function should be responsible are presented in AMC1 21.A.239(d), point (c)(1)(iv).

(f) Chief of the independent monitoring function

The role of the chief of the independent monitoring function should be to ensure that:

(1) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21.A.245(b);

(2) an audit plan is properly implemented, maintained, and continually reviewed and improved; and

(3) corrections and corrective action are requested, as necessary.

(g) Safety manager

If more than one person is designated for the development, administration, and maintenance of effective safety management processes as defined in point 21.A.239(c)(2), the HDO should identify the 'safety manager' as the unique focal point.

The role of the safety manager should be:

(1) to facilitate hazard identification, as well as risk assessment and management;

(2) to monitor the implementation of action taken to mitigate risks, as listed in the safety action plan, unless action follow-up is addressed by the independent monitoring function;

(3) to provide periodic reports on safety performance to the safety review board (the functions of the safety review board are defined in AMC1 21.A.239(c)(2));

(4) to ensure the maintenance of safety management documentation;

(5) to ensure that there is safety training available, and that it meets acceptable standards;

(6) to provide advice on safety matters; and

(7) to ensure the initiation and follow-up of internal investigations of occurrences.

GM1 21.A.245(c)(2) Resources

ED Decision 2022/021/R

DIRECT SUPERVISION OF THE AIRWORTHINESS FUNCTION BY THE HEAD OF THE DESIGN ORGANISATION

To cope with unexpected circumstances, for a period of time, it is possible for the head of the design organisation (HDO) to directly supervise the airworthiness function activities. This period of time should be limited and should typically not exceed 6 months.

Such a situation should be discussed with EASA and may be subject to certain limitations (e.g. only continued airworthiness activities may be allowed).

AMC1 21.A.245(d) Resources

ED Decision 2022/021/R

MANAGEMENT REPORTING LINES AND COMPETENCIES

(a) Managers that are nominated in accordance with point 21.A.245(b) should report directly to the HDO through either a hierarchical or a formal functional link.

(b) All prospective members of the design management staff and staff that is nominated in accordance with point 21.A.245(b) should:

(1) be assessed for their competency, qualifications, and capabilities that are related to their intended duties;

(2) be able to demonstrate their knowledge of, and compliance with, the design management organisation procedures that are applicable to their tasks; and

(3) be able to demonstrate an understanding of the safety management principles, as well as human factors (HF) issues and human performance (HP) issues that are related to their tasks.

(c) The chief of the airworthiness function should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the product certification and continued airworthiness, including knowledge of, and experience in, managing the design assurance system.

(d) The chief of the independent monitoring function should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the activities of the organisation, including knowledge of, and experience in, independent system monitoring.

(e) The competency of the person that assumes (or the persons that assume) the function of the safety manager should include, but not be limited to, the following:

(1) knowledge of the International Civil Aviation Organization (ICAO) standards and EU requirements for safety management;

(2) an understanding of management systems, including compliance monitoring systems;

(3) an understanding of risk management;

(4) an understanding of safety investigation techniques;

(5) an understanding of HF, including HP and limitations;

(6) an understanding of a positive safety culture and of its promotion; and

(7) operational experience related to the activities of the organisation.

AMC1 21.A.245(e) Resources

ED Decision 2022/021/R

STAFF, FACILITIES, AND COORDINATION

(a) *General*

The handbook that is submitted in accordance with point 21.A.243 should show that sufficient skilled personnel are available, and that suitable technical and organisational provisions are made for carrying out the type investigation that is defined in GM1 21.A.239(d), point (b)(3).

(b) *Personnel*

The organisation should show that the personnel that is available to comply with point 21.A.245(e)(1) are able, based on their special qualifications and numbers, to provide assurance of the design or modification of a product, as well as of the compilation and verification of all the data that is needed to meet the applicable type certification basis, operational suitability data (OSD) certification basis, and environmental protection requirements, while taking into account the state of the art and new experience.

The organisation should have a system in place to plan the availability of staff to ensure that the organisation has sufficient appropriately qualified staff to plan, perform, supervise, inspect, and monitor the organisation's activities in accordance with the organisation's terms of approval.

(c) *Technical*

The organisation should have access to:

(1) workshops and production facilities that are suitable for manufacturing prototype models and test specimens; and

(2) accommodation and test facilities that are suitable for carrying out the tests and measurements that are needed to demonstrate compliance with the type certification basis, OSD certification basis, and environmental protection requirements; the test facilities may be subject to additional technical conditions that are related to the nature of the tests performed.

(d) *Organisation*

The handbook that is submitted in accordance with point 21.A.243 should show that:

(1) the responsibilities for all the tasks that are related to the certification process are assigned in such a way that gaps in authority are excluded;

(2) the responsibility for a number of tasks as in point (d)(1) may be assigned to one person, especially in cases of simple projects; and

(3) coordination between technical departments and the persons in charge of the system monitoring that is required by point 21.A.239(e) is established:

(i) to ensure the quick and efficient reporting and resolution of difficulties that are encountered using the handbook and associated procedures;

(ii) to maintain the design management system; and

(iii) to optimise auditing activities.

(e) *Competency and training*

(1) The organisation should establish and control the competency of the staff that is involved in the activities of the organisation, as detailed in the organisation's terms of approval, in accordance with documented procedures. In addition to the necessary expertise that is related to the job function, the competency of the staff should include an understanding of safety management and human factors (HF) principles, which is appropriate to the staff member's function and responsibilities in the organisation.

(2) To assist in the assessment of competency and to perform the analysis of the training needs, job (job family) descriptions are recommended, which should contain sufficient criteria to enable the required competency assessment throughout the duration of the employment/contract.

(3) The organisation should develop a procedure that describes the process for assessing the competency of the staff. The procedure should specify:

(i) the staff that are responsible for that process;

(ii) the means and methods for the initial assessment;

(iii) the means and methods for the continuous control of the competency of the personnel, including feedback on their performance;

(iv) the action to be taken if the assessment is not satisfactory; and

(v) how to record assessment results.

(4) Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. This training should be adapted based on experience that is gained within the organisation (for safety training, refer also to AMC1 21.A.239(c)(5)(i)).

(5) The organisation should record the training that is provided as described in point (e)(4).

21.A.247 Changes in the design management system

Regulation (EU) 2022/201

After the issue of a design organisation approval, each change to the design management system that is significant to the demonstration of compliance or to the airworthiness, operational suitability and environmental protection of the product, part or appliance shall be approved by the Agency before being implemented. The design organisation shall submit to the Agency an application for approval demonstrating, on the basis of the proposed changes to the handbook, that it will continue to comply with this Annex.

AMC1 21.A.247 Changes to the design management system

ED Decision 2022/021/R

APPLICATION FOR APPROVAL OF SIGNIFICANT CHANGES OR CHANGES IN THE TERMS OF APPROVAL OF A DESIGN ORGANISATION

An application for approval of significant changes or changes in the terms of approval of a design organisation (DO) should be submitted in writing to EASA. The design organisation (DO) should demonstrate to EASA, on the basis of the submission of any proposed changes to the handbook or the DOA, and before the implementation of the changes, that it will continue to comply with Part 21 after the implementation.

GM1 21.A.247 Significant changes to the design management system

ED Decision 2022/021/R

In addition to a change in ownership (see point 21.A.249), the following changes to the design management system should be considered to be 'significant' for the demonstration of compliance, or for the airworthiness, operational suitability, or environmental protection of the products:

(a) Organisation

- Relocation to new premises (see also GM 21.A.249);
- A change in the industrial organisation (partnership, subcontractors, design work sharing), unless it can be shown that the independent verification function of the demonstration of compliance is not affected;
- A change in the parts of the organisation that contribute directly to the airworthiness, operational suitability, or environmental protection (independent verification function, airworthiness function (or equivalent));
- A change to the independent monitoring principles of compliance and adequacy (see point 21.A.239(e).

(b) Responsibilities

- Change of the management personnel:
  - the head of the design organisation (HDO) (see point 21.A.245(a))
  - the chief of the airworthiness function (see point 21.A.245(b)); and
  - the chief of the independent monitoring function of compliance and adequacy of the design management system (see point 21.A.245(b)(2)); and
  - the safety manager (see point 21.A.239(c)(2)).
- Reporting lines between the personnel that is nominated in accordance with point 21.A.245(b) and the HDO.
- Allocation of responsibilities that affect safety, airworthiness, operational suitability, or environmental protection.

(c) Procedures

Change to the principles of procedures related to:

- the type certification;
- the classification of changes and repairs as 'major' or 'minor' (see point 21.A.263(c)(1));
- the handling of major changes and major repairs;
- the approval of the design of minor changes and minor repairs (see point 21.A.263(c)(2));
- the approval of the design of certain major repairs (see point 21.A.435(b) or 21.A.263(c)(5));
- the approval of the conditions under which a permit to fly can be issued (see point 21.A.263(c)(6));
- the issue of a permit to fly (see point 21.A.263(c)(7));

— the approval of certain major changes to a type certificate (TC) (see point 21.A.263(c)(8));

— the approval of certain supplemental type certificates (STCs) (see point 21.A.263(c)(9));

— the approval of certain major changes to certain STCs; (see point 21.A.263(c)(9));

— continued airworthiness or continued operational suitability (see point 21.A.3B);

— the configuration control, when airworthiness, operational suitability or environmental protection is affected;

— the acceptability of design tasks that are undertaken by partners or subcontractors (see point 21.A.239(d)(3));

— the issue of data and information under the obligation of point 21.A.265(h); and

— the safety risk management process (see point 21.A.239(c)(3)).

(d) Resources

— A substantial reduction in the number and/or experience of personnel (see point 21.A.245(d)(1)).

21.A.249 Transferability

Regulation (EU) No 748/2012

Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.247, a design organisation approval is not transferable.

GM1 21.A.249 Transferability

ED Decision 2023/014/R

GENERAL

1. Transfer of the approval would normally only be agreed in cases where the organisation itself remains substantially unchanged.

2. An acceptable transfer situation could be for example a change of company name (supported by the appropriate certificate from the National Companies Registration Office or equivalent) but with no changes to site address or senior company manager. However, if the same legal entity were to relocate to new premises with a new senior company manager and/or new departmental heads, then a substantial investigation by EASA would be necessary such that the change would be classified as a re-approval.

3. In the event of receivership there may be good technical justification for continuation of the approval provided that the company continues to function in a satisfactory manner. It is likely that at a later stage the approval might be surrendered by the receiver or transferred to another legal entity in which case the former paragraphs apply.

GM1 21.A.149 and 21.A.249 Transferability

ED Decision 2022/021/R

GENERAL

A transfer of approval to another production or design organisation is, by default, excluded by points 21.A.149 or 21.A.249 respectively. These points only allow it exceptionally if it is a direct consequence of a transfer of ownership in an approved production or design organisation, which is then considered a significant change to the existing approval (to which point 21.A.147 or 21.A.247 applies).

As a consequence, and in order to apply this exception, the production or design organisation has to demonstrate to the competent authority the existence of a change in ownership which resulted in the fact that a different legal entity is now conducting the approved production or design functions while remaining effectively unchanged.

An example of such an exception is a change of ownership that leads to a re-registration of the organisation (supported by the appropriate certificate from the National Companies Registration Office or equivalent). In order to demonstrate that the organisation remains effectively unchanged, the organisation needs to demonstrate that there are no changes affecting the initial demonstration of compliance of the organisation with Subpart G or Subpart J. If, for instance, the change of ownership would, in addition, lead to a change of address, facilities, type of work, staff, accountable manager or persons nominated under points 21.A.145 or 21.A.245, then it is not an acceptable transfer situation; the exception does not apply in this case. A new investigation by the competent authority would be necessary. The new organisation would have to apply for its own approval. In such a case where the organisation applies for a new approval, the demonstration of compliance in accordance with points 21.A.135 or 21.A.235 may be limited to the demonstration that the changes in the organisation comply with the Subpart G or Subpart J requirements, while referring for the rest to the compliance demonstration of the previous approval holder.

A pure name change, where the ownership does not change, does not require a transfer of the approval. In this case, the natural or legal person that holds the approval remains the same. However, as a consequence of the name change, the approval document needs to be amended to reflect the new company name. This is a significant change, to which point 21.A.147 or 21.A.247 applies.

Another example of a transfer of ownership, which may be exceptionally accepted under points 21.A.149 or 21.A.249, may be the event of receivership (bankruptcy, insolvency or another equivalent legal process). In this case, there is no change to the production or design organisation, except that the custodial responsibility for its property, including its tangible and intangible assets and rights, is transferred to a receiver or insolvency administrator. The receivership aims to continue the business of the same organisation.

21.A.251 Terms of approval

Regulation (EU) 2019/897

The terms of approval shall identify the types of design work, the categories of products, parts and appliances for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform with regard to the airworthiness, operational suitability and environmental characteristics of the products. For design organisation approvals covering type-certification or European Technical Standard Order (ETSO) authorisation for auxiliary power units (APUs), the terms of approval shall contain in addition the list of products or APUs. Those terms shall be issued as part of a design organisation approval.

GM No 1 to 21.A.251 Terms of approval

ED Decision 2012/020/R

1. The terms of approval are stated on the certificate of approval issued by the Agency. The certificate states the scope of work and the products, changes or repairs thereof, with the appropriate limitations for which the approval has been granted. For design organisation approval covering type certification or ETSO authorisation for APU, the list of product types covered by the design assurance system should be included.
2. Approval of a change in the terms of approval in accordance with 21.A.253 will be confirmed by an appropriate amendment of the certificate of approval.
3. The certificate references the handbook of the approved design organisation, provided in accordance with 21.A.243. This handbook defines the tasks which may be performed under the approval.
4. Scopes of work are, for example, 'subsonic turbojet aeroplanes', 'turbopropeller aeroplanes', 'small aeroplanes', 'rotorcraft'... Technologies are quoted in the scope of work when it is considered by the Agency as a limitation for the design organisation approval.
5. For repair design activities, the certificate states the scope of work with the appropriate limitations for which the approval has been granted.

GM No 2 to 21.A.251 Terms of approval – Organisations that design minor changes to type design or minor repairs to products

ED Decision 2019/018/R

Terms of approval issued for organisations designing minor changes to type design or minor repairs to products should contain:

1. Scope of work

   This design organisation approval has been granted for:

   — designing minor changes to type design or minor repairs to [aircraft, engine, propeller] in accordance with the applicable CS and environmental protection requirements,

   — demonstrating and verifying the compliance with these CS and environmental protection requirements.

2. Category of products

   Any other indication if the Agency has found a limitation related to aircraft systems or technologies and reducing the scope as defined in paragraph 1.

3. Privileges

   The holder of this approval is entitled to list the privileges granted with the approval, pursuant to 21.A.263(c)(1) and (2).

21.A.253 Changes to the terms of approval

Regulation (EU) No 748/2012

Each change to the terms of approval shall be approved by the Agency. An application for a change to the terms of approval shall be made in a form and manner established by the Agency. The design organisation shall comply with the applicable requirements of this Subpart.

21.A.258 Findings and observations

Regulation (EU) 2022/201

(a) After the receipt of the notification of findings in accordance with point 21.B.433, the holder of the design organisation approval shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;
2. establish a corrective action plan;
3. demonstrate the implementation of the corrective action to the satisfaction of the Agency.

(b) The actions referred to in point (a) shall be performed within the period agreed by the Agency in accordance with point 21.B.433.

(c) The observations received in accordance with point 21.B.433(e) shall be given due consideration by the holder of the design organisation approval. The organisation shall record the decisions taken in respect of those observations.

GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings and observations

ED Decision 2022/021/R

ROOT CAUSE ANALYSIS

(a) It is important that the analysis does not primarily focus on establishing who or what caused the non-compliance, but on why it was caused. Establishing the root cause(s) of non-compliance often requires an overarching view of the events and circumstances that led to it, to identify all the possible systemic and contributing factors (human factors (HF), regulatory, organisational, technical factors, etc.) in addition to the direct factors.

(b) A narrow focus on single events or failures, or the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the non-compliance, may not properly reflect the complexity of the issue, and therefore, there is a risk that important factors that must be considered to prevent reoccurrence will be ignored.

Such an inappropriate or partial root cause analysis often leads to applying ‘quick fixes’ that only address the symptoms of the non-compliance. A peer review of the results of the root cause analysis may increase its reliability and objectivity.

AMC1 21.A.125B(a)(3), 21.A.158(a)(3) and 21.A.258(a)(3) Findings and observations

ED Decision 2022/021/R

FINDING-RELATED CORRECTIVE-ACTION PLAN AND IMPLEMENTATION

After receipt of notification of findings, the organisation should identify and define the action for all findings, to address the effects of the non-compliance, as well as its root cause(s) and contributing factor(s).

Depending on the issues identified, the organisation may need to take immediate corrective action.

The corrective action plan should:

— include the correction of the issue, corrective and preventive action, as well as the planning to implement them; and

— be timely submitted to the competent authority for acceptance before it is effectively implemented.

After receiving the competent authority's acceptance of the corrective action plan, the organisation should implement the associated action.

Within the agreed period, the organisation should inform the competent authority that the corrective action plan has been implemented and should send the associated pieces of evidence, on request from the competent authority.

AMC1 21.A.125B(c), 21.A.158(c), 21.A.258(c) Findings and observations

ED Decision 2022/021/R

DUE CONSIDERATION TO OBSERVATIONS

For each observation that is notified by the competent authority, the organisation should analyse the related issues and determine when action is needed.

The handling of the observations may follow a process similar to the handling of the findings by the organisation.

The organisation should record the analysis and the related outputs, such as action taken, or the reasons why no action was taken.

21.A.259 Duration and continued validity

Regulation (EU) 2022/201

(a) A design organisation approval shall be issued for an unlimited period of time. It shall remain valid subject to the design organisation's compliance with all the following conditions:

1. the design organisation continues to comply with Regulation (EU) 2018/1139 and its delegated and implementing acts; taking into account the provisions of point 21.B.433 of this Annex related to the handling of findings;
2. the holder of the design organisation approval or any of its partners or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;
3. the design organisation is able to provide the Agency with evidence showing that the design management system of the organisation maintains satisfactory control and supervision of the design of products, repairs and changes thereto under the approval;
4. the certificate has not been revoked by the Agency under point 21.B.65, or surrendered by the design organisation.

(b) Upon surrender or revocation, the certificate shall be returned to the Agency.

21.A.263 Privileges

Regulation (EU) 2022/1358

(a) (Reserved)

(b) (Reserved)

(c) The holder of a design organisation approval shall be entitled, within the scope of its terms of approval issued under point 21.A.251 and under the relevant procedures of the design management system:

1. to classify changes to a type certificate or to a supplemental type certificate and repair designs as 'major' or 'minor';
2. to approve minor changes to a type certificate or to a supplemental type certificate and minor repair designs under this Annex (Part 21) or under Annex Ib (Part 21 Light);
3. to declare the compliance of a minor change or minor repair to the design of an aircraft for which design compliance has been declared by the declarant under point 21L.A.43 of Subpart C of Section A of Annex Ib (Part 21 Light;)
4. to declare compliance of a changed aircraft design, in accordance with point 21L.A.43 of Annex Ib (Part 21 Light), in the event that the natural or legal person who originally made a declaration of design compliance with respect to that aircraft under point 21L.A.43 of Annex Ib (Part 21 Light) is no longer active or is unresponsive to requests for the declaration of compliance of design changes;
5. to approve certain major repair designs under Subpart M of this Annex to products or auxiliary power units (APUs);
6. to approve for certain aircraft the flight conditions under which a permit to fly can be issued in accordance with point 21.A.710(a)(2), except for permits to fly to be issued for the purpose of point 21.A.701(a)(15);
7. to issue a permit to fly in accordance with point 21.A.711(b) for an aircraft it has designed or modified, or for which it has approved, in accordance with point 21.A.263(c)(6), the flight conditions under which the permit to fly can be issued, and where the holder of a design organisation approval itself:
   (i) controls the configuration of the aircraft, and
   (ii) attests conformity with the design conditions approved for the flight;
8. to approve certain major changes to a type certificate under Subpart D of this Annex or under Subpart D of Section A of Annex Ib (Part 21 Light); and
9. to issue certain supplemental type certificates under Subpart E of this Annex or under Subpart E of Section A of Annex Ib (Part 21 Light) and approve certain major changes to those certificates.

AMC1 21.A.263(c)(1) Privileges

ED Decision 2023/014/R

PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TYPE CERTIFICATE (TC) OR TO A SUPPLEMENTAL TYPE CERTIFICATE (STC), AND OF REPAIR DESIGNS AS 'MINOR' OR 'MAJOR'

1. INTENT

This AMC provides the means to develop a procedure for the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs.

Each design organisation approval (DOA) applicant should develop its own internal classification procedure following this AMC in order to obtain the associated privilege under 21.A.263(c)(1).

2. PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TC, APU ETSO, OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND REPAIR DESIGNS

2.1 Content

The procedure should address the following points:

— the identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs;

— classification;

— justification of the classification;

— acceptance of the classification by authorised signatories; and

— supervision of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs initiated by subcontractors.

2.2 Identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs

The procedure should indicate how the following are identified:

— items (consisting of areas, systems, parts, or appliances) to be affected by the change or repair following the definitions provided in paragraph 3.9 of GM 21.A.101;

— airworthiness directives which have, or might have, an impact on any of the identified items affected by the change or repair;

— other constituents of the TC and of the pre-existing change(s) to the TC as applicable to the affected items (for instance, operating limitations, OSD constituents, manuals — see also point 21.A.90A and the associated GM) to be affected by the change or repair;

— the existing type-certification basis of the affected items containing, as applicable, the certification specifications, special conditions, deviations from the applicable certification specifications and the equivalent level of safety findings incorporated by reference in the TC of the product to be changed;

— the existing OSD certification basis;

— the definition of the change or repair to the affected items and to the other affected constituents of the TC and of the pre-existing change(s) to the TC, if applicable, in accordance with the provisions of points 21.A.31 and 21.A.91;

— the certification basis of the change or repair determined in accordance with point 21.A.101 with the support of GM 21.A.101 (point 21.A.433 for repairs); this might lead to preclassification of the change as 'major significant' as per the associated definitions (see point 2.3 below).

The procedure should request the applicant to record a justification that the information, on which those identifications are based, is adequate. This may be done either by using the DOA holder's own resources, or through an arrangement with the TC holder, or any other design approval holder as relevant.

The procedure should address cases where the pre-existing configuration of the type design is the result of multiple changes or repairs applied to the same areas, systems, parts, equipment or appliances.

2.3 Classification

The procedure should show how the effects on airworthiness, operational suitability and environmental protection are analysed, from the very beginning, by reference to the specific applicable requirements of the affected items.

If no specific CSs or environmental protection requirements are applicable to the affected items, the above review should be carried out at the level of the part or system where the affected items are integrated and where specific CSs or environmental protection requirements are applicable.

For changes to a TC, the criteria used for the classification should be in compliance with point 21.A.91 and follow the guidelines provided in GM 21.A.91.

For repairs, the criteria used for the classification should be in compliance with point 21.A.435 and follow the guidelines provided in GM 21.A.435(a).

The procedure should define provisions to contact EASA in case of doubts regarding the classification.

The procedure should take into consideration that a change to a TC may have been found to be significant according to point 21.A.101 and following the definitions provided in GM 21.A.101. Therefore, it is already preclassified at the stage of the determination of the certification basis (see point 2.2 above).

2.4 Justification of the classification

All decisions on the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs classified as 'major' or 'minor' should be recorded, and, for those which are not straightforward, also justified according to the procedure and criteria in point 2.3 above. These records should be easily accessible to EASA for sample checking.

2.5 Acceptance of the classification by the authorised signatories

All classifications of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs should be accepted by an appropriately authorised signatory, belonging to the airworthiness function, as explained in AMC1 21.A.239(d).

The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

For those changes or repairs that are handled by subcontractors, as described under point 2.6, a description should be provided of how the DOA holder manages its classification responsibility.

The final classification may be:

— major changes significant to a TC;

— major changes not significant to a TC or major repairs;

— minor changes to a TC or minor repairs where additional work is necessary to demonstrate compliance with the certification basis, the operational suitability data certification basis, where applicable, and the environmental protection requirements; or

— minor changes to a TC or minor repairs requiring no further demonstration of compliance.

The procedure should indicate how the above four classes of changes/repairs are identified, taking into consideration the requirements laid down in point 21.A.31.

2.6 Supervision of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs initiated by subcontractors

The procedure should indicate, directly or by cross reference to written procedures, how changes to a TC, or to that part of the product covered by an STC, and repair designs may be initiated and classified by subcontractors, and are controlled and supervised by the DOA holder, taking into consideration the requirements laid down in point 21.A.239(d)(3) and its associated guidance material.

AMC2 21.A.263(c)(1) Privileges

ED Decision 2021/001/R

ORGANISATIONS THAT DESIGN MINOR CHANGES TO A TYPE CERTIFICATE (TC) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC), AND MINOR REPAIRS TO PRODUCTS: CLASSIFICATION PROCEDURE

1. Content

The procedure should address the following points:

— the configuration control rules, especially the identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs;

— the classification in compliance with point 21.A.91 and considering GM 21.A.91 for changes and GM 21.A.435(a) for repairs;

— the justification of the decisions for the classification; and

— the acceptance of the classification by authorised signatories.

2. Identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs

The procedure should indicate how the following are identified:

— the items (consisting of areas, systems, parts, or appliances) to be affected by the change or repair as per the definitions provided in paragraph 3.9 of GM 21.A.101; these include the parts, appliances, systems or areas affected, and also the other TC constituents (see definitions in GM to 21.A.90A; for instance, operating limitations, OSD constituents, manuals, etc.);

— airworthiness directives which have, or might have, an impact on any of the identified items affected by the change or repair;

— the existing type-certification basis of the affected items containing, as applicable, the certification specifications, special conditions, deviations from the applicable certification specifications and the equivalent level of safety findings incorporated by reference in the TC of the product to be changed;

— the existing OSD certification basis;

— the definition of the change or repair to the affected items in accordance with the provisions of point 21.A.31;

— the certification basis of the change or repair determined in accordance with point 21.A.101 with the support of GM 21.A.101 (point 21.A.433 for repairs); this might lead to preclassification of the change as 'major significant' as per the associated definitions (see paragraph 3 below).

3. Classification

The procedure should show how the effects on airworthiness, operational suitability and environmental protection are analysed, from the very beginning, by reference to the specific applicable requirements of the affected items.

If no specific CSs or environmental protection requirements are applicable to the affected items, the above review should be carried out at the level of the part or system where the affected items are integrated and where specific CSs or environmental protection requirements are applicable.

For repairs, the criteria used for the classification should be in compliance with point 21.A.435 and follow the guidelines provided in GM 21.A.435(a).

The procedure should define provisions to contact EASA in case of doubts regarding the classification.

4. Justification of the classification

All decisions on the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs classified as 'minor', should be recorded, and, for those which are not straightforward, also justified according to the procedure and the criteria defined in paragraph 3 above.

These records should be easily accessible to EASA for sample checking.

The justification may be in the format of meeting notes or a register.

5. Acceptance of the classification by the authorised signatories

All classifications of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs should be accepted by an appropriately authorised signatory.

The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

The final classification may be:

— minor changes to a TC or minor repairs where additional work is necessary for the demonstration of compliance with the certification basis, the operational suitability data certification basis (where applicable), and the environmental protection requirements; or

— minor changes to a TC or minor repairs that require no further demonstration of compliance.

AMC1 21.A.263(c)(2) Privileges

ED Decision 2023/014/R

PROCEDURE FOR THE APPROVAL OF MINOR CHANGES AND MINOR REPAIRS TO A TYPE CERTIFICATE (TC), AN AUXILIARY POWER UNIT EUROPEAN TECHNICAL STANDARD ORDER (APU ETSO) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC)

1. INTENT

This AMC provides the means to develop a procedure for the approval of minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs.

Each design organisation approval (DOA) applicant should develop its own internal procedures following this AMC in order to obtain the associated privilege under 21.A.263(c)(2).

2. PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A TC, AN APU ETSO OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND MINOR REPAIRS

2.1 Content

The procedure should address the following points:

— compliance documentation;

— approval under the DOA privilege;

— authorised signatories; and

— supervision of minor changes to a TC, an APU ETSO or to that part of the product covered by an STC or minor repairs handled by subcontractors.

2.2 Compliance documentation

For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, compliance documentation should be established and independently verified as required by point 21.A.239(d)(2).

The procedure should describe how the compliance documentation is produced and checked. For compliance documentation, see also AMC 21.A.20(c).

2.3 Approval under the DOA privilege

2.3.1 For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

— a brief description of the change or repair and the reasons for the change or repair;

— identification of the initial configuration of the affected area and other items (which determines the eligibility for installation of the change or repair into an aircraft);

— identification of the final configuration of the affected area, and of supplements to manuals and to OSD constituents;

— the applicable CSs or environmental protection requirements and methods of compliance;

— references to the compliance documents;

— the effects, if any, on the limitations and on the approved documentation;

— evidence of the independent checking function of the demonstration of compliance;

— evidence of the approval under the privilege of point 21.A.263(c)(2) by an authorised signatory; and

— the date of the approval.

For repairs, see AMC1 21.A.5 and AMC1 21.A.433(b).

2.3.2 For the other minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs, the procedure should define a means to identify the change or repair and the reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function may be delegated by the Office of Airworthiness but should be controlled by the Office of Airworthiness, either directly or through appropriate procedures of the DOA holder's design assurance system.

2.4 Authorised signatories

The persons authorised to sign for the approval under the privilege of point 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

2.5 Supervision of minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs handled by subcontractors

For the minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs described in 2.3.2 which are handled by subcontractors, the procedure should indicate, directly or by cross reference to written procedures, how these minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs are approved at the subcontractor level and the arrangements made for the control and supervision by the DOA holder.

AMC2 21.A.263(c)(2) Privileges

ED Decision 2023/014/R

ORGANISATIONS THAT DESIGN MINOR CHANGES TO A TYPE CERTIFICATE (TC), AN AUXILIARY POWER UNIT EUROPEAN TECHNICAL STANDARD ODER (APU ETSO) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC) AND MINOR REPAIRS TO PRODUCTS: PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A TC, AN APU ETSO OR MINOR REPAIRS

1. Content

The procedure should address the following points:

— compliance documentation;

— approval under the DOA privilege; and

— authorised signatories.

2. Compliance documentation

For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, compliance documentation should be established and independently verified as required by point 21.A.239(d)(2).

The procedure should describe how the compliance documentation is produced and checked. For compliance documentation, see also AMC 21.A.20(c).

3. Approval under the DOA privilege

3.1. For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs or environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

(a) a brief description of the change or the repair and the reason for change or repair;

(b) identification of the initial configuration of the affected area and other items (which determines the eligibility for installation of the change or repair into an aircraft);

(c) identification of the final configuration of the affected area, and of supplements to manuals and to OSD constituents;

(d) the applicable CSs or environmental protection requirements and methods of compliance;

(e) references to the compliance documents;

(f) the effects, if any, on the limitations and on the approved documentation;

(g) evidence of the independent checking function of the demonstration of compliance;

(h) evidence of the approval under the privilege of point 21.A.263(c)(2) by an authorised signatory; and

(i) the date of the approval.

For repairs, see also AMC 21.A.433(b) and 21.A.447.

3.2. For the other minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs, the procedure should define a means to identify the change or repair and the reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function should be controlled through appropriate procedures of the DOA holder's design assurance system.

4. Authorised signatories

The persons authorised to sign for the approval under the privilege of 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

AMC No 3 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (TC) which affect the aircraft flight manual (AFM)

ED Decision 2019/018/R

1. Intent

This AMC provides additional guidance for developing a procedure for the approval of minor changes to a TC which affect the aircraft flight manual (AFM).

Each design organisation approval (DOA) applicant/holder should develop its own internal procedure, based on these guidelines. For guidance on the classification of changes to a TC which affect the AFM, see GM 21.A.91.

2. Procedure for the approval of minor changes to a TC which affect the AFM

2.1 Content

The procedure should address the following points:

— assessment of any change to a TC for the impact of the change on the AFM;

— preparation of revisions or supplements to the AFM;

— classification of the change to a TC, taking into account the impact on the AFM;

— classification of stand-alone revisions or supplements to the AFM;

— control of the configuration of the AFM;

— approval of the revisions or supplements to the AFM; and

— the approval statement.

2.2 Assessment of a change for its impact on the AFM The procedure should include an assessment of whether or not the AFM is impacted by the change.

2.3 Preparation

The procedure should indicate how revisions or supplements to the AFM are prepared and how the coordination among the persons in charge of design changes is performed.

2.4 Classification

The procedure should indicate how changes to a TC which affect the AFM are classified, in accordance with the criteria of GM 21.A.91 Section 3.4.

The procedure should indicate how classification decisions are recorded, documented and signed.

Easy accessibility of these records to EASA for sample checking should be ensured. All classifications should be accepted by an appropriately authorised signatory. The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

2.5 Configuration control of the AFM

The procedure should explain the traceability of changes in order to understand who has approved what. Especially if a given page or data module has been revised several times, it should be traceable which part(s) of the page or data module has (have) been approved directly by EASA under which approval, and which part(s) has (have) been approved under the privilege of a DOA holder.

2.6 Approval

The procedure should indicate how the approval under the privilege of point 21.A.263(c)(2) is formalised.

The authorised signatories should be identified (name, signature), together with the scope of the authorisation, in a document that is linked to the DOA handbook.

2.7 Approval statement

The amended AFM, or the supplement to the AFM, approved under the privilege of point 21.A.263(c)(2) should be issued under the obligation of point 21.A.265(h) (see point 21.A.265(h) and the related GM) with a respective statement in the log of revisions.

AMC1 21.A.263(c)(6) Privileges

ED Decision 2021/001/R

PROCEDURE FOR THE APPROVAL OF THE CONDITIONS FOR THE ISSUE OF A PERMIT TO FLY (PtF)

1. INTENT

— This AMC provides the means to develop a procedure to determine that an aircraft can fly, under the appropriate restrictions compensating for non-compliance with the certification specifications applicable to the specific aircraft category.

— Each DOA applicant or DOA holder should develop its own internal procedure following this AMC, in order to obtain the privilege to make this determination and approve the associated conditions without EASA's involvement, under point 21.A.263(c)(6). When the privilege does not apply, the DOA applicant or the DOA holder will prepare all the

necessary data required for the determination in accordance with the same procedure required for the privilege, and will apply for EASA's approval.

— The establishment of flight conditions may include conditions related to engines/propellers without a type certificate or with unapproved changes that are fitted to the aircraft, for which a permit to fly (PtF) is requested. These conditions (i.e. the installation, operating limitations, maintenance conditions or limitations) should be defined by the organisation responsible for the design of the engine/propeller and provided to the organisation responsible for the design of the aircraft.

— These conditions should be established and substantiated under an arrangement between the organisation responsible for the design of the aircraft and the organisation responsible for the design of the engine/propeller. However, the establishment and substantiation of the flight conditions for the aircraft, including its engine(s), is ultimately the responsibility of the organisation responsible for the design of the aircraft.

2. PROCEDURE FOR THE APPROVAL OF THE CONDITIONS FOR THE ISSUE OF A PERMIT TO FLY (PtF)

2.1 Content

The procedure should address the following points:

— the decision to exercise the privilege;

— management of the aircraft configuration;

— determination of the conditions that should be complied with to safely perform a flight;

— documentation of substantiations of flight conditions;

— approval under the DOA privilege, when applicable; and

— the authorised signatories.

2.2 Decision to exercise the privilege of point 21.A.263(c)(6)

The procedure should include a decision to determine the flights for which the privilege of point 21.A.263(c)(6) will be exercised.

2.3 Management of the aircraft configuration

The procedure should indicate:

— how the aircraft, for which an application for a permit to fly is made, is identified; and

— how changes to the aircraft will be managed.

2.4 Determination of the conditions that should be complied with to safely perform a flight

The procedure should describe the process used by the DOA holder to justify that the aircraft can perform the intended flight(s) safely. This process should include:

— with reference to point 21.A.701(a), identification of the applicable airworthiness requirements which the aircraft does not meet, or has not been shown to meet, if applicable, and of the purpose of the flight(s); for flight conditions raised to cover unapproved changes, the identification of the applicable airworthiness requirements which the aircraft does not meet, or has not been shown to meet, can be fulfilled by referring to the certification programme of the unapproved changes;

— the analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can safely perform a flight (the flights);

— the establishment of specific maintenance instructions and conditions to perform these instructions;

— an independent technical verification of the analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can perform the intended flight(s) safely;

— a statement by the office of airworthiness (or equivalent), that the determination has been made in accordance with the related procedure and that the aircraft has no features and characteristics that render it unsafe for the intended operation(s) under the identified conditions and restrictions; and

— approval by an authorised signatory.

2.5 Documentation of flight conditions substantiations

1. The analysis, calculations, tests, or other means used to determine under which conditions or restrictions the aircraft can safely perform a flight (or the flights) should be compiled in compliance documents. These documents should be signed by the author and by the person performing the independent technical verification.

2. Each compliance document should have a number and an issue date. The various issues of a document should be controlled.

3. The data submitted and approved by the TC holder can be used as substantiations. In that case, the independent technical verification referred to in 2.4 is not required.

2.6 Approval under the DOA privilege

2.6.1 Initial approval

The procedure should include the following EASA Form 18A (as an alternative, the DOA holder should provide an equivalent template containing the same level of information) to support the approval under the DOA privilege:

FLIGHT CONDITIONS FOR A PERMIT TO FLY — APPROVAL FORM	
1. Applicant: **Approval No:** *[Name and organisation approval number of the organisation providing the flight conditions and associated substantiations]*	**2. Approval form No:** **Issue:** *[Number and issue, for traceability purposes]*
3. Aircraft manufacturer/type	**4. Serial number(s)**
5. Purpose [Purpose in accordance with point 21.A.701(a)]	
6. Aircraft configuration The above aircraft, for which a permit to fly is requested, is defined in *[add reference to the document(s) identifying the detailed configuration of the aircraft]* *[For change(s) affecting the initial approval form: a description of the change(s). This form must be reissued]*	
7. Substantiations *[References to the document(s) justifying that the aircraft (as described in block 6) can perform the intended flight(s) safely under the defined conditions or restrictions.]* *[For change(s) affecting the initial approval form: reference(s) to additional substantiation(s). This form must be reissued]*	
8. Conditions/Restrictions The above aircraft must be used with the following conditions or restrictions: *[Details of these conditions/restrictions, or a reference to the relevant document, including specific maintenance instructions and conditions to perform these instructions.]*	
9. Statement The determination of the flight conditions has been made in accordance with the relevant DOA procedure agreed by EASA. The aircraft, as defined in block 6 above, has no features or characteristics that render it unsafe for the intended operation(s) under the identified conditions and restrictions.	
[strike through what is not applicable] **10a. Approved under the authority of DOA EASA.21J.xyz** [when the privilege of point 21.A.263(c)(6) applies] **10b. Submitted under the authority of DOA EASA.21J.xyz** [when the privilege of point 21.A.263(c)(6) does not apply]	
11. Date of issue	**12. Name and signature** *[Authorised signatory]*
13. EASA approval and date [when the privilege of point 21.A.263(c)(6) does not apply]	

EASA Form 18A — Issue 4

When the privilege of point 21.A.263(c)(6) is not applicable, the signed form should be presented by the office of airworthiness (or equivalent) to EASA.

2.6.2 Approval of changes

Except for changes that do not affect the conditions approved for the issue of the permit to fly, the procedure should specify how changes will be approved by the DOA holder. The EASA Form 18A should be updated.

2.7 Authorised signatories

The person(s) authorised to sign the approval form should be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the DOA handbook.

AMC 21.A.263(c)(7) Procedure for the issue of a permit to fly

ED Decision 2012/020/R

1. INTENT

This acceptable means of compliance provides means to develop a procedure for the issue of a permit to fly.

Each DOA applicant or holder must develop its own internal procedure following this AMC, in order to obtain the privilege of 21.A.263(c)(7)to issue permits to fly for aircraft it has designed or modified, or for which it has approved under 21.A.263(c)(6) the conditions under which the permit to fly can be issued, and when the design organisation itself is controlling under its DOA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight.

2. PROCEDURE FOR THE ISSUE OF A PERMIT TO FLY

2.1 Content

The procedure must address the following points:

— conformity with approved conditions;

— issue of the permit to fly under the DOA privilege;

— authorised signatories;

— interface with the local authority for the flight.

2.2 Conformity with approved conditions

The procedure must indicate how conformity with approved conditions is made, documented and attested by an authorised person.

2.3 Issue of the permit to fly under the DOA privilege

The procedure must describe the process to prepare the EASA Form 20b and how compliance with 21.A.711(b) and (e) is established before signature of the permit to fly.

2.4 Authorised signatories

The person(s) authorised to sign the permit to fly under the privilege of 21.A.263(c)(7) must be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the DOA handbook.

2.5 Interface with the local authority for the flight

The procedure must include provisions describing the communication with the local authority for compliance with the local requirements which are outside the scope of the conditions of 21.A.708(b) (see 21.A.711(e)).

AMC No 1 to 21.A.263(c)(5), (8) and (9) Scope and criteria

ED Decision 2019/018/R

1. Definition of 'certain major repairs'

'Certain major repairs' for which privileges may be granted as per point 21.A.263(c)(5) are:

(a) major repairs to products or auxiliary power units (APUs) for which the design organisation approval (DOA) holder holds the type certificate (TC) or the supplemental type certificate (STC) or the European technical standard order authorisation (ETSOA); or

(b) major repairs to products or APUs for which the DOA holder does not hold the TC or the STC or ETSOA and that meet the criteria of 3(a), (b) and (c) below.

1.1 Criteria for limitations on eligibility

An EASA approval may be required in cases of major repairs proposed by DOA holders who are the TC, STC or APU ETSOA holders if the major repair is:

(a) related to a new interpretation of any item of the certification basis as used for the type certification (such as the certification specifications (CSs), certification review items (CRIs) for special conditions, equivalent safety findings, deviations or 'elect to comply'); and

(b) related to the application of a CS that is different from the one used for type certification. Note: This should be established at the time of granting the privilege to the DOA holder, or later through an EASA-agreed procedure.

2. Definition of 'certain major changes' and 'certain supplemental type certificates'

'Certain major changes' and 'certain supplemental type certificates' for which privileges may be granted as per point 21.A.263(c)(8) and (9) are changes similar to those that have been previously approved by EASA for the same DOA holder.

The similarity of the changes is to be seen in terms of the design, the installation, and the operational characteristics, whereas their repetitiveness is seen in terms of the applicable requirements and the compliance demonstration.

In this context, a 'requirement' means any element of the type-certification basis as specified in point 21.B.80, or the operational suitability data (OSD) certification basis as specified in point 21.B.82, or the environmental protection requirements as specified in point 21.B.85.

2.1 Criteria for limitations on eligibility

The following types of changes are not eligible:

(a) changes that require a revision to a type certificate data sheet (TCDS) (e.g. the introduction of a derivative model or variant) or a type certificate data sheet for noise (TCDSN);

(b) changes that require an amendment to the existing certification basis by a special condition, equivalent safety finding, deviation or 'elect to comply';

(c) changes that revise airworthiness limitations or operating limitations, unless otherwise agreed with EASA;

(d) changes that are intended to be used as alternative method of compliance (AMOC) to an airworthiness directive (AD);

(e) changes that are made mandatory by an AD or that are the terminating action of an AD;

(f) changes that are classified as 'significant' in accordance with point 21.A.101;

(g) changes for which, in the affected area and for the operations for which the design is to be certified, more conservative certification requirements are applicable which were not used in the description of the EASA-approved procedure of the DOA holder, e.g. in the case of a type, model or modification with a later, more stringent certification basis;

(h) changes that affect the noise and/or emissions characteristics of the changed product, unless otherwise agreed with EASA;

(i) changes that affect a part or system, a single failure of which may have a catastrophic effect upon the product, and for which critical characteristics have been identified, which should be controlled to ensure the required level of integrity;

(j) changes to engines or propellers, a single failure of which may have a hazardous effect upon the product, and for which critical characteristics have been identified, which should be controlled to ensure the required level of integrity; and

(k) changes for which a non-compliance has been found in the referenced change during the continued-airworthiness process.

3 Criteria for major repairs, major changes and STCs for which the privileges of point 21.A.263(c)(5), (8) and (9) may be granted

The following criteria need to be met:

(a) Similarity

The installation on the product, the design, the operation, and the equipment qualification are basically the same as in projects for which EASA has already been involved and issued an approval for the same DOA holder.

(b) Repetitiveness of the certification process

The whole certification process is repetitive, i.e. identical to, or part of, an already approved referenced process. For a change or repair that is a part of the referenced 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates', the certification process is still identical to the one for the affected change. This is the case when each compliance demonstration is performed to the same extent in accordance with the same requirements, GM, and content of the interpretative material, as well as with the same means and method of compliance (not only the same means-of-compliance (MoC) code).

Note: In this AMC, a 'requirement' means any element of the type-certification basis as specified in point 21.B.80, or OSD certification basis as specified in point 21.B.82, or an environmental protection requirement as specified in point 21.B.85.

(c) Performance and experience in previous projects

EASA should have classified as 'medium' or 'high' the level of performance of the organisation during at least the latest project referenced, to demonstrate 'similarity' and 'repetitiveness'.

In addition, EASA should have classified as 'low' or 'very low' the likelihood of an unidentified non-compliance for all the included compliance demonstration items (CDIs) identified in at least the latest project referenced, to demonstrate 'similarity' and 'repetitiveness' (applying the criteria for the determination of EASA's level of involvement (LoI) in product certification, see AMC 21.B.100(a) and 21.A.15(b)(6)).

The process to obtain and to use the privileges of point 21.A.263(c)(5), (8) and (9) is described in AMC No 2 to 21.A.263(c)(5), (8) and (9).

AMC No 2 to 21.A.263(c)(5), (8) and (9) Procedure for the approval of a major repair, a major change to a type certificate (TC), or a supplemental type certificate (STC) by a design organisation approval (DOA) holder under their privileges

ED Decision 2019/018/R

This AMC describes the process to be followed in order to obtain and use the privilege to approve 'certain major repairs' and 'certain major changes' to a TC, and 'certain supplemental type certificates' as defined in points 1(b) and 2 of AMC No 1 to 21.A.263(c)(5), (8) and (9).

1. PROCESS FOR OBTAINING A PRIVILEGE

A DOA holder that applies for the privileges referred to in point 21.A.263(c)(5), (8) or (9) should do the following:

(a) Submit to EASA an application for a significant change in the design assurance system (see points 21.A.247 and 21.A.253).

(b) Establish internal procedures for the application of the privilege covering the following elements, and add them to the application:

(1) The definition of the 'list associated with the privilege' of certain major repairs/changes/STCs. The 'list associated with the privilege' is a list of all 'certain major changes', 'certain STCs' and 'certain major repairs' (or families thereof) plus the associated 'justification document' references for which the privileges as per point 21.A.263(c)(5), (8) and (9) have been granted.

(2) A 'justification document' for a 'certain major repair', 'certain major change' or a 'certain STC', as applicable. The 'justification document' should contain:

(i) The reference(s) to the EASA-approved major change(s), STC(s) and major repair(s), which is (are) used to demonstrate the DOA holder's experience and performance.

Note: The number of already EASA-approved major change(s), STC(s) or major repair(s) used to demonstrate the DOA holder's experience and performance is based on an assessment of the scope of the 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates' which is requested to be added to the 'list associated with the privilege', as well as on the performance of the DOA holder during previous projects.

(ii) The certification programme(s) of the major change(s), STC(s), or major repair(s), accepted by EASA, used to demonstrate the applicant's experience and performance.

(iii) The applicable product configuration(s).

The applicant should list the type(s) and model(s) to which the major change(s)/STC(s)/repair(s) applies (apply) or may apply. Exceptionally, this may be done for a dedicated product, system or equipment if the type or model has no technical influence on the major change(s)/STC(s)/repair(s), i.e. when the installation issues are negligible (e.g. the TCAS 7.1 software change for a certain equipment), such a listing is not mandatory, but it needs to be justified.

(iv) The list of 'requirements' for the demonstration of compliance, if not identical to the ones referenced in the certification programme.

(v) The certification process, if not identical to the one referenced in the certification programme.

(vi) A detailed description with all the technical data relevant to the installation of the product, the design, the operation and the qualification which ensures the proper use of the privilege for future major changes, major repairs or STCs. This description should include the criteria defining the conditions that should be met in order to apply the privileges.

(vii) Any other limits on the use of the privilege.

(3) The assessment of the acceptability of using the privilege for major repairs, major changes or STCs against the 'list associated with the privilege' and the 'justification document' of 'certain major repairs', 'certain major changes' or 'certain STCs'.

(4) The approval process, including the templates to be used, the authorised signatories, records management and the provision of a 'summary list' of major changes, major repairs and STCs approved under the privilege of point 21.A.263(c)(5), (8) and (9). This process should clarify that the approval is issued under the DOA holder's privilege.

The persons authorised under the privilege of point 21.A.263(c)(5), (8) and (9) should be identified by their names, signatures and scopes of authority in the appropriate documents and referenced in the procedure.

A 'summary list' of all the major changes, STCs and major repairs approved under a privilege should be provided to EASA on a regular basis, as agreed with EASA.

(5) Extension of the 'list associated with the privilege' after the privilege is granted.

After the granting of the privilege, the initial list of 'certain major repairs', 'certain major changes' and 'certain STCs' under the privilege may be further extended by an EASA agreement, as shown in Section 2 as well as in Figures 2 and 3 below.

(c) Identify in the 'list associated with the privilege' the eligible major changes, major repairs or STCs proposed for inclusion in the scope of the privilege (see also AMC No 1 to 21.A.263(c)(5), (8) and (9)).

(d) Provide a 'justification document' for each proposed certain major change, certain major repair or certain STC identified under (c) above.

Note: The 'list associated to the privilege' identifying all certain major repairs, certain major changes and certain STCs and the associated 'justification document(s)' are to be referenced in the DOA holder procedure mentioned under (b) above.

The process for obtaining the privilege, referred to in 21.A.263(c)(5), (8) and (9), is summarised in Figure 1 below:

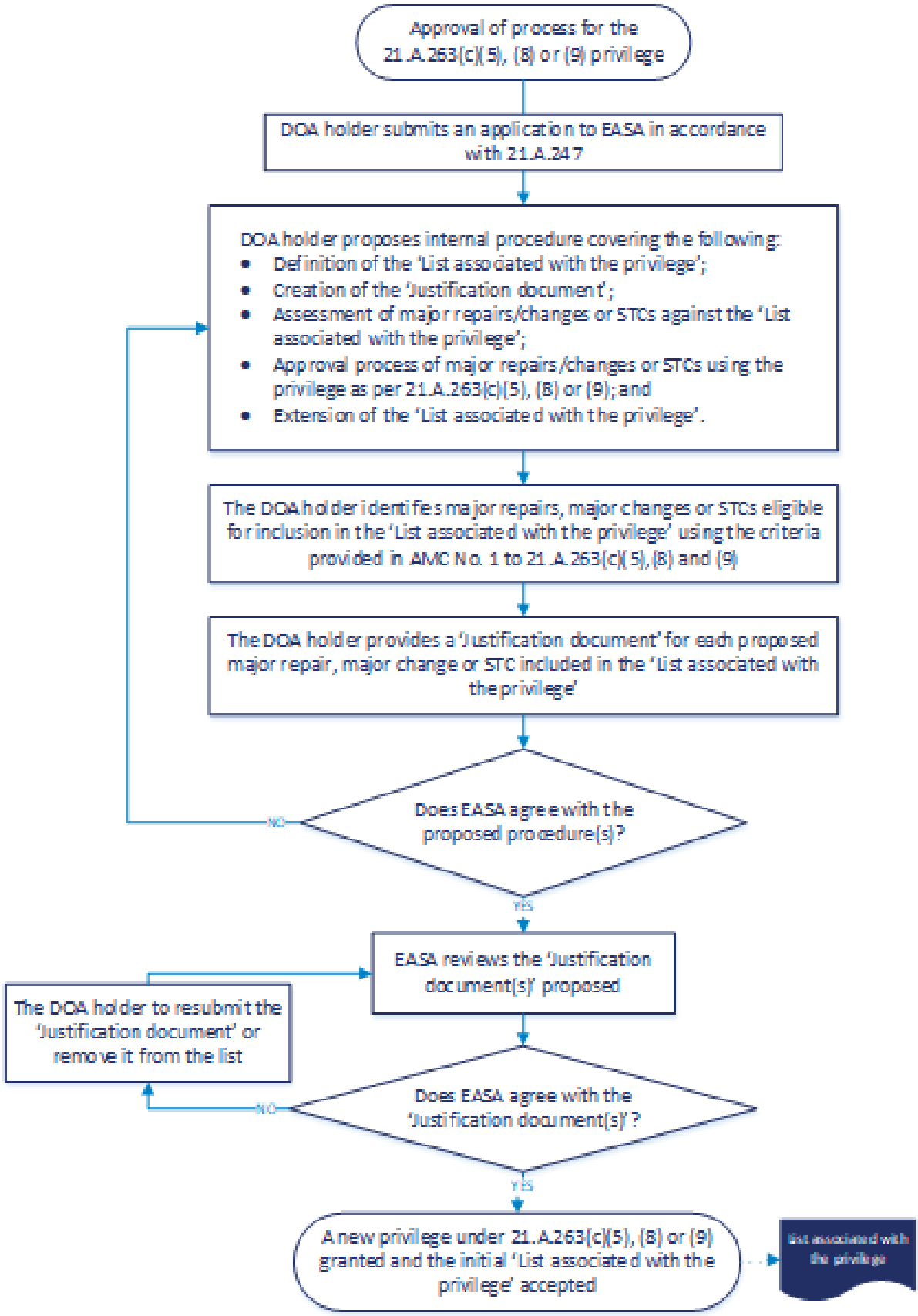

Approval of process for the 21.A.263(c)(5), (8) or (9) privilege
DOA holder submits an application to EASA in accordance with 21.A.247
DOA holder proposes internal procedure covering the following:
Definition of the 'List associated with the privilege';
Creation of the 'Justification document';
Assessment of major repairs/changes or STCs against the 'List associated with the privilege';
Approval process of major repairs/changes or STCs using the privilege as per 21.A.263(c)(5), (8) or (9); and
Extension of the 'List associated with the privilege'.
The DOA holder identifies major repairs, major changes or STCs eligible for inclusion in the 'List associated with the privilege' using the criteria provided in AMC No. 1 to 21.A.263(c)(5), (8) and (9)
The DOA holder provides a 'Justification document' for each proposed major repair, major change or STC included in the 'List associated with the privilege'
Does EASA agree with the proposed procedure(s)?
NO
YES
EASA reviews the 'Justification document(s)' proposed
The DOA holder to resubmit the 'Justification document' or remove it from the list
Does EASA agree with the 'Justification document(s)'?
NO
YES
A new privilege under 21.A.263(c)(5), (8) or (9) granted and the initial 'List associated with the privilege' accepted

Figure 1

The privilege referred to in point 21.A.263(c)(5), (8) and (9) may be used by a DOA holder for the approval of major repairs, major changes or STCs, as applicable, under the following conditions:

(a) the privilege has already been granted by EASA;

(b) the major repair/change/STC to be approved falls under the 'List associated with the privilege' agreed by EASA; and

(c) the criteria established in the relevant 'Justification document' are met and the relevant assessment is recorded.

If all the above conditions are met, the privilege may be used and the approval of major repairs, major changes or STCs, as applicable, can be obtained by the DOA holder without EASA's involvement.

Note: If a DOA holder applies for a third-country validation after having approved a modification under its DOA holder privilege, EASA may review some of the compliance demonstration data in order to support the validation activity.

2. EXTENSION OF THE 'PRIVILEGE LIST' OF 'CERTAIN MAJOR REPAIRS', 'CERTAIN MAJOR CHANGES' OR 'CERTAIN STCs' AFTER THE PRIVILEGE IS GRANTED

When the DOA holder intends to update the 'List associated with the privilege', a 'Justification document' needs to be provided to EASA, as described in Section 1(b)(2) above. After EASA agrees with the updated 'privilege list' as part of the DOA holder's procedure, the DOA holder may proceed as per Section 4 below.

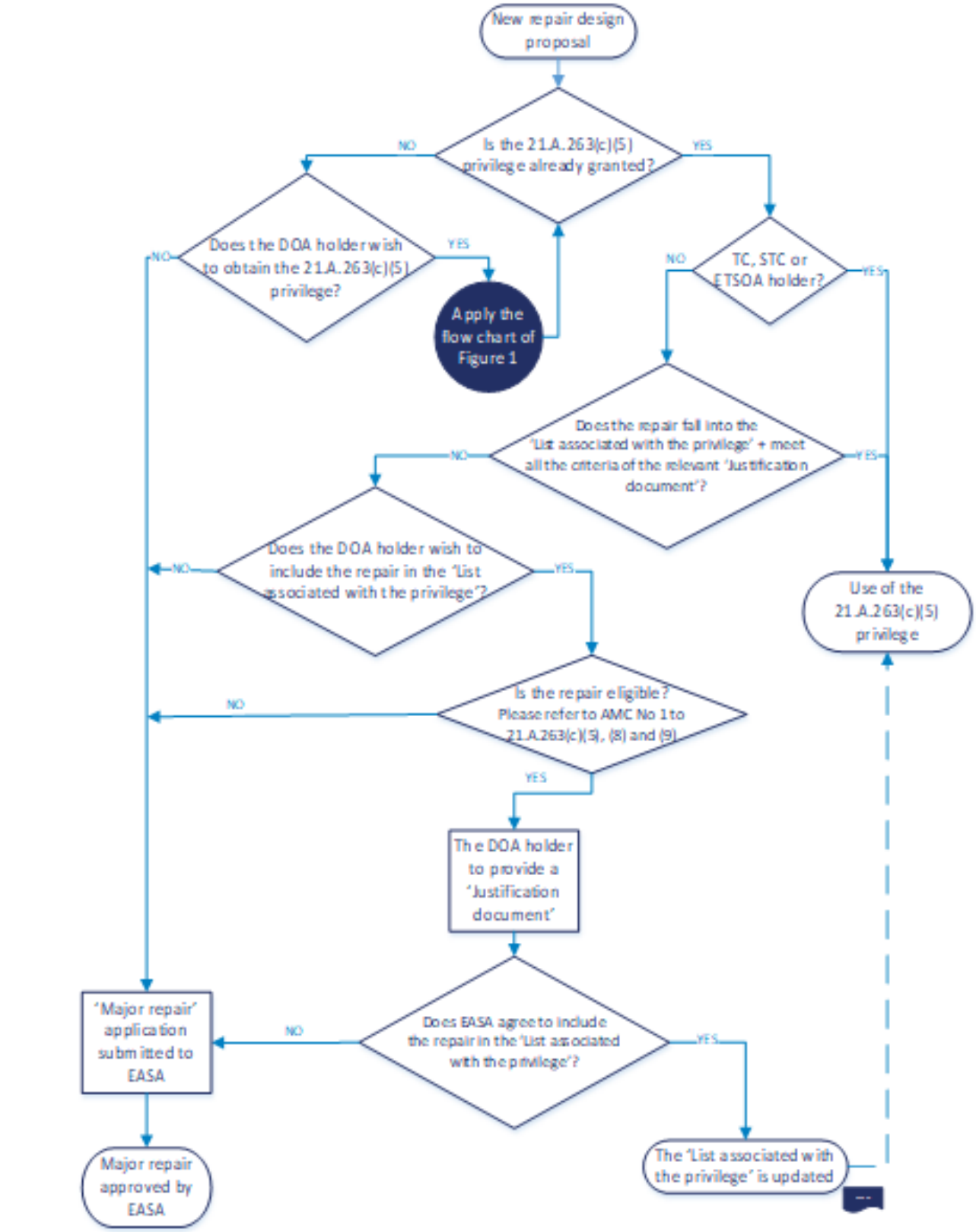

New repair design proposal
Is the 21.A.263(c)(5) privilege already granted?
NO
YES
Does the DOA holder wish to obtain the 21.A.263(c)(5) privilege?
NO
YES
Apply the flow chart of Figure 1
TC, STC or ETSOA holder?
NO
YES
Does the repair fall into the 'List associated with the privilege' + meet all the criteria of the relevant 'Justification document'?
NO
YES
Does the DOA holder wish to include the repair in the 'List associated with the privilege'?
NO
YES
Use of the 21.A.263(c)(5) privilege
Is the repair eligible? Please refer to AMC No 1 to 21.A.263(c)(3), (8) and (9)
NO
YES
The DOA holder to provide a 'Justification document'
'Major repair' application submitted to EASA
NO
Does EASA agree to include the repair in the 'List associated with the privilege'?
YES
Major repair approved by EASA
The 'List associated with the privilege' is updated

Figure 2

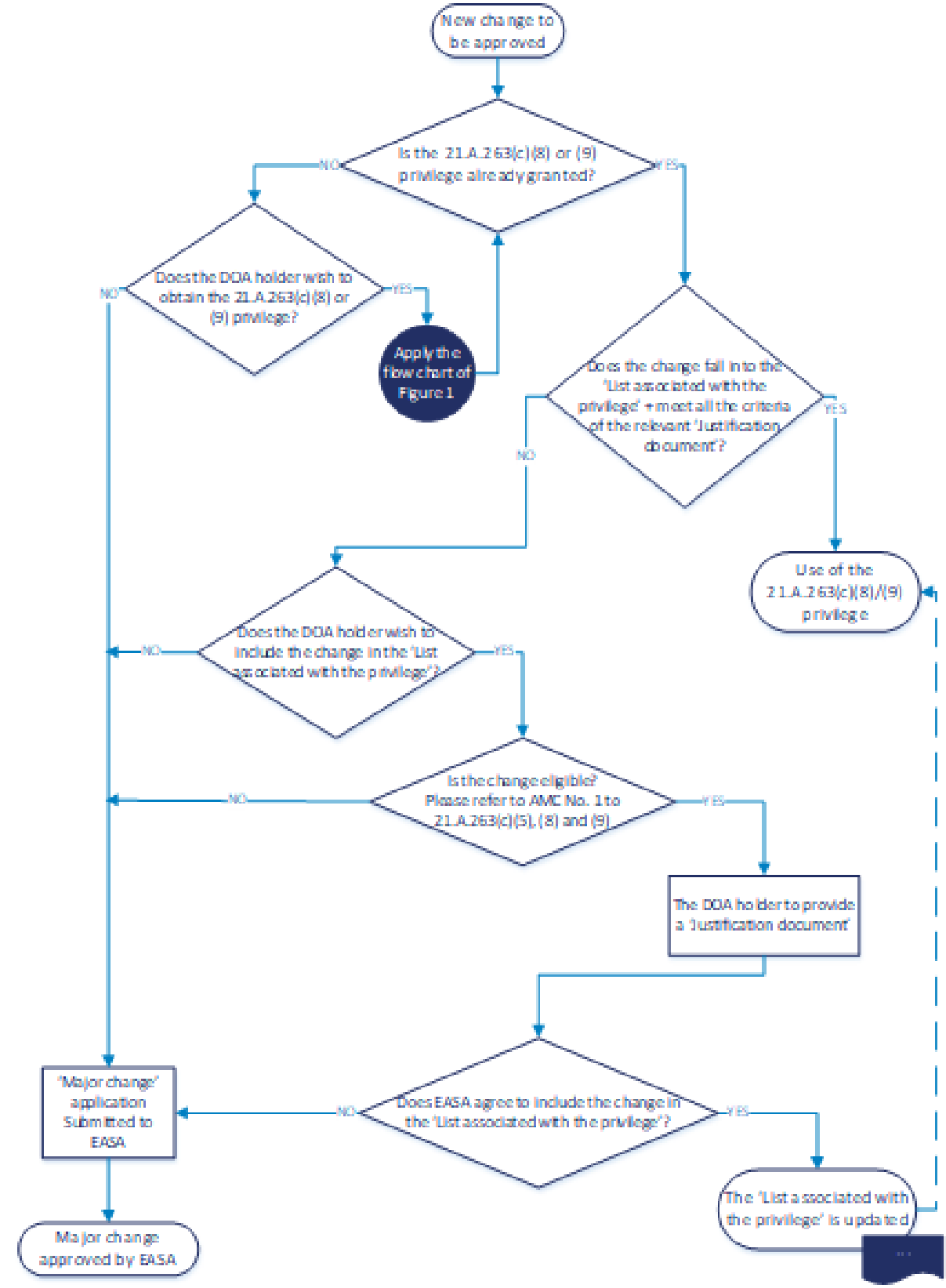

New change to be approved
Is the 21.A.263(c)(8) or (9) privilege already granted?
NO
YES
Does the DOA holder wish to obtain the 21.A.263(c)(8) or (9) privilege?
NO
YES
Apply the flowchart of Figure 1
Does the change fall into the 'List associated with the privilege' + meet all the criteria of the relevant 'Justification document'?
NO
YES
Use of the 21.A.263(c)(8),/(9) privilege
Does the DOA holder wish to include the change in the 'List associated with the privilege'?
NO
YES
Is the change eligible? Please refer to AMC No. 1 to 21.A.263(c)(5), (8) and (9)
NO
YES
The DOA holder to provide a 'Justification document'
'Major change' application Submitted to EASA
Does EASA agree to include the change in the 'List associated with the privilege'?
NO
YES
Major change approved by EASA
The 'List associated with the privilege' is updated

Figure 3

3. TC, STC OR APU ETSOA HOLDER APPROVAL OF A MAJOR REPAIR UNDER A MAJOR REPAIR PRIVILEGE — SPECIFIC CONSIDERATIONS

TC, STC or APU ETSOA DOA holders that intend to approve a major repair design under the privilege of point 21.A.263(c)(5) should ensure that:

(a) the type-certification basis for the product, part or appliance to be repaired is identified, together with all the other relevant requirements;

(b) all the records and substantiation data, including the documents that demonstrate compliance with all the relevant requirements, are provided to EASA for review; and

(c) for repair designs created for a specific product serial number, an assessment is made as to whether or not the repair design is affected by the presence of any embodied STC, change or repair.

4. DOA HOLDER'S APPROVAL BASED ON THE PRIVILEGE FOR A MAJOR REPAIR, MAJOR CHANGE OR STC — SPECIFIC CONSIDERATIONS

For the approval of:

— major repairs by DOA holders that are not the TC, STC or APU ETSO authorisation holders;

— major changes; and

— STCs

by a DOA holder under the privilege of point 21.A.263(c)(5), (8) and (9), the following should be considered.

4.1 Eligibility of the proposed major repair, major change or STC

The DOA holder should assess the proposed major repair, major change or STC against the 'list associated with the privilege' and the 'justification document' of 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates' in order to determine whether the criteria of AMC No 1 to 21.A.263(c)(5), (8) and (9), Section 2.2, are met.

4.2 Forms for approval certificates

The DOA holder should use the following forms for the issuance of an approval under their privilege:

— EASA Form 991[1] for an STC;

— EASA Form 993[1] for a major change; and

— EASA Form 994[1] for a major repair.

If the DOA holder chooses to use their own forms, it must be ensured that at least the same information as requested on the EASA forms is presented.

For the numbering of major changes to TCs, STCs, as well as of major repairs approved under the privilege of point 21.A.263(c)(5), (8) or (9), please refer to GM 21.A.263(c)(5), (8) and (9).

[1] https://www.easa.europa.eu/easa-and-you/aircraft-products/design-organisations#group-easa-downloads

4.3 Approval under the DOA holder's privilege

When the DOA holder makes use of the privilege of point 21.A.263(c)(5), (8) or (9), they should include the following in the certification data package:

— a record of the assessment as described in 4.1 above;

— the reference to the 'justification document';

— the applicable product configuration;

— the applicable CSs or environmental protection requirements and methods of compliance;

— the compliance documents;

— the effects, if any, on limitations and on the approved documentation;

— the evidence of the independent checking of the compliance demonstration;

— the approval document containing the statement of the approval under the privilege of point 21.A.263(c)(5), (8) and (9) by an authorised signatory; and

— the date of approval.

In any case, before the major change, STC or major repair is approved under the DOA privilege, the DOA holder should ensure that the Part 21 requirements, in particular points 21.A.97, 21.A.115 and 21.A.433, are met.

4.4 Authorised signatories

An authorised person that is identified and authorised as described in Section 1(b)(4) above should sign the approval under the privilege of point 21.A.263(c)(5), (8) and (9).

4.5 Summary list

The DOA holder should add to the 'summary list' as described in Section 1(b)(4) above the major change, STC or major repair approved under the privilege of point 21.A.263(c)(5), (8) and (9).

GM 21.A.263(c)(5), (8) and (9) Numbering system for supplemental type certificates (STCs), major changes and major repairs issued by design organisation approval (DOA) holders, and information to EASA

ED Decision 2019/018/R

STCs, major changes and major repairs issued by a DOA holder under their privilege of point 21.A.263(c)(5), (8) and (9) should each be given a unique and consecutive reference number.

The following numbering system may be considered:

DOA holder reference	Type of certificate	Year of approval	Dash	Sequential number	Issue reference
21Jxxx	STC or MCH or MRE	17	—	001	A

Example: 21J999STC17—001A

Note: 'MCH' refers to 'major changes', 'MRE' to 'major repairs'.

With reference to STCs only, after the STC approval, the DOA holder should send a copy of the STC to EASA in a timely manner (as agreed with EASA).

21.A.265 Obligations of the holder

Regulation (EU) 2022/1358

The holder of a design organisation approval shall, within the scope of its terms of approval, as established by the Agency:

(a) maintain the handbook required under point 21.A.243 in conformity with the design assurance system;

(b) ensure that this handbook or the relevant procedures included by cross-reference are used as a basic working document within the organisation;

(c) determine that the design of the products, or of the changes or repairs to them, complies with the applicable type-certification basis, technical specifications concerning the making of declarations, operational suitability data certification basis, and the environmental protection requirements and have no unsafe features;

(d) provide the Agency with statements and associated documentation confirming compliance with point (c), except for approval processes carried out in accordance with point 21.A.263(c);

(e) provide to the Agency data and information related to the actions required under point 21.A.3B;

(f) determine, in accordance with point 21.A.263(c)(6), the flight conditions under which a permit to fly can be issued;

(g) establish, in accordance with point 21.A.263(c)(7), compliance with points (b) and (e) of point 21.A.711 before issuing a permit to fly to an aircraft;

(h) designate data and information issued under the authority of the approved design organisation within the scope of its terms of approval as established by the Agency with the following statement: "The technical content of this document is approved under the authority of the DOA ref. EASA. 21J.[XXXX]";

(i) comply with Subpart A of this Section.

AMC1 21.A.265(a) Obligations of the holder

ED Decision 2021/001/R

ADMINISTRATION OF THE HANDBOOK

1. The handbook of the applicant must be in the language which will permit the best use of it by all personnel charged with the tasks performed for the purpose of the design organisation. The applicant may be requested to provide an English translation of the handbook and other supporting documents as necessary for the investigation.

2. The handbook must be produced in a concise form with sufficient information to meet 21.A.243 relevant to the scope of approval sought by the applicant. The handbook must include the following:

a. Organisation name, address, telephone, telex and facsimile numbers.

b. Document title, and company document reference No (if any).

c. Amendment or revision standard identification for the document.

d. Amendment or revision record sheet.

e. List of effective pages with revision/date/amendment identification for each page.

f. Contents list or index.

g. A distribution list for the Handbook.

h. An introduction, or foreword, explaining the purpose of the document for the guidance of the organisation's own personnel. Brief general information concerning the history and development of the organisation and, if appropriate, relationships with other organisations which may form part of a group or consortium, must be included to provide background information for the Agency.

i. The certificate of approval must be reproduced in the document.

j. Identification of the department responsible for administration of the Handbook.

Note: In the case of an initial or revised approval it is recognised that certificate will be issued after EASA agreement to the handbook content in draft form. Arrangements for formal publication in a timely manner must be agreed before the certificate of approval is issued.

3. An updating system must be clearly laid down for carrying out required amendments and modifications to the handbook.

4. The handbook may be completely or partially integrated into the company organisation manual. In this case, identification of the information required by 21.A.243 must be provided by giving appropriate cross-references, and these documents must be made available, on request, to the Agency.

AMC2 21.A.265(a) Obligations of the holder

ED Decision 2021/001/R

HANDBOOK FORMAT AND PUBLICATION MEANS

The term 'handbook' is meant to describe a means to document the design organisation's processes and procedures. This may be in an electronic or paper format, as a stand-alone document or integrated in a management system. It may consist of:

— an online integrated management system with flowcharts and descriptions embedded in it;

— an online system referring to single documents;

— a classic handbook with references to online procedures;

— or any other combination of the above.

In any case, as required by point (c) of point 21.A.243, independently of the system chosen by the design organisation, the relevant content and the means to update the system should be clearly identified.

GM1 21.A.265(b) Obligations of the holder

ED Decision 2023/014/R

USE OF THE HANDBOOK

1. The handbook should be signed by the senior company manager and the head of the design organisation and declared as a binding instruction for all personnel charged with the development and type investigation of products. This binding statement should be provided independently of the means chosen by the design organisation to document its processes and procedures.

2. All procedures referenced in the handbook are considered as parts of the handbook and therefore as basic working documents.

GM 21.A.265(h) Designation of data and information issued under the authority of a design organisation approval (DOA) holder

ED Decision 2021/007/R

1. INTENT

This GM provides guidance for complying with the obligation of 21.A.265(h), and addresses the various aspects that the DOA holder should cover in order to have a comprehensive procedure for the designation of data and information.

2. SCOPE

The term 'data and information' as used in point 21.A.265(h) also includes instructions.

Data and information referred to in point 21.A.265(h) are issued by a DOA holder and cover the following:

— embodiment instructions for design changes or repairs (usually in the form of a service bulletin, a modification bulletin, repair instructions or engineering order, etc.);

— manuals required by Part 21 or the applicable CSs (such as the aircraft flight manual (AFM), rotorcraft flight manual, instructions for continuing airworthiness (ICAs), etc.);

— operation suitability data (OSD);

— continued-airworthiness instructions (usually in the form of service bulletins) which may be covered by airworthiness directives (ADs);

— additional data to be defined by the DOA holder (e.g. alternative maintenance instructions that are not, per se, ICAs).

Note: This data and information may be issued in a digital or paper format.

The obligation does not apply to, and the statement provided with the data and information should not be used on, the following documents:

— certification documents (e.g. the certification programme, compliance checklist, etc.);

— compliance documents;

— design data transferred to production organisations; and

— production deviations (also referred to as 'unintended deviations' or 'concessions').

3. RATIONALE

The purpose of this obligation is to give certainty to the end users about the approval status of the data and information issued by the DOA holder.

4. PROCEDURE

For the information and instructions issued under point 21.A.265(h), the DOA holder should establish a procedure that addresses the following aspects:

— their preparation;

— verification of their technical consistency with the corresponding approved change(s), repair(s) or approved data, including their effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;

— verification of their feasibility in practical applications, when relevant and feasible;

— the authorised signatories.

The procedure should include the information or the instructions prepared by suppliers, and declared applicable to its products by the DOA holder.

5. STATEMENT

The statement provided with the data and information should also cover those items prepared by subcontractors or vendors that the DOA holder has declared as applicable to their products. The technical content of the statement is related to the type certificate data and information.

The approval included in the statement means that:

— the type certificate data has been appropriately approved; and

— the information contains practical and well-defined installation or inspection methods, and, when those methods are implemented, the product is in conformity with the approved type certificate data.

Note: Data and information related to the measures required by point 21.A.3B(b) (airworthiness directives (ADs)) are submitted to EASA to ensure their compatibility with the content of an AD (see point 21.A.265(e)), and contain a statement that they are, or will be, subject to an AD issued by EASA.

SUBPART K — PARTS AND APPLIANCES

21.A.301 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure relating to the approval of parts and appliances.

21.A.303 Compliance with applicable requirements

Regulation (EU) No 748/2012

The showing of compliance of parts and appliances to be installed in a type-certificated product shall be made:

(a) in conjunction with the type-certification procedures of Subpart B, D or E for the product in which it is to be installed; or

(b) where applicable, under the ETSO authorisation procedures of Subpart O; or

(c) in the case of standard parts, in accordance with officially recognised Standards.

AMC 21.A.303(c) Standard Parts

ED Decision 2012/020/R

1. In this context a part is considered as a 'standard part' where it is designated as such by the design approval holder responsible for the product, part or appliance, in which the part is intended to be used. In order to be considered a 'standard part', all design, manufacturing, inspection data and marking requirements necessary to demonstrate conformity of that part should be in the public domain and published or established as part of officially recognised Standards, or

2. For sailplanes and powered sailplanes, where it is a non-required instrument and/or equipment certified under the provision of CS 22.1301(b), if that instrument or equipment, when installed, functioning, functioning improperly or not functioning at all, does not in itself, or by its effect upon the sailplane and its operation, constitute a safety hazard.

'Required' in the term 'non-required' as used above means required by the applicable certification specifications (CS 22.1303, 22.1305 and 22.1307) or required by the relevant operating regulations and the applicable Rules of the Air or as required by Air Traffic Management (e.g. a transponder in certain controlled airspace).

Examples of equipment which can be considered standard parts are electrical variometers, bank/slip indicators ball type, total energy probes, capacity bottles (for variometers), final glide calculators, navigation computers, data logger / barograph / turnpoint camera, bug-wipers and anti-collision systems.

Equipment which must be approved in accordance to the certification specifications shall comply with the applicable ETSO or equivalent and is not considered a standard part (e.g. oxygen equipment).

GM No 2 to 21.A.303(c) Officially recognised Standards

ED Decision 2012/020/R

In this context 'officially recognised Standards' means:

1. Those standards established or published by an official body whether having legal personality or not, which are widely recognised by the air transport sector as constituting good practice.
2. The standard used by the manufacturer of the equipment as mentioned in paragraph 2 of AMC 21.A.303(c).

21.A.305 Approval of parts and appliances

Regulation (EU) No 748/2012

In all cases where the approval of a part or appliance is explicitly required by Union law or Agency measures, the part or appliance shall comply with the applicable ETSO or with the specifications recognised as equivalent by the Agency in the particular case.

21.A.307 The eligibility of parts and appliances for installation

Regulation (EU) 2022/1358

(a) A part or appliance is eligible for installation in a type-certified product when it is in a condition for safe operation, marked in accordance with Subpart Q and accompanied by an authorised release certificate (EASA Form 1), certifying that the item was manufactured in conformity with approved design data.

(b) By way of derogation from point (a) and provided that the conditions in point (c) are met, the following parts or appliances do not require an EASA Form 1 in order to be eligible for installation in a type-certified product:

(1) a standard part;

(2) in the case of ELA1 or ELA2, a part or appliance that is:

(i) not life limited, nor part of the primary structure, nor part of the flight controls;

(ii) identified for installation in the specific aircraft;

(iii) to be installed in an aircraft whose owner has verified compliance with the applicable conditions in (i) and (ii), and has accepted responsibility for this compliance;

(3) a part or appliance for which the consequences of a non-conformity with its approved design data has a negligible safety effect on the product and which is identified as such by the holder of the design approval in the instructions for continued airworthiness. In order to determine the safety effects of a non-conforming part or appliance, the design approval holder may establish in the instructions for continued airworthiness specific verification activities to be conducted by the installer of the part or appliance on the product;

(4) in the case of the embodiment of a standard change in accordance with point 21.A.90B or a standard repair in accordance with point 21.A.431B, a part or appliance, for which the consequences of a non-conformity with its design data have a negligible safety effect on the product, and which is identified as such in the certification specifications for standard changes and standard repairs issued in accordance with point (a)(2) of point 21.A.90B and point (a)(2) of point 21.A.431B. In order to determine the safety

effects of a non-conforming part or appliance, specific verification activities to be conducted by the person that installs the part or appliance on the product may be established in the certification specifications referred to above;

(5) a part or appliance that is exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012 ([1]); and

(6) a part or appliance that is an item of a higher assembly identified in points (b)(1) to (b)(5).

(7) a part or appliance manufactured by a person or organisation referred to in Article 9(4) of this Regulation;

(c) Parts and appliances listed in point (b) are eligible for installation in a type-certified product without being accompanied by an EASA Form 1, provided that the installer holds a document issued by the person or organisation that manufactured the part or appliance, which declares the name of the part or appliance, the part number, and the conformity of the part or appliance with its design data, and which contains the issuance date.

AMC1 21.A.307(b)(3) and (b)(4) Verification activities to be conducted on the part or appliance or release documentation prior to installation

ED Decision 2021/007/R

To prevent a non-negligible safety effect on the product, due to the installation of a part or appliance referred to in point 21.A.307(b)(3) and (b)(4) that could potentially not conform to its design, the design approval holder (DAH) or EASA may identify in the ICA (in the case of 21.A.307(b)(3)) or in CS-STAN (in the case of 21.A.307(b)(4)) any specific verification activities to be conducted by the installer on the part or appliance before installing it on the product in accordance with Regulation (EU) No 1321/2014.

When assessing the safety effect of a part or appliance identified in point 21.A.307(b)(3) and (b)(4), the DAH or EASA should assume that the installer would conduct, in accordance with Regulation (EU) No 1321/2014, any specific verification activities on the part or appliance or release documentation, as identified in the ICA or in CS-STAN.

Example: Information from the DAH contained in the ICA: 'Part XXX-YY must comply with flammability requirement JJJ-KKK'.

GM1 21.A.307(b)(3) and (b)(4) Meaning of 'negligible safety effect'

ED Decision 2021/007/R

For the purpose of 21.A.307(b)(3) and (b)(4), when 'a part or appliance for which the consequences of non-conformity to its design has a negligible safety effect when installed on the product' is mentioned, it means that any non-conformity of the part or appliance not identified by the installer that conducted the specific verification activities mentioned in 21.A.307(c):

(a) for ELA1 and ELA2 aircraft, at worst:

(1) slightly reduces the operational or functional certified capabilities of the aircraft or its safety margins;

[1] Commission Regulation (EU) No 379/2014 of 7 April 2014 amending Commission Regulation (EU) No 965/2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 123, 24.4.2014, p. 1).

(2) causes some physical discomfort to its occupants; and

(3) slightly increases the workload of the flight crew; and

(b) for any other aircraft:

(1) has no effect on the operational or functional certified capabilities of the aircraft, or on its safety margins;

(2) causes no physical discomfort to the occupants; and

(3) has no effect on the flight crew.

GM1 21.A.307(b)(4) Certification specifications referred to in point 21.A.307(b)(4)

ED Decision 2021/007/R

The corresponding certification specifications issued by EASA and mentioned in point 21.A.307(b)(4) are the Certification Specifications for Standard Changes and Standard Repairs (CS-STAN).

GM1 21.A.307(b)(5) Equipment exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012

ED Decision 2021/007/R

The equipment exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012 that can be installed during maintenance as new equipment on an aircraft under point 21.A.307(b)(5) is the equipment identified in the following points:

— CAT.IDE.A.100(a),

— CAT.IDE.H.100(a),

— NCC.IDE.A.100(b) and (c),

— NCC.IDE.H.100(b) and (c),

— NCO.IDE.A.100(b) and (c),

— NCO.IDE.H.100(b) and (c),

— NCO.IDE.S.100(b) and (c),

— NCO.IDE.B.100(b) and (c),

— SPO.IDE.A.100(b) and (c),

— SPO.IDE.H.100(b) and (c),

— SPO.IDE.S.100(b) and (c), and

— SPO.IDE.B.100(b) and (c)

of Commission Regulation (EU) No 965/2012.

GM1 21.A.307(b)(6) Part or appliance that is part of a higher-level assembly

ED Decision 2021/007/R

An EASA Form 1 is not required for a part or appliance when that part or appliance is an element of a higher-level assembly for which an EASA Form 1 is not required.

(SUBPART L — NOT APPLICABLE)

SUBPART M — REPAIRS

21.A.431A Scope

Regulation (EU) 2019/897

(a) This Subpart establishes the procedure for the approval of a repair design of a product, part or appliance and establishes the rights and obligations of the applicants for, and holders of, those approvals.

(b) This Subpart defines standard repairs that are not subject to an approval process under this Subpart.

(c) A “repair” means the elimination of damage and/or restoration to an airworthy condition following the initial release to service by the manufacturer of any product, part or appliance.

(d) The elimination of damage by replacement of parts or appliances without the necessity for design activity shall be considered as a maintenance task and shall therefore require no approval under this Annex.

(e) A repair to an ETSO article other than an Auxiliary Power Unit (APU) shall be treated as a change to the ETSO design and shall be processed in accordance with point 21.A.611.

(f) In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

GM 21.A.431A Scope

ED Decision 2019/018/R

Manuals and other instructions for continued airworthiness (such as the Manufacturers Structural Repair Manual, Maintenance Manuals and Engine Manuals provided by the holder of the type-certificate, supplemental type-certificate, or APU ETSO authorisation as applicable) for operators, contain useful information for the development and approval of repairs.

When these data are explicitly identified as approved, they may be used by operators without further approval to cope with anticipated in-service problems arising from normal usage provided that they are used strictly for the purpose for which they have been developed.

Approved data is data which is approved either by the Agency, or by an appropriately approved design organisation.

When specific repair data is approved outside of the Community, conditions for acceptance may be defined in the bilateral arrangements between the Community and the competent authority of a third country. In the absence of such arrangement, the repair data shall follow the approval route as if it was designed and approved within the Community.

GM 21.A.431A(e) Repairs to European technical standard order (ETSO) articles other than auxiliary power units (APUs)

ED Decision 2012/020/R

A repair to an ETSO article other than an APU can be either be seen:

1. Under 21.A.611 in the context of an ETSO authorisation, i.e., when an article as such is specifically approved under Subpart O, with dedicated rules that give specific rights and obligations to the designer of the article, irrespective of any product type design or change to the type design. For a repair to such an article, irrespective of installation on any aircraft, Subpart O, and 21.A.611 in particular, should be followed; or
2. When an airline or a maintenance organisation is designing a new repair (based on data not published in the TC holder or Original Equipment Manufacturer documentation) on an article installed on an aircraft, such a repair can be considered as a repair to the product in which the article is installed, not to the article taken in isolation. Therefore Subpart M can be used for the approval of this repair, that will be identified as 'repair to product x affecting article y', but not 'repair to article y'.

21.A.431B Standard repairs

Regulation (EU) 2021/699

(a) Standard repairs are repairs:

(1) in relation to:

(i) aeroplanes of 5 700 kg Maximum Take-Off Mass (MTOM) or less;

(ii) rotorcraft of 3 175 kg MTOM or less;

(iii) sailplanes and powered sailplanes, balloons and airships as defined in ELA1 or ELA2.

(2) that follow design data included in certification specifications issued by the Agency, containing acceptable methods, techniques and practices for carrying out and identifying standard repairs, including the associated instructions for continued airworthiness; and

(3) that are not in conflict with TC holders data.

(b) Points 21.A.432A to 21.A.451 are not applicable to standard repairs.

GM 21.A.431B Standard repairs – Certification Specifications

ED Decision 2015/016/R

CS-STAN contains the certification specifications referred to in 21.A.431B(a)(2). Guidance on the implementation of Standard Changes and Standard Repairs can be found in AMC M.A.801 of the AMC to Part-M.

21.A.432A Eligibility

Regulation (EU) No 748/2012

(a) Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability under point 21.A.432B shall be eligible as an applicant for a major repair design approval under the conditions laid down in this Subpart.

(b) Any natural or legal person shall be eligible to apply for approval of a minor repair design.

21.A.432B Demonstration of capability

Regulation (EU) 2019/897

(a) An applicant for approval of a major repair design shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Subpart.

(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.432C(b).

GM 21.A.432B(b) Alternative procedures

ED Decision 2019/018/R

See AMC 21.A.14(b) for the details of the alternative procedures.

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

   a. Scope: The FTOM covers flight test operations.

      The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

   b. Format

      The FTOM may:

      — be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

      — be a separate manual.

      The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

   c. Use by contractors or sub-contractors:

      When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part 21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

   a. Exposition (not applicable in the case of APDOA):

      If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

  — for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

  — for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

  — for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

21.A.432C Application for a repair design approval

Regulation (EU) 2021/699

(a) An application for a repair design approval shall be made in a form and manner established by the Agency.

(b) An application for a major repair design approval shall include, or be supplemented after the initial application by, a certification programme containing:

1. a description of the damage and repair design identifying the configuration of the type design upon which the repair is made;

2. an identification of all areas of the type design and the approved manuals that are changed or affected by the repair design;

3. an identification of any reinvestigations necessary to demonstrate compliance of the repair design and areas affected by the repair design with the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;

4. any proposed amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;

5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including the means and process proposed to be followed to demonstrate compliance with point 21.A.433(a)(1) and references to related compliance documents;

6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis and the potential impact of that non-compliance on product safety. The proposed assessment shall take into account at least the elements set out in subpoints (1)-(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and

7. the specification whether the certification data is prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.

AMC 21.A.432C(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application forms for the approval of major changes/major repair designs (FO.CERT.00031)[2] or for the approval of minor changes/minor repair designs (FO.CERT.00032)[3], which may be downloaded from the EASA website.

The forms should be completed in accordance with the instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[4].

[1] https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

[2] https://www.easa.europa.eu/document-library/application-forms/focert00031 (changes to the link provided may not be reflected in this document).

[3] https://www.easa.europa.eu/document-library/application-forms/focert00032 (changes to the link provided may not be reflected in this document).

[4] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

AMC 21.A.432C(b) Certification programme for a repair design approval

ED Decision 2019/018/R

Clarification of 21.A.432C(b)(1): the description of the repair should consist of:

— the pre- and post-repair configuration;

— a drawing or outline of the repair;

— a list of the detailed features;

— a description of the type and extent of the inspection; and

— an outline of the damage.

Clarification of 21.A.432C(b)(3): the identification of reinvestigations does not refer to the demonstration of compliance itself, but to the list of the affected certification specifications (CSs), together with the means of compliance.

21.A.433 Requirements for approval of a repair design

Regulation (EU) 2021/699

(a) A repair design shall only be approved:

1. when it has been demonstrated, following the certification programme referred to in point 21.A.432C(b), that the repair design complies with the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation, as well as with any amendments established and notified by the Agency in accordance with point 21.B.450;

2. when compliance with the type-certification basis that applies in accordance with point (a)(1) has been declared and the justifications of compliance have been recorded in the compliance documents;

3. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested;

4. where the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.432C(b)(7):

   (i) when the holder has indicated that it has no technical objection to the information submitted under point (a)(2); and

   (ii) when the holder has agreed to collaborate with the repair design approval holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with point 21.A.451.

5. when, for a repair to an aeroplane subject to point 26.302 of Annex I to Regulation (EU) 2015/640, it has been demonstrated that the structural integrity of the repair and affected structure is at least equivalent to the level of structural integrity established for the baseline structure by point 26.302 of Annex I to Regulation (EU) 2015/640.

(b) The applicant shall submit to the Agency the declaration referred to in point (a)(2) and, on request by the Agency, all necessary substantiation data.

AMC1 21.A.433(a)(5) Requirements for the approval of repairs to large aeroplanes subject to point 26.302 of Part-26

ED Decision 2021/007/R

For repairs that affect fatigue-critical structures of turbine-powered large aeroplanes certified to carry 30 passengers or more, or with a payload capacity of 3 402 kg (7 500 lbs) or more, damage-tolerance evaluations demonstrate compliance with point 21.A.433(a)(5) when the certification basis used for the repair is:

(a) Amdt 19 to CS 25.571, or subsequent amendments; or

(b) the certification basis of the aeroplane, unless it precedes JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, in which case the certification basis for the repair should be:

(1) JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, or later amendments; or

(2) the specifications used for compliance with the applicable points of Part-s26 for the fatigue-critical structures affected by the repair.

AMC1 21.A.433(b) Requirements for approval of a repair design

ED Decision 2023/014/R

RECORD KEEPING

(a) Relevant substantiation data associated with a new major repair design and record keeping should include:

(1) the identification of the damage and the reporting source;

(2) the major repair design approval sheet identifying the applicable specifications and references of justifications;

(3) the repair drawing and/or instructions and scheme identifier;

(4) the correspondence with the holder of the type certificate (TC), supplemental type certificate (STC), or auxiliary power unit European technical standard order (APU ETSO) authorisation, if its advice on the design has been sought;

(5) the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to this data;

(6) the effect on the aircraft, engines and/or systems (performance, flight handling, etc., as appropriate);

(7) the effect on the maintenance programme;

(8) the effect on airworthiness limitations, the flight manual and the operating manual;

(9) any weight and moment changes; and

(10) special test requirements.

(b) Relevant minor repair documentation includes paragraphs (a)(1) and (a)(3). Other points of paragraph (a) may be included where necessary. If the repair is outside the approved data, a justification for the classification is required.

(c) Special consideration should be given to repairs that impose subsequent limitations on the part, product or appliance (e.g. engine turbine segments that may only be repaired a finite number of times, the number of repaired turbine blades per set, oversizing of fastener holes, etc.).

(d) Special consideration should also be given to life-limited parts and critical parts, notably with the involvement of the TC or STC holder, when deemed necessary under 21.A.433(a)(4).

(e) Repairs to engine or APU critical parts would normally only be accepted with the involvement of the TC holder.

21.A.435 Classification and approval of repair designs

Regulation (EU) 2019/897

(a) A repair design shall be classified as either “major” or “minor” in accordance with the criteria set out in point 21.A.91 for a change to the type-certificate.

(b) A repair design shall be classified and approved by:

1. the Agency; or

2. an approved design organisation within the scope of its privileges provided for in points (1), (2) and (5) of point 21.A.263(c), as recorded in the terms of approval.

GM 21.A.435(a) Classification of repairs

ED Decision 2012/020/R

1. Clarification of the terms Major/Minor

In line with the definitions given in 21.A.91, a new repair is classified as 'major' if the result on the approved type design has an appreciable effect on structural performance, weight, balance, systems, operational characteristics or other characteristics affecting the airworthiness of the product, part or appliance. In particular, a repair is classified as major if it needs extensive static, fatigue and damage tolerance strength justification and/or testing in its own right, or if it needs methods, techniques or practices that are unusual (i.e., unusual material selection, heat treatment, material processes, jigging diagrams, etc.)

Repairs that require a re-assessment and re-evaluation of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements, are to be considered as major repairs.

Repairs whose effects are considered minor and require minimal or no assessment of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements, are to be considered ‘minor’.

It is understood that not all the certification substantiation data will be available to those persons/organisations classifying repairs. A qualitative judgement of the effects of the repair will therefore be acceptable for the initial classification. The subsequent review of the design of the repair may lead to it being re-classified, owing to early judgements being no longer valid.

2. Airworthiness concerns for Major/Minor classification

The following should be considered for the significance of their effect when classifying repairs. Should the effect be considered to be significant then the repair should be classified 'Major'. The repair may be classified as 'Minor' where the effect is known to be without appreciable consequence.

i) Structural performance

Structural performance of the product includes static strength, fatigue, damage tolerance, flutter and stiffness characteristics. Repairs to any element of the structure should be assessed for their effect upon the structural performance.

ii) Weight and balance

The weight of the repair may have a greater effect upon smaller aircraft as opposed to larger aircraft. The effects to be considered are related to overall aircraft centre of gravity and aircraft load distribution. Control surfaces are particularly sensitive to the changes due to the effect upon the stiffness, mass distribution and surface profile which may have an effect upon flutter characteristics and controllability.

iii) Systems

Repairs to any elements of a system should be assessed for the effect intended on the operation of the complete system and for the effect on system redundancy. The consequence of a structural repair on an adjacent or remote system should also be considered as above, (for example: airframe repair in area of a static port).

iv) Operational characteristics

Changes may include:

— stall characteristics

— handling

— performance and drag

— vibration

v) Other characteristics

— changes to load path and load sharing

— change to noise and emissions

— fire protection / resistance

Note: Considerations for classifying repairs 'Major/Minor' should not be limited to those listed above.

3. Examples of 'Major' repairs

i) A repair that requires a permanent additional inspection to the approved maintenance programme, necessary to ensure the continued airworthiness of the product. Temporary repairs for which specific inspections are required prior to installation of a permanent repair do not necessarily need to be classified as 'Major'. Also, inspections and changes to inspection frequencies not required as part of the approval to ensure continued airworthiness do not cause classification as 'Major' of the associated repair.

ii) A repair to life limited or critical parts.

iii) A repair that introduces a change to the Aircraft Flight Manual.

GM 21.A.435(b) Repair design approval

ED Decision 2019/018/R

(a) REPAIR DESIGN APPROVAL BY EASA

(1) Products first type-certified by EASA or first type-certified by a Member State (covering those type-certified through Joint Aviation Authorities (JAA) procedures or under national regulations and those nationally certified without a type certificate (TC))

EASA approval is required in cases of major repair designs proposed by design organisation approval (DOA) holders that do not hold the necessary privilege as per point 21.A.263(c)(5) to approve certain major repair designs, as well as in cases of minor repair designs proposed by persons or organisations that do not hold a DOA.

(2) Products first type-certified by the competent authority (CA) of a third country

EASA approval is always required for major repairs on products first type-certified by the CA of a third country. Approval privileges granted to DOA holders (see point 21.A.435(b)) are not available to TC holders of products first type-certified by the CA of a third country unless this third country has since become an EASA Member State. TC holders of products first type-certified by the CA of a third country may need to be involved in a repair design when an arrangement with the TC holder has been determined to be necessary under point 21.A.433(a)(4).

For repairs approved by the CA of a third country, the conditions for acceptance may be defined in the bilateral arrangement between EASA and the third country. In the absence of such an arrangement, the repair data should follow the approval route of Part 21.

(b) REPAIR DESIGN APPROVAL BY THE DOA HOLDER

(1) Approval by the DOA holder

Approval of repairs through the use of procedures agreed with EASA implies that the DOA holder issues the approval without EASA's involvement. EASA will monitor the application of this procedure within the surveillance plan for the relevant organisation. When the organisation exercises this privilege, the repair release documentation should clearly show that the approval is issued on the basis of its privilege.

(2) Previously approved data for other applications

When it is intended to use previously approved data for other applications, it is expected that an appropriately approved design organisation has checked the applicability and effectiveness of this data. After damage identification, if a repair solution exists in the available approved data, and if the application of this solution to the identified damage remains justified by the previously approved repair design (structural justifications still valid, possible airworthiness limitations unchanged), the solution may be considered to be approved and may be used again.

(3) Temporary repairs

These are life-limited repairs to be removed and replaced by permanent repairs after a limited service period. These repairs should be classified under point 21.A.435, and the service period should be defined when the temporary repair is approved.

(4) Fatigue and damage tolerance

An approved design issued before the fatigue- and damage-tolerance evaluation has been completed should specify the limited service period.

21.A.439 Production of repair parts

Regulation (EU) No 748/2012

Parts and appliances to be used for the repair shall be manufactured in accordance with production data based upon all the necessary design data as provided by the repair design approval holder:

(a) under Subpart F; or

(b) by an organisation appropriately approved in accordance with Subpart G; or

(c) by an appropriately approved maintenance organisation.

21.A.441 Repair embodiment

Regulation (EU) 2020/570

(a) the embodiment of a repair shall be made in accordance with Annex I (Part-M), Annex II (Part-145), Annex Vb (Part-ML) or Annex Vd (Part-CAO) of Regulation (EU) No 1321/2014, or by a production organisation approved in accordance with Subpart G of this Annex, in accordance with the privilege provided for in point 21.A.163(d);

(b) The design organisation shall transmit to the organisation performing the repair all the necessary installation instructions.

21.A.443 Limitations

Regulation (EU) No 748/2012

A repair design may be approved subject to limitations, in which case the repair design approval shall include all necessary instructions and limitations. These instructions and limitations shall be transmitted by the repair design approval holder to the operator in accordance with a procedure agreed with the Agency.

21.A.445 Unrepaired damage

Regulation (EU) No 748/2012

(a) When a damaged product, part or appliance, is left unrepaired, and is not covered by previously approved data, the evaluation of the damage for its airworthiness consequences may only be made;

1. by the Agency; or
2. by an appropriately approved design organisation under a procedure agreed with the Agency.

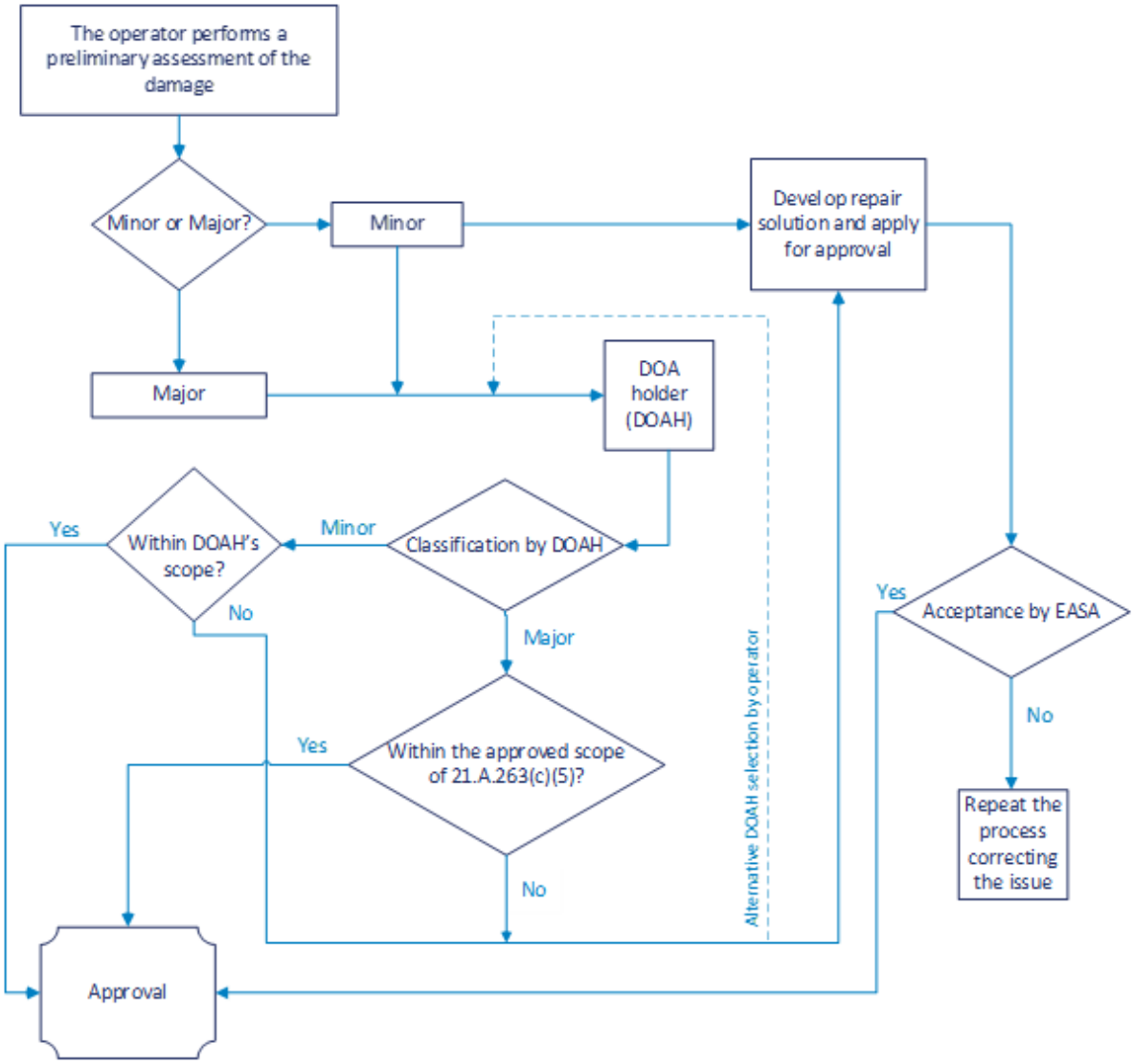
Any necessary limitations shall be processed in accordance with the procedures of point 21.A.443.

(b) Where the organisation evaluating the damage under point (a) is neither the Agency nor the type-certificate, supplemental type-certificate or APU ETSO authorisation holder, this organisation shall justify that the information on which the evaluation is based is adequate either from its organisation's own resources or through an arrangement with the type-certificate, supplemental type-certificate or APU ETSO authorisation holder, or manufacturer, as applicable.

GM 21.A.445 Unrepaired damage

ED Decision 2019/018/R

This is not intended to supersede the normal maintenance practices defined by the type-certificate holder, (e.g., blending out corrosion and re-protection, stop drilling cracks, etc.), but addresses specific cases not covered in the manufacturer's documentation.



21.A.451 Obligations and EPA marking

Regulation (EU) 2022/201

(a) Each holder of a major repair design approval shall:

1. undertake the obligations:

(i) laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9, 21.A.439, 21.A.441 and 21.A.443;

(ii) implicit in the collaboration with the type-certificate, supplemental type-certificate and with the APU ETSO authorisation holder under point 21.A.433(b), as appropriate.

2. specify the marking, including EPA letters, in accordance with point 21.A.804(a).

(b) Except for type-certificate holders or APU authorisation holders for which point 21.A.44 applies, the holder of a minor repair design approval shall:

1. undertake the obligations laid down in points 21.A.4, 21.A.5 and 21.A.7;

2. specify the marking, including EPA letters, in accordance with point 21.A.804(a).

(SUBPART N — NOT APPLICABLE)

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.A.601 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure for issuing ETSO authorisations and the rules governing the rights and obligations of applicants for, or holders of, such authorisations.

21.A.602A Eligibility

Regulation (EU) No 748/2012

Any natural or legal person that produces or is preparing to produce an ETSO article, and that has demonstrated, or is in the process of demonstrating, its capability under point 21.A.602B shall be eligible as an applicant for an ETSO authorisation.

21.A.602B Demonstration of capability

Regulation (EU) No 748/2012

Any applicant for an ETSO authorisation shall demonstrate its capability as follows:

(a) for production, by holding a production organisation approval, issued in accordance with Subpart G, or through compliance with Subpart F procedures; and

(b) for design:

1. for an Auxiliary Power Unit, by holding a design organisation approval, issued by the Agency in accordance with Subpart J;

2. for all other articles, by using procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Annex I (Part 21).

AMC 21.A.602B(b)(2) Procedures for ETSO authorisations

ED Decision 2012/020/R

1. Scope

1.1 A manual of procedures must set out specific design practices, resources and sequence of activities relevant for the specific projects, taking account of Part 21 requirements.

1.2 These procedures must be concise and limited to the information needed for quality and proper control of activities by the applicant/holder, and by the Agency.

2. Management of the ETSO authorisation process

A procedure explaining how the application to the Agency and certification process to obtain an ETSOA will be made, must be established.

3. Management of design changes

3.1 A procedure taking into account 21.A.611, must be established for the classification and approval of design changes on articles under ETSO authorisation

3.2 Procedure for the classification and approval of repairs and unintentional deviations from the approved design data occurring in production (concessions or non-conformance's) must be established.

4. Obligations addressed in 21.A.609

The applicant should establish the necessary procedures to show to the Agency how it will fulfil the obligations under 21.A.609.

For issue of information and instructions, a procedure following the principles of AMC 21.A.14(b), paragraph 4 must be established.

5. Control of design sub-contractors

The applicant must establish the necessary procedures to show to the Agency how it will control design sub-contractors.

21.A.603 Application

Regulation (EU) No 748/2012

(a) An application for an ETSO authorisation shall be made in a form and manner established by the Agency and shall include an outline of the information required by point 21.A.605.

(b) When a series of minor changes in accordance with point 21.A.611 is anticipated, the applicant shall set forth in its application the basic model number of the article and the associated part numbers with open brackets after it to denote that suffix change letters or numbers (or combinations of them) will be added from time to time.

21.A.604 ETSO authorisation for an auxiliary power unit (APU)

Regulation (EU) 2022/201

With regard to an ETSO authorisation for an APU:

(a) by way of derogation from points 21.A.9, 21.A.603, 21.A.610 and 21.A.621, the following points shall apply: points 21.A.15, 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44, 21.A.47, 21.B.75 and 21.B.80. However, an ETSO authorisation shall be issued in accordance with point 21.A.606 instead of the type-certificate;

(b) by way of derogation from point 21.A.611, the requirements of Subpart D shall apply to the approval of design changes by the APU ETSO authorisation holder and design changes from other applicants classified as a minor change, and the requirements of Subpart E shall apply to the approval of design changes by other applicants classified as a major change. Where the requirements of Subpart E apply, a separate ETSO authorisation shall be issued instead of a supplemental type certificate; and

(c) the requirements of Subpart M shall apply to the approval of repair designs.

21.A.605 Data requirements

Regulation (EU) 2019/897

(a) The applicant shall submit to the Agency the following documents:

1. a certification programme for the ETSO authorisation, setting out the means to demonstrate compliance with point 21.A.606(b);
2. a statement of compliance certifying that the applicant has met the requirements of this Subpart;
3. a declaration of design and performance (DDP), stating that the applicant has demonstrated that the article complies with the applicable ETSO in accordance with the certification programme;
4. a copy of the technical data required in the applicable ETSO;
5. the exposition, or a reference to the exposition, referred to in point 21.A.143 for the purpose of obtaining an appropriate production organisation approval under Subpart G or the manual, or a reference to the manual, referred to in point 21.A.125A(b) for the purpose of manufacturing under Subpart F without production organisation approval;
6. for an APU, the handbook, or a reference to the handbook, referred to in point 21.A.243 for the purpose of obtaining an appropriate design organisation approval under Subpart J;
7. for all other articles, the procedures, or a reference to the procedures, referred to in point 21.A.602B(b)(2);

(b) The applicant shall report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation.

AMC 21.A.605(a)(1) Certification programme

ED Decision 2019/018/R

(a) For the purpose of the compliance demonstration in accordance with point 21.A.606(b), the applicant should:

(1) establish a certification programme;

(2) submit the certification programme to EASA; and

(3) keep the certification programme updated during the authorisation process.

(b) The certification programme should contain the following information:

(1) a detailed description of the relevant European technical standard order (ETSO) article, including all of its configurations to be certified, and the identification of ETSO and non-ETSO functions, if any;

(2) the applicable CS-ETSO, in case of different minimum performance standard (MPS) available, the selected MPS, the other requirements and any optional aspects (applicable standards, applicable requirements, choice of classes (if applicable)) as well as the expected deviations;

(3) the operating characteristics and the expected limitations;

(4) the intended use of the article and the kind of operations for which the approval is requested;

(5) the proposed means of compliance, including the list of documents and deliverables for EASA;

(6) an overview of the safety assessment for the functions supported by the article, including the main failure conditions, their classification, the associated assumptions, and architectural features supporting the safety aspects;

(7) the way in which the applicant will record the justifications of compliance; and

(8) a project schedule, including major milestones.

GM 21.A.605(b) Reporting from the compliance demonstration process and updates to the certification programme

ED Decision 2019/018/R

The applicant should report to EASA any unexpected difficulty or event encountered during the compliance demonstration which invalidates or appreciably affects the assumptions previously made, e.g.:

— an increase in the severity of the consequences of a certain condition (e.g. a failure mode) of the article;

— one or more significantly reduced margins on the 'pass–fail' criteria of the compliance demonstration;

— an unusual interpretation of the results of the compliance demonstration;

— a deviation from the agreed means as defined in the certification programme;

— a change to the conditions set out in the AMC No 2 to 21.B.100(b); and

— any potential deviations discovered by the applicant.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact on the certification programme and, if necessary, they should amend the certification programme as per point 21.A.603.

21.A.606 Requirements for the issuance of an ETSO authorisation

Regulation (EU) 2019/897

In order to be issued an ETSO authorisation, the applicant shall:

(a) demonstrate its capability in accordance with point 21.A.602B;

(b) demonstrate that the article complies with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any;

(c) comply with the requirements of this Subpart; and

(d) declare that no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.

AMC 21.A.606(d) Declaration

ED Decision 2019/018/R

The related declaration should confirm that compliance with the applicable ETSO is successfully demonstrated and that all the assumptions, constraints, deviations, limitations, and open problem reports that are relevant for the approval of the installation are defined for both the ETSO and the non-ETSO functions.

Additionally, the applicant should demonstrate and declare that the non-ETSO functions do not interfere with the ETSO functions.

21.A.607 ETSO authorisation privileges

Regulation (EU) No 748/2012

The holder of an ETSO authorisation is entitled to produce and to mark the article with the appropriate ETSO marking.

21.A.608 Declaration of Design and Performance (DDP)

Regulation (EU) No 748/2012

(a) The DDP shall contain at least the following information:

1. information corresponding to point 21.A.31(a) and (b), identifying the article and its design and testing standard;
2. the rated performance of the article, where appropriate, either directly or by reference to other supplementary documents;
3. a statement of compliance certifying that the article has met the appropriate ETSO;
4. reference to relevant test reports;
5. reference to the appropriate Maintenance, Overhaul and Repair Manuals;
6. the levels of compliance, where various levels of compliance are allowed by the ETSO;
7. list of deviations accepted in accordance with point 21.A.610.

(b) The DDP shall be endorsed with the date and signature of the holder of the ETSO authorisation, or its authorised representative.

AMC 21.A.608 Declaration of Design and Performance

ED Decision 2012/020/R

STANDARD FORM

DDP No. ……

ISSUE No. …….

1. Name and address of manufacturer.
2. Description and identification of article including:

   Type No

   Modification Standard

   Master drawing record

   Weight and overall dimensions
3. Specification reference, i.e., ETSO No. and Manufacturer's design specification.
4. The rated performance of the article directly or by reference to other documents.
5. Particulars of approvals held for the equipment.
6. Reference to qualification test report.
7. Service and Instruction Manual reference number.
8. Statement of compliance with the appropriate ETSO and any deviations therefrom.
9. A statement of the level of compliance with the ETSO in respect of the ability of the article to withstand various ambient conditions or to exhibit various properties.

The following are examples of information to be given under this heading depending on the nature of the article and the specifications of the ETSO.

(a) Environmental Qualification

   i. Temperature and Altitude

   ii. Temperature Variation

   iii. Humidity

   iv. Operational Shocks and Crash Safety

   v. Vibration

   vi. Explosion Proofness

   vii. Waterproofness

   viii. Fluids Susceptibility

   ix. Sand and Dust

   x. Fungus Resistance

xi. Salt Spray

xii. Magnetic Effect

xiii. Power Input

xiv. Voltage Spike

xv. Audio Frequency Conducted Susceptibility - Power Inputs

xvi. Induced Signal Susceptibility

xvii. Radio Frequency Susceptibility (Radiated and Conducted)

xviii. Emission of Radio Frequency Energy

xix. Lightning Induced Transient Susceptibility

xx. Lightning Direct Effects

xxi. Icing

xxii. Electrostatic Discharge

xxiii. Fire, Flammability

(Note: The manufacturer should list environmental categories for each of the sections of the issue of EUROCAE ED-14/RTCA DO-160 that was used to qualify the article.)

(b) For radio transmitters the transmitting frequency band, maximum transmitting power, and emission designator.

(c) Working and ultimate pressure or loads.

(d) Time rating (e.g., continuous, intermittent) or duty cycle.

(e) Limits of accuracy of measuring instruments.

(f) Any other known limitations which may limit the application in the aircraft e.g., restrictions in mounting attitude.

10. A statement of the software level(s) used or 'None' if not applicable.

(Note: Software levels (software development assurance levels (DAL)) are those defined in the industry document referred in the latest edition of AMC 20-115)

11. A statement of design assurance level for complex hardware or a statement indicating whether complex hardware is embedded or not in the product.

(Note: Complex hardware design assurance levels are those defined in the applicable issue of EUROCAE ED–80/RTCA DO-254.)

12. The declaration in this document is made under the authority of

……..(name of manufacturer)

(Manufacturer's name) cannot accept responsibility for equipment used outside the limiting conditions stated above without their agreement.

Date: ……Signed……..(Manufacturer's authorised representative)

21.A.609 Obligations of holders of ETSO authorisations

Regulation (EU) 2022/201

The holder of an ETSO authorisation under this Subpart shall:

(a) manufacture each article in accordance with Subpart G or Subpart F that ensures that each completed article conforms to its design data and is safe for installation;

(b) prepare and maintain, for each model of each article for which an ETSO authorisation has been issued, an updated set of complete technical data and records in accordance with point 21.A.5;

(c) prepare, maintain and update master copies of all manuals required by the applicable airworthiness specifications for the article;

(d) make available to users of the article and to the Agency on request those maintenance, overhaul and repair manuals necessary for the usage and maintenance of the article, and changes to those manuals;

(e) mark each article in accordance with point 21.A.807;

(f) comply with points 21.A.3A, 21.A.3B, 21.A.4 and 21.A.9;

(g) continue to meet the qualification requirements of point 21.A.602B.

AMC1 21.A.609(c) and (d) Obligations of holders of ETSO authorisations

ED Decision 2021/007/R

In CS-ETSO, there is no specification related to ICA, neither in Subpart A, nor in each specific ETSO.

Although an ETSO article itself typically does not require ICA, the applicable airworthiness standards may require the design approval holder (DAH) or the design approval applicant (DAA) who install an ETSO article into their product to develop ICA that describe an ETSO article's installation requirements, within the context of the product, to the extent necessary to ensure the product's continued airworthiness.

In addition, if the DAH or the DAA who install an ETSO article into their product explicitly uses ETSO provisions to demonstrate compliance with an installation requirement, they should review all the maintenance and inspection instructions for the particular ETSO article when defining the ICA of the product.

It may be necessary for the DAH or the DAA to incorporate these instructions into the ICA of the product to ensure that the ETSO article continues to satisfy the terms of its ETSO authorisation after installation.

Any DAH or DAA who wishes to install an ETSO article should comply with point 21.A.303.

For this, the applicant for an ETSO authorisation may provide by the time of the application and before the authorisation is issued (in accordance with point 21.A.605) the following:

— instructions that cover periodic maintenance, calibration, and repair for the continued airworthiness of the article, including specific guidance on the limits of wear and damage that would warrant replacement;

— the recommended inspection intervals, which may be affected by storage and operating conditions (i.e. temperature, humidity, etc.).

21.A.610 Approval for deviation

Regulation (EU) No 748/2012

(a) Each manufacturer who requests approval to deviate from any performance standard of an ETSO shall demonstrate that the standards from which a deviation is requested are compensated for by factors or design features providing an equivalent level of safety.

(b) The request for approval to deviate, together with all pertinent data, shall be submitted to the Agency.

21.A.611 Design changes

Regulation (EU) No 748/2012

(a) The holder of the ETSO authorisation may make minor design changes (any change other than a major change) without further authorisation by the Agency. In this case, the changed article keeps the original model number (part number changes or amendments shall be used to identify minor changes) and the holder shall forward to the Agency any revised data that are necessary for compliance with point 21.A.603(b).

(b) Any design change by the holder of the ETSO authorisation that is extensive enough to require a substantially complete investigation to determine compliance with an ETSO is a major change. Before making such a change, the holder shall assign a new type or model designation to the article and apply for a new authorisation under point 21.A.603.

(c) No design change by any natural or legal person other than the holder of the ETSO authorisation who submitted the statement of compliance for the article is eligible for approval under this Subpart O unless the person seeking the approval applies under point 21.A.603 for a separate ETSO authorisation.

GM to 21.A.611 Design changes

ED Decision 2012/020/R

A change to an ETSO article can either be seen:

— under this 21.A.611 in the context of an ETSO authorisation, i.e., when an article as such is specifically approved under Subpart O, with dedicated rules that give specific rights and obligations to the designer of the article, irrespective of any product type design or change to the type design. For a change to such an article, irrespective of installation on any aircraft, Subpart O, and this 21.A.611 in particular, should be followed; or

— when an airline or a maintenance organisation is designing a change (based on data not published in the TC holder or Original Equipment Manufacturer documentation) on an article installed on an aircraft, such a change can be considered as a change to the product in which the article is installed, not to the article taken in isolation. Therefore Subpart D can be used for the approval of this change that will be identified as ‘change to product x affecting article y’, but not ‘change to article y’.

21.A.619 Duration and continued validity

Regulation (EU) 2022/201

(a) An ETSO authorisation shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the conditions set when the ETSO authorisation was granted continue to be observed by the applicant;
2. the obligations specified in point 21.A.609 continue to be discharged by the ETSO authorisation holder;
3. the holder of the ETSO authorisation or any of its partners, suppliers or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;
4. it has been proved that the ETSO article does not give rise to unacceptable hazards in service;
5. the ETSO authorisation has not been revoked by the Agency under point 21.B.65, or surrendered by its holder.

(b) Upon surrender or revocation, the ETSO authorisation shall be returned to the Agency.

21.A.621 Transferability

Regulation (EU) No 748/2012

Except for a change in ownership of the holder, which shall be regarded as a change of significance, and shall therefore comply with points 21.A.147 and 21.A.247 as applicable, an ETSO authorisation issued under this Annex I (Part 21) is not transferable.

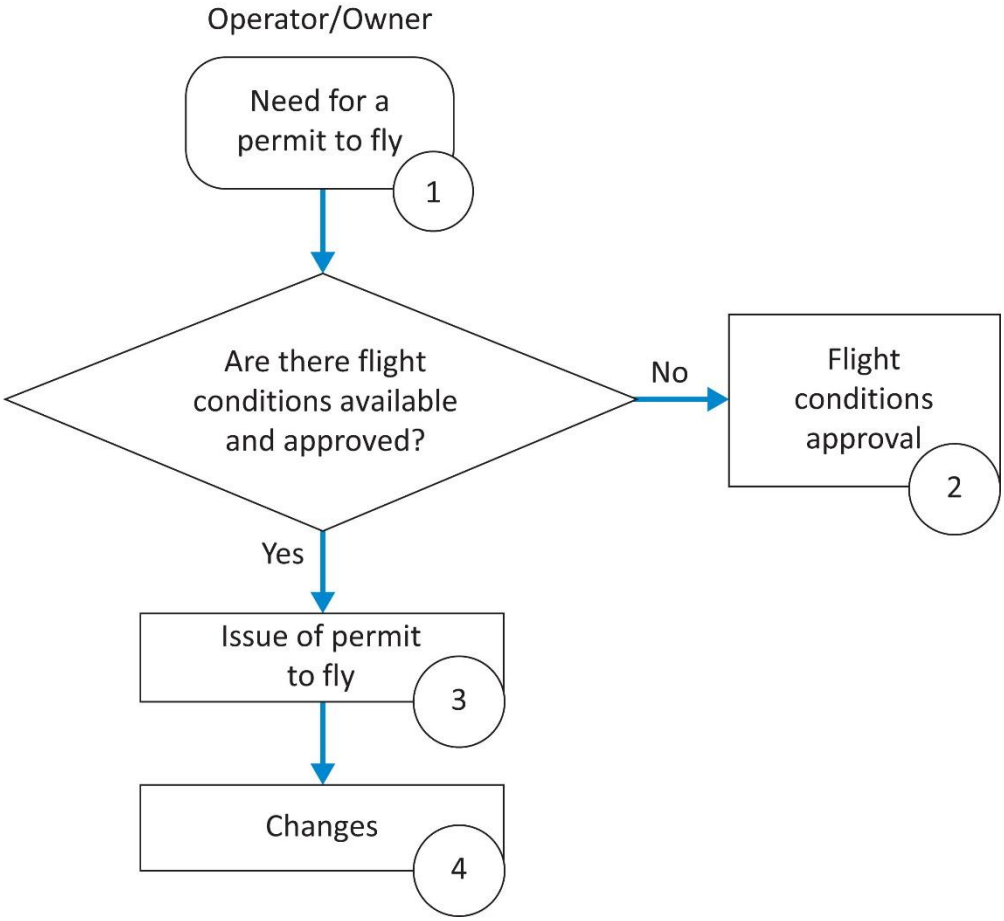
SUBPART P — PERMIT TO FLY

GM to Subpart P

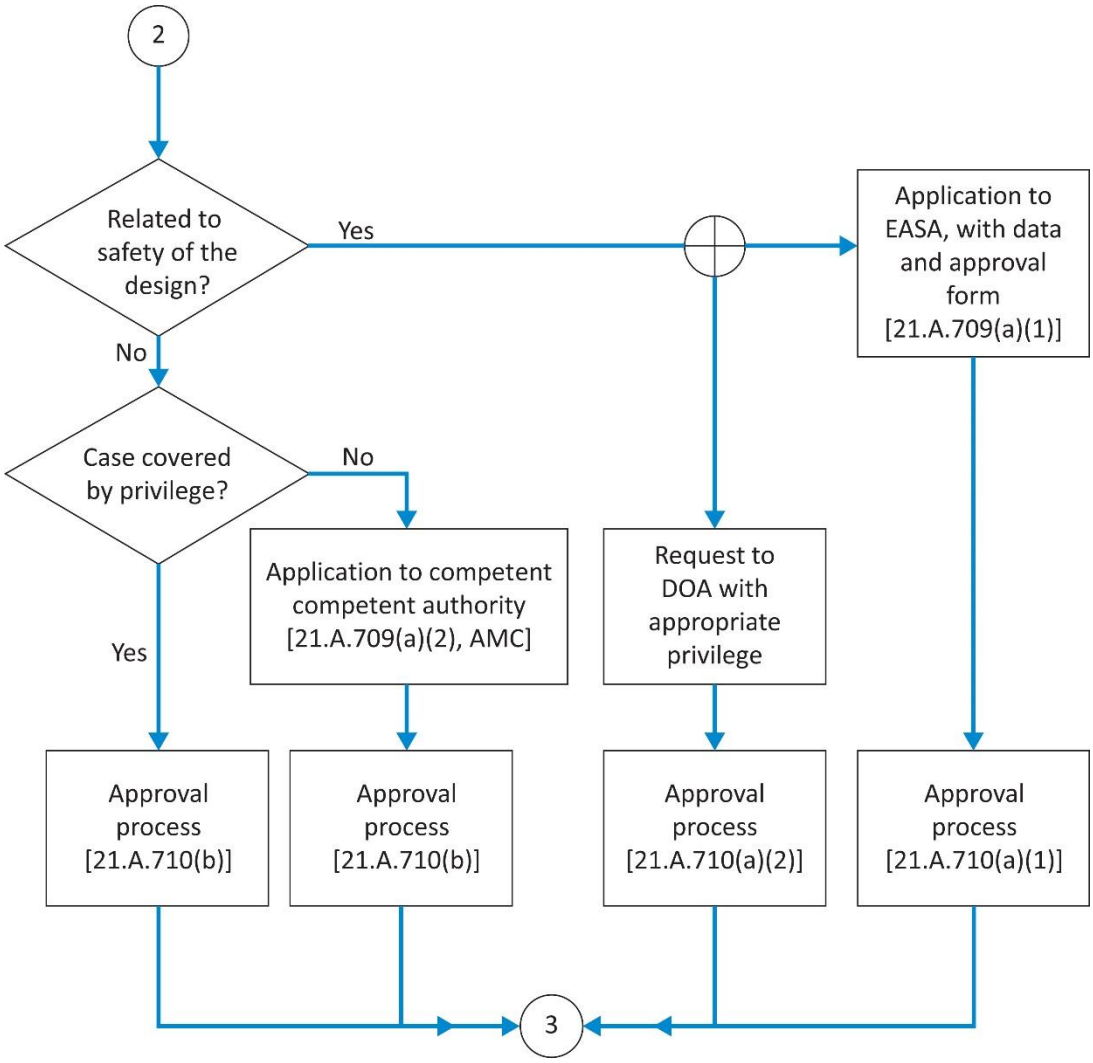
ED Decision 2012/020/R

The process allowing a flight under a permit to fly can be described as follows:

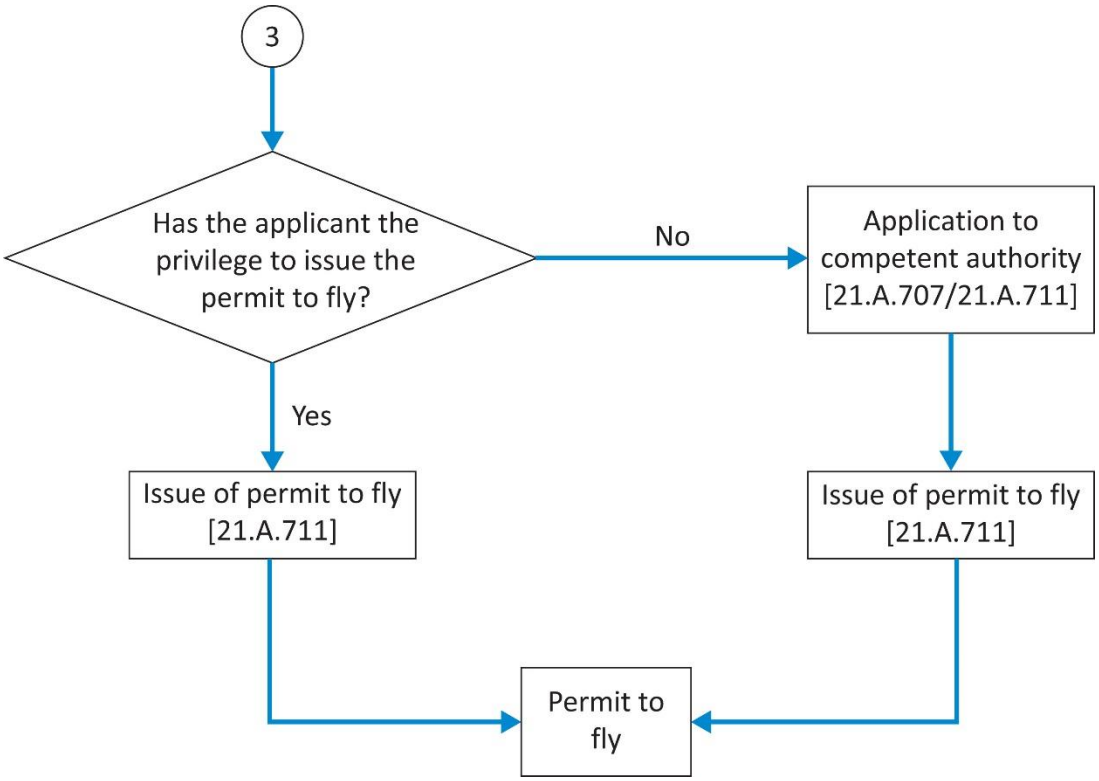
1. Flow-chart 1: overview
2. Flow-chart 2: approval of flight conditions
3. Flow-chart 3: issue of permit to fly
4. Flow-chart 4: changes after first issue of permit to fly



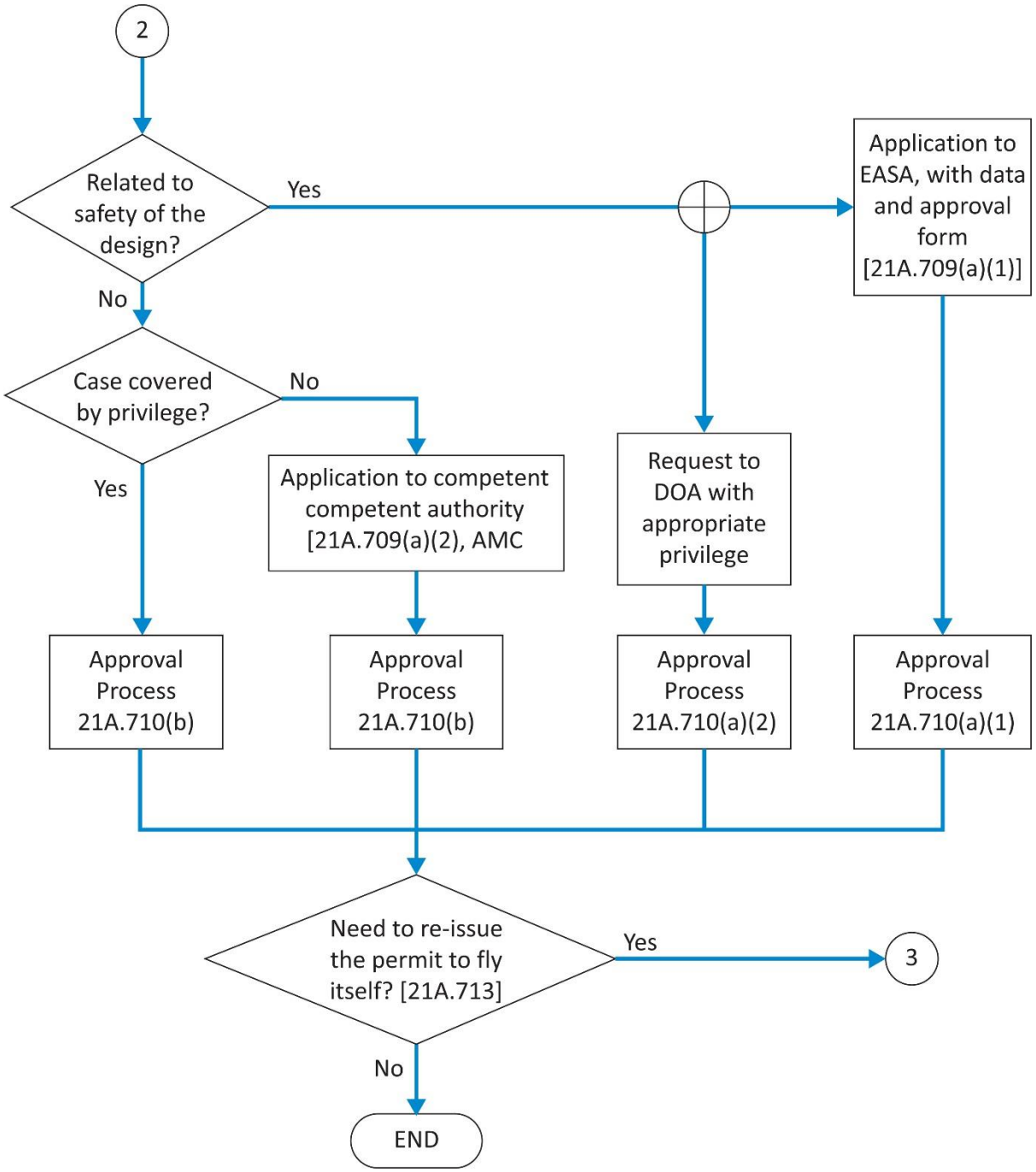
Flow-chart 1: overview



Flow-chart 2: approval of flight conditions



Flow-chart 3: issue of permit to fly



Flow-chart 4: changes after first issue of permit to fly

21.A.701 Scope

Regulation (EU) 2019/897

(a) Permits to fly shall be issued in accordance with this Subpart to aircraft that do not meet, or have not been shown to meet, applicable airworthiness requirements but are capable of safe flight under defined conditions and for the following purposes:

1. development;
2. showing compliance with regulations or certification specifications;
3. design organisations or production organisations crew training;
4. production flight testing of new production aircraft;
5. flying aircraft under production between production facilities;
6. flying the aircraft for customer acceptance;
7. delivering or exporting the aircraft;
8. flying the aircraft for Authority acceptance;
9. market survey, including customer's crew training;
10. exhibition and air show;
11. flying the aircraft to a location where maintenance or airworthiness review are to be performed, or to a place of storage;
12. flying an aircraft at a weight in excess of its maximum certificated takeoff weight for flight beyond the normal range over water, or over land areas where adequate landing facilities or appropriate fuel is not available;
13. record breaking, air racing or similar competition;
14. flying aircraft meeting the applicable airworthiness requirements before conformity to the environmental requirements has been found;
15. for non-commercial flying activity on individual non-complex aircraft or types for which a certificate of airworthiness or restricted certificate of airworthiness is not appropriate.
16. flying an aircraft for troubleshooting purposes or to check the functioning of one or more systems, parts or appliances after maintenance.

(b) This Subpart establishes the procedure for issuing permits to fly and approving associated flight conditions, and establishes the rights and obligations of the applicants for, and holders of, those permits and approvals of flight conditions.

GM 21.A.701 Scope

ED Decision 2012/020/R

An aircraft registered outside the Member States and used for flight testing by an organisation which has its principle place of business in a Member State, remains under the authority of its state of registry. The Agency or an appropriately approved design organisation can provide, on request, technical assistance to the state of registry for the issue of a permit to fly, or equivalent authorisation, under the state of registry applicable regulations.

GM 21.A.701(a) Permit to fly when a certificate of airworthiness or a restricted certificate of airworthiness is not appropriate

ED Decision 2019/018/R

A certificate of airworthiness or restricted category certificate of airworthiness may not be appropriate for an individual aircraft or aircraft type when it is not practicable to comply with the normal continued airworthiness requirements and the aircraft is to a design standard that is demonstrated to be capable of safe flight under defined conditions. Point 21.A.701 identifies cases where the issuance of a (restricted) certificate of airworthiness may not be possible or appropriate and this GM provides further information and typical examples for clarification where appropriate: -

Note: This list of examples is not exhaustive

(1) Development:

— testing of new aircraft or modifications

— testing of new concepts of airframe, engine, propeller and equipment;

— testing of new operating techniques;

(2) Demonstration of compliance with regulations or certification specifications:

— certification flight testing for type certification, supplemental type certificates, changes to type certificates or ETSO authorisation;

(3) Design organisations or production organisations crew training:

— Flights for training of crew that will perform design or production flight testing before the design approval or Certificate of Airworthiness (C of A) can be issued.

(4) Production flight testing of new production aircraft:

— For establishing conformity with the approved design, typically this would be the same program for a number of similar aircraft;

(5) Flying aircraft under production between production facilities:

— green aircraft ferry for follow on final production.

(6) Flying the aircraft for customer acceptance:

— Before the aircraft is sold and/or registered.

(7) Delivering or exporting the aircraft:

— Before the aircraft is registered in the State where the C of A will be issued.

(8) Flying the aircraft for Authority acceptance:

— In the case of inspection flight test by the authority before the C of A is issued.

(9) Market survey, including customer's crew training:

— Flights for the purpose of conducting market survey, sales demonstrations and customer crew training with non type-certificated aircraft or aircraft for which conformity has not yet been established or for non-registered a/c and before the Certificate of Airworthiness is issued.

(10) Exhibition and air show:

— Flying the aircraft to an exhibition or show and participating to the exhibition or show before the design approval is issued or before conformity with the approved design has been shown.

(11) Flying the aircraft to a location where maintenance or airworthiness review are to be performed, or to a place of storage:

— Ferry flights in cases where maintenance is not performed in accordance with approved programmes, where an AD has not been complied with where certain equipment outside the Master Minimum Equipment List (MMEL) is unserviceable or when the aircraft has sustained damage beyond the applicable limits.

(12) Flying an aircraft at a weight in excess of its maximum certificated take-off weight for flight beyond the normal range over water, or over land areas where adequate landing facilities or appropriate fuel is not available:

— Oversees ferry flights with additional fuel capacity.

(13) Record breaking, air racing or similar competition:

— Training flight and positioning flight for this purpose are included

(14) Flying aircraft meeting the applicable certification specifications before conformity to the environmental requirements has been found:

— Flying an aircraft which has been demonstrated to comply with all applicable certification specifications but not with environmental requirements.

(15) For non-commercial flying activity on individual non-complex aircraft or types for which a certificate of airworthiness or restricted certificate of airworthiness is not appropriate.

— For aircraft which cannot practically meet all applicable certification specifications, such as certain aircraft without TC-holder (‘generically termed orphan aircraft’) or aircraft which have been under national systems of Permit to Fly and have not been demonstrated to meet all applicable requirements. The option of a permit to fly for such an aircraft should only be used if a certificate of airworthiness or restricted certificate of airworthiness cannot be issued due to conditions which our outside the direct control of the aircraft owner, such as the absence of properly certified spare parts.

(16) Flying an aircraft for troubleshooting purposes or to check the functioning of one or more systems, parts or appliances after maintenance.

— After maintenance, when the diagnosis of the functioning of an aircraft system needs to be made in flight and the design approval holder has not issued instructions to perform this diagnosis within the approved aircraft limitations, the flight should be conducted under a permit to fly. Further guidance is available in subparagraph (b) of GM M.A.301(i) of the AMC and GM to Part-M.

Note: The above listing is of cases when a permit to fly MAY be issued; it does not mean that in the described cases a permit to fly MUST be issued. If other legal means are available to allow the intended flight(s), they can also be used.

21.A.703 Eligibility

Regulation (EU) No 748/2012

(a) Any natural or legal person shall be eligible as an applicant for a permit to fly except for a permit to fly requested for the purpose of point 21.A.701(a)(15) where the applicant shall be the owner.

(b) Any natural or legal person shall be eligible for application for the approval of the flight conditions.

GM 21.A.703 Applicant for a permit to fly

ED Decision 2019/018/R

The applicant for a permit to fly may be a person other than the registered owner of the aircraft. As the holder of this permit will be responsible for ensuring that all the conditions and limitations associated with the permit to fly are continuously satisfied, the applicant for the permit should be a person or organisation suitable for assuming these responsibilities. In particular, the organisations designing, modifying or maintaining the aircraft should normally be the holder of the associated permits to fly.

21.A.707 Application for permit to fly

Regulation (EU) No 748/2012

(a) Pursuant to point 21.A.703 and when the applicant has not been granted the privilege to issue a permit to fly, an application for a permit to fly shall be made to the competent authority in a form and manner established by that authority.

(b) Each application for a permit to fly shall include:

1. the purpose(s) of the flight(s), in accordance with point 21.A.701;
2. the ways in which the aircraft does not comply with the applicable airworthiness requirements;
3. the flight conditions approved in accordance with point 21.A.710.

(c) Where the flight conditions are not approved at the time of application for a permit to fly, an application for approval of the flight conditions shall be made in accordance with point 21.A.709.

GM 21.A.707(b) Application

ED Decision 2012/020/R

EASA Form 21 (see AMC 21.B.520(b)) should be obtained from the competent authority.

21.A.708 Flight conditions

Regulation (EU) 2015/1039

Flight conditions include:

(a) the configuration(s) for which the permit to fly is requested;

(b) any condition or restriction necessary for safe operation of the aircraft, including:

1. the conditions or restrictions put on itineraries or airspace, or both, required for the flight(s);

2. any conditions or restrictions put on the flight crew to fly the aircraft, in addition to those defined in Appendix XII to this Annex I (Part 21);

3. the restrictions regarding carriage of persons other than flight crew;

4. the operating limitations, specific procedures or technical conditions to be met;

5. the specific flight test programme (if applicable);

6. the specific continuing airworthiness arrangements including maintenance instructions and regime under which they will be performed;

(c) the substantiation that the aircraft is capable of safe flight under the conditions or restrictions of point (b);

(d) the method used for the control of the aircraft configuration, in order to remain within the established conditions.

GM 21.A.708(b)(6) Continuing airworthiness

ED Decision 2012/020/R

In most cases a simple reference to existing maintenance requirements will suffice for aircraft that have a temporarily invalid C of A.

For other aircraft it will have to be proposed by the applicant as part of the flight conditions. For approved organisations they can be included in their procedures.

GM No 1 to 21.A.708(c) Safe flight

ED Decision 2012/020/R

Safe flight normally means continued safe flight and landing but in some limited cases (e.g. higher risk flight testing) it can mean that the aircraft is able to fly in a manner that will primarily ensure the safety of overflown third parties, the flight crew and, if applicable other occupants.

This definition of 'safe flight' should not be interpreted as allowing a test pilot, equipped with a parachute and operating over a sparsely populated area, to set out on a test flight in the full knowledge that there is a high probability of losing the aircraft. The applicant should take reasonable care to minimise safety risks and to be satisfied that there is a reasonable probability that the aircraft will carry out the flight without damage or injury to the aircraft and its occupants or to other property or persons whether in the air or on the ground.

GM No 2 to 21.A.708(c) Substantiations

ED Decision 2012/020/R

The substantiations should include analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can perform safely a flight.

GM No 3 to 21.A.708(c) Operation of Overweight Aircraft

ED Decision 2012/020/R

This GM provides information and guidance with respect to permit to fly for operating an aircraft in excess of its maximum certificated take-off weight, for flight beyond the normal range over water, or over land areas where adequate landing facilities or appropriate fuel is not available.

1. GENERAL.

The excess weight that may be authorized for overweight operations should be limited to additional fuel, fuel carrying facilities, and navigational equipment necessary for the flight.

It is recommended that the applicant discuss the proposed flight with the TC holder of the aircraft to determine the availability of technical data on the installation of additional fuel carrying facilities and/or navigational equipment.

2. CRITERIA USED TO DETERMINE THE SAFETY OF ADDITIONAL FACILITIES.

In evaluating the installation of additional facilities, the Agency or the design organisation must find that the changed aircraft is safe for operation. To assist in arriving at such a determination, the following questions are normally considered:

a. Does the technical data include installation drawings, structural substantiating reports, weight, balance, new centre of gravity limits computations, and aircraft performance limitations in sufficient detail to allow a conformity inspection of the aircraft to be made?

b. In what ways does the aircraft not comply with the applicable certification specifications?

c. Are the fuel tanks vented to the outside? Are all areas in which tanks are located ventilated to reduce fire, explosion, and toxicity hazards?

d. Are the tanks even when empty strong enough to withstand the differential pressure at maximum operating altitude for a pressurized aircraft?

e. Have means been provided for determining the fuel quantity in each tank prior to flight?

f. Are shutoff valves, accessible to the pilot, provided for each additional tank to disconnect these tanks from the main fuel system?

g. Are the additional fuel tank filler connections designed to prevent spillage within the aircraft during servicing?

h. Is the engine oil supply and cooling adequate for the extended weight and range?

3. LIMITATIONS.

The following types of limitations may be necessary for safe operation of the aircraft:

a. Revised operational airspeeds for use in the overweight condition.

b. Increased pilot skill requirements.

c. A prescribed sequence for using fuel from various tanks as necessary to keep the aircraft within its centre of gravity range.

d. Notification to the control tower of the overweight take-off condition to permit use of a runway to minimize flight over congested areas.

e. Avoidance of severe turbulence. If encountered, the aircraft should be inspected for damage as soon as possible.

EXAMPLE of operating limitations which may be prescribed as part of the permit to fly:

Aircraft type: xxxxxx Model: yyyy

Limitations:

1. Maximum weight must not exceed 8 150 pounds.
2. Maximum quantity of fuel carried in auxiliary tanks must not exceed 106 gallons in fwd tank, 164 gallons in centre tank, and 45 gallons in aft tank.
3. Centre of gravity limits must not exceed (fwd) +116.8 and (aft) +124.6.
4. Aerobatics are prohibited.
5. Use of autopilot while in overweight condition is prohibited.
6. Weather conditions with moderate to severe turbulence should be avoided.
7. When an overweight landing is made or the aircraft has been flown through moderate or severe turbulence while in an overweight condition, the aircraft must be inspected for damage after landing. The inspections performed and the findings must be entered in the aircraft log. The pilot must determine, before the next take-off, that the aircraft is airworthy.
8. When operated in the overweight condition, the cruising speed (Vc) shall not exceed 185 m.p.h. and the maximum speed (Vne) shall not exceed 205 m.p.h.
9. Operation in the overweight condition must be conducted to avoid areas having heavy air traffic, to avoid cities, towns, villages, and congested areas, or any other areas where such flights might create hazardous exposure to person or property on the ground.

GM 21.A.708(d) Control of aircraft configuration

ED Decision 2012/020/R

The applicant should establish a method for the control of any change or repair made to the aircraft, for changes and repairs that do not invalidate the conditions established for the permit to fly.

All other changes should be approved in accordance with 21.A.713 and when necessary a new permit to fly should be issued in accordance with 21.A.711.

21.A.709 Application for approval of flight conditions

Regulation (EU) No 748/2012

(a) Pursuant to point 21.A.707(c) and when the applicant has not been granted the privilege to approve the flight conditions, an application for approval of the flight conditions shall be made:

1. when approval of the flight conditions is related to the safety of the design, to the Agency in a form and manner established by the Agency; or
2. when approval of the flight conditions is not related to the safety of the design, to the competent authority in a form and manner established by that authority.

(b) Each application for approval of the flight conditions shall include:

1. the proposed flight conditions;
2. the documentation supporting these conditions; and
3. a declaration that the aircraft is capable of safe flight under the conditions or restrictions of point 21.A.708(b).

AMC1 21.A.709(b) Application for the approval of flight conditions

ED Decision 2021/001/R

SUBMISSION OF DOCUMENTATION SUPPORTING THE ESTABLISHMENT OF FLIGHT CONDITIONS

The applicant should submit, together with the application, the documentation required by point 21.A.709(b) with the approval form (EASA Form 18B) defined below, completed with all the relevant information. The same approval form (EASA Form 18B) should be used when the application is submitted by a DOA holder that does not have the privilege to approve flight conditions or when it has such a privilege, but the respective flight conditions are outside the approved scope of work. If the complete set of data is not available at the time of application, the missing elements can be provided later. In such cases, the approval form should be provided only when all the data is available, to allow the applicant to make the statement required in block of the form.

<table>
<tr><th colspan="2">FLIGHT CONDITIONS FOR A PERMIT TO FLY – APPROVAL FORM</th></tr>
<tr><td>1. Applicant
[Name of organisation providing the flight conditions and associated substantiations]</td><td>2. Approval form No:
Issue:
[Number and issue, for traceability purpose]</td></tr>
<tr><td>3. Aircraft manufacturer/type</td><td>4. Serial number(s)</td></tr>
<tr><td colspan="2">5. Purpose
[Purpose in accordance with 21.A.701(a)]</td></tr>
<tr><td colspan="2">6. Aircraft configuration
The above aircraft for which a permit to fly is requested is defined in [add reference to the document(s) identifying the configuration of the aircraft]
[For change(s) affecting the initial approval form: description of change(s). This form must be re-issued]</td></tr>
<tr><td colspan="2">7. Substantiations
[References to the document(s) justifying that the aircraft (as described in 6.) can perform the intended flight(s) safely under the defined conditions or restrictions.]
[For change(s) affecting the initial approval form: reference(s) to additional substantiation(s). This form must be re-issued]</td></tr>
<tr><td colspan="2">8. Conditions/Restrictions
The above aircraft must be used with the following conditions or restrictions:
[Details of these conditions/restrictions, or reference to relevant document, including specific maintenance instructions and conditions to perform these instructions]</td></tr>
<tr><td colspan="2">9. Statement
The flight conditions have been established and justified in accordance with 21.A.708.
The aircraft as defined in block 6 above has no features and characteristics making it unsafe for the intended operation under the identified conditions and restrictions.</td></tr>
<tr><td colspan="2">[when approved under a privilege of an approved organisation]
10. Approved under [ORGANISATION APPROVAL NUMBER]’</td></tr>
<tr><td>11. Date of issue</td><td>12. Name and signature
[Authorised signatory]</td></tr>
<tr><td colspan="2">[when not approved under a privilege of an approved organisation]
13. Approval and date
[the appropriate approval: EASA, competent authority]</td></tr>
</table>

EASA Form 18B Issue 3

When the flight conditions are approved under a privilege, this form should be used by the approved organisation to document the approval.

21.A.710 Approval of flight conditions

Regulation (EU) No 748/2012

(a) When approval of the flight conditions is related to the safety of the design, the flight conditions shall be approved by:

1. the Agency; or
2. an appropriately approved design organisation, under the privilege of point 21.A.263(c)(6).

(b) When approval of the flight conditions is not related to the safety of the design, the flight conditions shall be approved by the competent authority, or the appropriately approved organisation that will also issue the permit to fly.

(c) Before approving the flight conditions, the Agency, the competent authority or the approved organisation must be satisfied that the aircraft is capable of safe flight under the specified conditions and restrictions. The Agency or the competent authority may make or require the applicant to make any necessary inspections or tests for that purpose.

GM 21.A.710 Approval of flight conditions

ED Decision 2012/020/R

1. The approval of flight conditions is related to the safety of the design, when:
   a. the aircraft does not conform to an approved design; or
   b. an Airworthiness Limitation, a Certification Maintenance Requirement or an Airworthiness Directive has not been complied with; or
   c. the intended flight(s) are outside the approved envelope;
   d. the permit to fly is issued for the purpose of 21.A.701(a)(15).
2. Examples when the approval of flight conditions is not related to the safety of the design are:
   a. production flight testing for the purpose of conformity establishment;
   b. delivery / export flight of a new aircraft the design of which is approved;
   c. demonstrating continuing conformity with the standard previously accepted by the Agency for the aircraft or type of aircraft to qualify or re-qualify for a (restricted) certificate of airworthiness.

21.A.711 Issuance of a permit to fly

Regulation (EU) 2022/201

(a) A permit to fly (EASA Form 20a, see Appendix III) may be issued by the competent authority under the conditions specified in point 21.B.525.

(b) An appropriately approved design organisation may issue a permit to fly (EASA Form 20b, see Appendix IV) under the privilege granted under point 21.A.263(c)(7), when the flight conditions referred to in point 21.A.708 have been approved in accordance with point 21.A.710.

(c) An appropriately approved production organisation may issue a permit to fly (EASA Form 20b, see Appendix IV) under the privilege granted under point 21.A.163(e), when the flight conditions referred to in point 21.A.708 have been approved in accordance with point 21.A.710.

(d) An approved organisation may issue a permit to fly (EASA Form 20b, see Appendix IV) under the privilege granted in accordance with point M.A.711 of Annex I (Part-M) of Regulation (EU) No 1321/2014 or point CAMO.A.125 of Annex Vc (Part-CAMO) of Regulation (EU) No 1321/2014 or point CAO.A.095 of Annex Vd (Part-CAO) of Regulation (EU) No 1321/2014, when the flight conditions referred to in point 21.A.708 of this Annex have been approved in accordance with point 21.A.710 of this Annex.

(e) The permit to fly shall specify the purpose(s) and any conditions and restrictions which have been approved in accordance with point 21.A.710.

(f) For permits issued under points (b), (c) or (d), a copy of the permit to fly and associated flight conditions shall be submitted to the competent authority at the earliest opportunity but not later than 3 days.

(g) Upon evidence that any of the conditions specified in point 21.A.723(a) are not met for a permit to fly that an organisation has issued pursuant to points (b), (c) or (d), that organisation shall immediately revoke that permit to fly and inform without delay the competent authority.

GM 21.A.711(e) Additional conditions and restrictions

ED Decision 2012/020/R

The conditions and restrictions prescribed by the competent authority may include airspace restrictions to make the conditions approved under 21.A.710 more concrete, or conditions outside the scope of the ones mentioned in 21.A.708(b) such as a radio station license.

21.A.713 Changes

Regulation (EU) No 748/2012

(a) Any change that invalidates the flight conditions or associated substantiation established for the permit to fly shall be approved in accordance with point 21.A.710. When relevant an application shall be made in accordance with point 21.A.709.

(b) A change affecting the content of the permit to fly requires the issuance of a new permit to fly in accordance with point 21.A.711.

GM 21.A.713 Changes

ED Decision 2012/020/R

Changes to the conditions or associated substantiations that are approved but do not affect the text on the permit to fly do not require issuance of a new permit to fly.

In case a new application is necessary, the substantiation for approval of the flight conditions only needs to address the change.

21.A.715 Language

Regulation (EU) No 748/2012

The manuals, placards, listings, and instrument markings and other necessary information required by applicable certification specifications shall be presented in one or more of the official language(s) of the European Union acceptable to the competent authority.

21.A.719 Transferability

Regulation (EU) No 748/2012

(a) A permit to fly is not transferable.

(b) Notwithstanding, point (a) for a permit to fly issued for the purpose of point 21.A.701(a)(15), where ownership of an aircraft has changed, the permit to fly shall be transferred together with the aircraft provided the aircraft remains on the same register, or issued only with the agreement of the competent authority of the Member State of registry to which it is transferred.

GM 21.A.719 Transfer of a permit to fly

ED Decision 2012/020/R

Except for permits to fly issued under 21.A.701(a)(15), like aircraft without TC holder, a permit to fly is issued based upon the applicant's declaration of many aspects of the proposed flight or flights, some of which are specific to the applicant. Accordingly, the basis upon which a permit to fly has been issued necessarily is no longer fully in place when the holder of a permit to fly changes, ownership changes, and/or there is a change of register. Such changes necessitate a new application under 21.A.707.

21.A.723 Duration and continued validity

Regulation (EU) 2022/201

(a) A permit to fly shall be issued for a maximum period of 12 months and shall remain valid subject to compliance with all the following conditions:

1. the organisation continues to comply with the conditions and restrictions associated with the permit to fly as set out in point 21.A.711(e);
2. the holder or any of its partners, suppliers or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;
3. the permit to fly has not been revoked by the competent authority under point 21.B.65, or surrendered by its holder;
4. the aircraft remains on the same register.

(b) Notwithstanding point (a), a permit to fly issued for the purpose of point 21.A.701(a)(15) may be issued for unlimited duration.

(c) Upon surrender or revocation, the permit to fly shall be returned to the competent authority.

21.A.725 Renewal of permit to fly

Regulation (EU) No 748/2012

Renewal of the permit to fly shall be processed as a change in accordance with point 21.A.713.

21.A.727 Obligations of the holder of a permit to fly

Regulation (EU) No 748/2012

The holder of a permit to fly shall ensure that all the conditions and restrictions associated with the permit to fly are satisfied and maintained.

SUBPART Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

21.A.801 Identification of products

Regulation (EU) 2021/1088

(a) The identification of products shall include the following information:

1. the manufacturer's name;
2. the product designation;
3. the manufacturer's serial number;
4. the 'EXEMPT' mark in case of an engine, when the competent authority has granted an exemption from the environmental protection requirements;
5. any other information the Agency finds appropriate.

(b) Any natural or legal person that manufactures an aircraft or engine under Subpart G or Subpart F shall identify that aircraft or engine by means of a fireproof plate that has the information specified in point (a) marked on it by etching, stamping, engraving, or other approved method of fireproof marking. The identification plate shall be secured in such a manner that it is accessible and legible, and will not likely be defaced or removed during normal service, or lost or destroyed in an accident.

(c) Any natural or legal person that manufactures a propeller, propeller blade, or propeller hub under Subpart G or Subpart F shall identify it by means of a plate, stamping, engraving, etching or other approved method of fireproof identification that is placed on it on a non-critical surface, contains the information specified in point (a), and will not likely be defaced or removed during normal service or lost or destroyed in an accident.

(d) For manned balloons, the identification plate prescribed in point (b) shall be secured to the balloon envelope and shall be located, if practicable, where it is legible to the operator when the balloon is inflated. In addition, the basket, load frame assembly and any heater assembly shall be permanently and legibly marked with the manufacturer's name, part number, or equivalent, and serial number, or equivalent.

21.A.803 Handling of identification data

Regulation (EU) No 748/2012

(a) No person shall remove, change, or place identification information referred to in point 21.A.801(a) on any aircraft, engine, propeller, propeller blade, or propeller hub, or in point 21.A.807(a) on an APU, without the approval of the Agency.

(b) No person shall remove or install any identification plate referred to in point 21.A.801, or in point 21.A.807 for an APU, without the approval of the Agency.

(c) By way of derogation from points (a) and (b), any natural or legal person performing maintenance work under the applicable associated implementing rules may, in accordance with methods, techniques and practices established by the Agency:

1. remove, change, or place the identification information referred to in point 21.A.801(a) on any aircraft, engine, propeller, propeller blade, or propeller hub, or in point 21.A.807(a) on an APU; or

2. remove an identification plate referred to in point 21.A.801, or point 21.A.807 for an APU, when necessary during maintenance operations.

(d) No person shall install an identification plate removed in accordance with point (c)(2) on any aircraft, engine, propeller, propeller blade, or propeller hub other than the one from which it was removed.

21.A.804 Identification of parts and appliances

Regulation (EU) No 2021/699

(a) Each part or appliance which is eligible for installation in a type-certified product shall be marked permanently and legibly with:

1. a name, trademark, or symbol identifying the manufacturer in a manner identified by the applicable design data;

2. the part number, as defined in the applicable design data; and

3. the letters EPA for parts or appliances produced in accordance with approved design data not belonging to the type-certificate holder of the related product, except for ETSO articles and for parts and appliances covered under point (b) of point 21.A.307.

(b) By way of derogation from point (a), if the Agency agrees that a part or appliance is too small or that it is otherwise impractical to mark a part or appliance with any of the information required by point (a), the authorised release document accompanying the part or appliance or its container shall include the information that could not be marked on the part or appliance.

GM 21.A.804(a)(1) Identification of parts and appliances

ED Decision 2012/020/R

It is not the intent of 21.A.804(a)(1) to introduce an obligation for a production organisation (manufacturer) to mark new parts or appliances with information which is not identified by the design approval holder. Therefore, the physical marking of parts and appliances is only required when established by the design approval (TC, STC, ETSO, repair, change) holder.

For designs (TC, STC, ETSO, repair, change) approved after 28 December 2009 (the date of entry into force of Commission Regulation (EC) No 1194/2009), the design approval holder is required to identify to the manufacturer how the marking in accordance with 21.A.804(a)(1) should be done. This can be limited to identifying a marking field, possible depth and/or means etc., without prescribing the actual text or symbols to be used.

GM1 21.A.804(a)(3) Identification of parts and appliances

ED Decision 2021/001/R

EUROPEAN PARTS APPROVAL (EPA) MARKING FOR REPAIR PARTS

The EPA marking only applies to the parts, specifically designed or modified for the repair, to be incorporated as part of the repair design. If the repair scheme does not require the addition of any new parts or the use of modified parts, there is no need to mark the repaired part with the letters 'EPA'.

AMC1 21.A.804(b) Identification of parts and appliances

ED Decision 2021/001/R

EASA AGREEMENT FOR THE DESIGN APPROVAL HOLDER TO DEROGATE FROM POINT 21.A.804(a)

A design approval holder may apply point 21.A.804(a) or make use of the derogation defined in point 21.A.804(b) by clarifying, in the relevant procedures, the conditions (e.g. the minimum dimensions of a (flat) area on a part suitable for marking) in which the marking on the part may be completely or partially omitted. This can also be supported by examples of parts or cases when certain parts do not have to be marked.

In such cases, the relevant design data (e.g. drawings) should specify the contents and location of the information that could not be marked on the part (i.e. the information to be provided in the authorised release document or on the container).

21.A.805 Identification of critical parts

Regulation (EU) No 748/2012

In addition to the requirement of point 21.A.804, each manufacturer of a part to be fitted on a type-certificated product which has been identified as a critical part shall permanently and legibly mark that part with a part number and a serial number.

GM1 21.A.805 Identification of critical parts

ED Decision 2021/001/R

PARTS TO BE MARKED

For the purposes of point 21.A.805, a part that requires individual traceability for the management of its continued airworthiness, as identified by the design approval holder, shall be permanently marked with a part number and a serial number.

The need for the design approval holder to identify and mark parts may be related to specific requirements for critical parts included in a certification specification. For instance, according to point (c) of CS-E 110 Drawings and Marking of Parts — Assembly of Parts: 'Certain parts (including Engine Critical Parts; see CS-E 515) as may be required by the Agency must be marked and the constructor must maintain records related to this marking such that it is possible to establish the relevant manufacturing history of the parts.' Another example is in point AC 29.602 of FAA AC 29-2C, as referenced in Book 2 of CS-29: '(7) – Critical parts are identified as required, and relevant records relating to the identification are maintained such that it is possible to establish the manufacturing history of the individual parts or batches of parts.'

Another typical case is for any part subject to an individually specified life limit or inspection requirement when it is also possible for that part to be removed from one serial number of the associated product during maintenance and installed on another serial number of the same product. In this case, the traceability of the part, which is necessary for continued airworthiness management purposes, is not assured through the serial number of the product alone, and it is necessary to maintain records for the part through its serial number.

21.A.807 Identification of ETSO articles

Regulation (EU) No 748/2012

(a) Each holder of an ETSO authorisation under Subpart O shall permanently and legibly mark each article with the following information:

1. the name and address of the manufacturer;
2. the name, type, part number or model designation of the article;
3. the serial number or the date of manufacture of the article or both; and
4. the applicable ETSO number.

(b) By way of derogation from point (a), if the Agency agrees that a part is too small or that it is otherwise impractical to mark a part with any of the information required by point (a), the authorised release document accompanying the part or its container shall include the information that could not be marked on the part.

(c) Each person who manufactures an APU under Subpart G or Subpart F shall identify that APU by means of a fireproof plate that has the information specified in point (a) marked on it by etching, stamping, engraving, or other approved method of fireproof marking. The identification plate shall be secured in such a manner that it is accessible and legible, and will not likely be defaced or removed during normal service, or lost or destroyed in an accident.

SECTION B — PROCEDURES FOR COMPETENT AUTHORITIES

SUBPART A — GENERAL PROVISIONS

21.B.10 Oversight documentation

Regulation (EU) 2022/203

The competent authority shall provide all the legislative acts, standards, rules, technical publications and related documents to the relevant personnel in order to allow them to perform their tasks and to discharge their responsibilities.

21.B.15 Information to the Agency

Regulation (EU) 2022/203

(a) The competent authority of the Member State shall notify the Agency in case of any significant problems with the implementation of Regulation (EU) 2018/1139 and its delegated and implementing acts within 30 days from the time the competent authority became aware of the problem.

(b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, the competent authority of the Member State shall provide the Agency as soon as possible with any safety-significant information stemming from the occurrence reports stored in the national database pursuant to Article 6(6) of Regulation (EU) No 376/2014.

(c) The competent authority of the Member State shall provide the Agency as soon as possible with safety- significant information stemming from the information security reports it has received pursuant to point IS.D.OR.230 of the Annex (Part-IS.D.OR) to Delegated Regulation (EU) 2022/1645.

[point (c) is applicable from 22 February 2026 – Regulation (EU) 2023/203]

AMC1 21.B.15(b) Information to the Agency

ED Decision 2022/021/R

AIRWORTHINESS DIRECTIVES

When the competent authority of a Member State receives an airworthiness directive from the competent authority of a non-Member State, that airworthiness directive should be transferred to EASA for dissemination in accordance with Article 76 of Regulation (EU) 2018/1139.

AMC2 21.B.15(b) Information to the Agency

ED Decision 2022/021/R

EXCHANGE OF SAFETY-SIGNIFICANT INFORMATION WITH EASA

Each competent authority should appoint a coordinator to act as the contact point for the exchange of safety-significant information between the competent authority and EASA.

GM1 21.B.15(b) Information to the Agency

ED Decision 2022/021/R

MEANING OF SAFETY-SIGNIFICANT INFORMATION THAT STEMS FROM OCCURRENCE REPORTS

Safety-significant information that stems from occurrence reports means:

(a) a conclusive safety analysis that summarises individual occurrence data and provides an in-depth analysis of a safety issue, and that may be relevant for EASA's safety action planning; and

(b) individual occurrence data for the cases in which EASA is the competent authority and which fulfils the reporting criteria of GM3 21.B.15(b).

GM2 21.B.15(b) Information to the Agency

ED Decision 2022/021/R

RECOMMENDED CONTENT FOR CONCLUSIVE SAFETY ANALYSES

A conclusive safety analysis should contain the following:

(a) a detailed description of the safety issue, including the scenario in which the safety issue takes place; and

(b) an indication of the stakeholders that are affected by the safety issue, including types of operations and organisations;

and, as appropriate:

(c) a risk assessment that establishes the severity and probability of all the possible consequences of the safety issue;

(d) information about the existing safety barriers that the aviation system has in place to prevent the likely consequences of the safety issue from occurring;

(e) any mitigating action that is already in place or developed to deal with the safety issue;

(f) recommendations for future action to control the risk; and

(g) any other element that the competent authority considers essential for EASA to properly assess the safety issue.

GM3 21.B.15(b) Information to the Agency

ED Decision 2022/021/R

OCCURRENCES IN WHICH EASA IS THE COMPETENT AUTHORITY

Occurrences that are related to organisations or products that are certified by EASA should be notified to EASA if:

(a) the occurrence is defined as a reportable occurrence in accordance with the applicable regulation;

(b) the organisation that is responsible for addressing the occurrence is certified by EASA; and

(c) the competent authority of the Member State comes to the conclusion that:

(1) the organisation that is certified by EASA to which the occurrence relates was not informed of the occurrence; or

(2) the occurrence was not properly addressed or was left unattended by the organisation that is certified by EASA.

Such occurrence data should be reported in a format that is compatible with the European Coordination Centre for Accident and Incident Reporting Systems (ECCAIRS) and should provide all the relevant information for its assessment and analysis, including necessary additional files in the form of attachments.

21.B.20 Immediate reaction to a safety problem

Regulation (EU) 2022/203

(a) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, the competent authority shall implement a system to appropriately collect, analyse and disseminate safety information.

(b) The Agency shall implement a system to appropriately analyse any relevant safety information received and, without undue delay, provide the relevant authority of the Member States and the Commission with any information, including recommendations or corrective actions to be taken, that is necessary for them to react in a timely manner to a safety problem involving products, parts, appliances, persons or organisations that are subject to Regulation (EU) 2018/1139 and its delegated and implementing acts.

(c) Upon receiving the information referred to in points (a) and (b), the competent authority shall take adequate measures to address the safety problem.

(d) The competent authority shall immediately notify measures taken under point (c) to all persons or organisations which need to comply with them under Regulation (EU) 2018/1139 and its delegated and implementing acts. The competent authority of the Member State shall also notify those measures to the Agency and, when combined action is required, to the other Member States concerned.

21.B.20A Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

Regulation (EU) 2023/203

(a) The competent authority shall implement a system to appropriately collect, analyse, and disseminate information related to information security incidents and vulnerabilities with a potential impact on aviation safety that are reported by organisations. This shall be done in coordination with any other relevant authorities responsible for information security or cybersecurity within the Member State to increase the coordination and compatibility of reporting schemes.

(b) The Agency shall implement a system to appropriately analyse any relevant safety-significant information received in accordance with point 21.B.15(c), and without undue delay provide the Member States and the Commission with any information, including recommendations or corrective actions to be taken, necessary for them to react in a timely manner to an information security incident or vulnerability with a potential impact on aviation safety involving products, parts, non-installed equipment, persons or organisations subject to Regulation (EU) 2018/1139 and its delegated and implementing acts.

(c) Upon receiving the information referred to in points (a) and (b), the competent authority shall take adequate measures to address the potential impact on aviation safety of the information security incident or vulnerability.

(d) Measures taken in accordance with point (c) shall immediately be notified to all persons or organisations that shall comply with them under Regulation (EU) 2018/1139 and its delegated and implementing acts. The competent authority of the Member State shall also notify those measures to the Agency and, when combined action is required, the competent authorities of the other Member States concerned.

[applicable from 22 February 2026 – Regulation (EU) 2023/203]

AMC1 21.B.20A Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

ED Decision 2023/010/R

(a) To appropriately collect and analyse information related to information security incidents and vulnerabilities with a potential impact on aviation safety, the competent authority should implement means that ensure the necessary confidentiality.

(b) When disseminating information related to information security incidents and vulnerabilities with a potential impact on aviation safety, the competent authority should properly select the appropriate recipient(s) to prevent the content of a report from being exploited to the detriment of aviation safety, by revealing, for instance, uncorrected vulnerabilities.

[applicable from 22 February 2026 – ED Decision 2023/10/R]

GM1 21.B.20A Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

ED Decision 2023/010/R

When deemed necessary, a two-step mechanism could be used: a report alerting about the information security event or incident and the availability of additional data that would require controlled and confidential distribution. This report should only alert recipients of the urgency and the necessity for organisations and competent authorities to establish further communication through secure means.

Therefore, the report should consist of two parts: one limited to mostly public information and one containing the sensitive data that should be restricted to the recipients who need to know. Wherever possible, reports should be based on an agreed taxonomy.

[applicable from 22 February 2026 – ED Decision 2023/10/R]

21.B.25 Management system

Regulation (EU) 2022/203

(a) The competent authority shall establish and maintain a management system, including as a minimum:

1. documented policies and procedures to describe its organisation, the means and methods for establishing compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts. The procedures shall be kept up to date, and serve as the basic working documents within that competent authority for all its related tasks;

2. a sufficient number of personnel to perform its tasks and discharge its responsibilities. A system shall be in place to plan the availability of personnel in order to ensure the proper completion of all tasks;

3. personnel that are qualified to perform their allocated tasks and that have the necessary knowledge and experience, and receive initial and recurrent training to ensure continuing competency;

4. adequate facilities and office accommodation for personnel to perform their allocated tasks;

5. a function to monitor the compliance of the management system with the relevant requirements, and the adequacy of the procedures, including the establishment of an internal audit process and a safety risk management process. Compliance monitoring shall include a feedback system of audit findings to the senior management of the competent authority to ensure the implementation of corrective actions as necessary;

6. a person or group of persons having a responsibility to the senior management of the competent authority for the compliance monitoring function.

(b) The competent authority shall, for each field of activity, including the management system, appoint one or more persons with the overall responsibility for the management of the relevant task(s).

(c) The competent authority shall establish procedures for the participation in a mutual exchange of all necessary information and assistance with any other competent authorities concerned, whether from the same Member State or from other Member States, including on:

1. all findings raised and any follow-up actions taken as a result of the oversight of persons and organisations that carry out activities in the territory of a Member State, but certified by the competent authority of another Member State or by the Agency;

2. information stemming from mandatory and voluntary occurrence reporting as required by 21.A.3A.

(d) A copy of the procedures related to the management system of the competent authority of the Member State and their amendments shall be made available to the Agency for the purpose of standardisation.

(e) In addition to the requirements contained in point (a), the management system established and maintained by the competent authority shall comply with Annex I (Part-IS.AR) to Implementing Regulation (EU) 2023/203 in order to ensure the proper management of information security risks which may have an impact on aviation safety.

[point (e) is applicable from 22 February 2026 – Regulation (EU) 2023/203]

AMC1 21.B.25 Management system

ED Decision 2023/014/R

GENERAL

(a) The competent authority should be organised in such a way that:

(1) there is specific and effective management authority in the conduct of all relevant activities;

(2) the functions and processes described in the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, AMC, CSs, and GM are be properly implemented;

(3) the competent authority's policy, organisation and operating procedures for the implementation of the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, AMC, CSs, and GM are properly documented and applied;

(4) all the competent authority's personnel who are involved in the related activities are provided with training where necessary;

(5) specific and effective provision is made for communicating and interfacing as necessary with EASA and other competent authorities; and

(6) all the functions related to implementing the applicable requirements are adequately described.

(b) A general policy in respect of the activities related to the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts activities should be developed, promoted and implemented by the manager at the highest appropriate level; for example the manager at the top of the functional area of the competent authority that is responsible for such activities.

(1) Appropriate steps should be taken to ensure that the policy is known and understood by all the personnel involved, and all the necessary steps should be taken to implement and maintain the policy.

(2) The general policy should, in particular, take into account:

(a) the provisions of Regulation (EU) 2018/1139

(b) the provisions of the applicable delegated and implementing acts, AMC, CSs, and GM;

(c) the needs of industry; and

(d) the needs of EASA and of the competent authority.

(3) The policy should define specific objectives for the key elements of the competent authority organisation and processes for implementating the related activities, including the corresponding control procedures and the measurement of the achieved standard.

AMC2 21.B.25 Management system

ED Decision 2023/014/R

ORGANISATIONAL STRUCTURE

(a) In deciding upon the required organisational structure, the competent authority should review:

(1) the number of certificates, approvals, authorisations and letters of agreements to be issued;

(2) the number, complexity and sizes of the Part 21 organisations under its oversight obligations;

(3) the possible use of qualified entities and of the resources of the competent authority of other Member States to fulfil the continuing oversight obligations;

(4) the complexity of the aviation industry, taking into consideration the diversity of the products and parts; and

(5) the potential growth of activities in the field of civil aviation.

(b) The competent authority should retain effective control of the important surveillance functions and not delegate them in such a way that Part 21 organisations, in effect, regulate themselves in airworthiness matters.

(c) The set-up of the organisational structure should ensure that the various tasks and obligations of the competent authority do not solely rely on individuals. The continuous and undisturbed fulfilment of these tasks and obligations of the competent authority should also be guaranteed in cases of illness, accidents or leave of individual employees.

GM1 21.B.25 Management system

ED Decision 2023/014/R

GENERAL – RELEVANT ACTIVITIES

For the purpose of the AMC and GM to point 21.B.25, the activities referred to are those activities related to the certification and surveillance of design or production organisations.

AMC1 21.B.25(a)(1) Management system

ED Decision 2023/014/R

DOCUMENTED POLICIES AND PROCEDURES

(a) The various elements of the organisation involved with the activities related to Regulation (EU) 2018/1139 and its delegated and implementing acts should be documented in order to establish a reference source for the establishment and maintenance of this organisation.

(b) The documented procedures should be established in a way that facilitates their use. They should be clearly identified, kept up to date and made readily available to all the personnel involved in the related activities.

(c) The documented procedures should cover, as a minimum, all of the following aspects:

(1) policies and objectives;

(2) the organisational structure;

(3) responsibilities and the associated authority;

(4) processes and procedures;

(5) internal and external interfaces;

(6) internal control procedures;

(7) the training of personnel;

(8) cross-references to associated documents; and

(9) assistance from other competent authorities or EASA (where required).

(d) It is likely that the information may be held in more than one document or series of documents, and suitable cross-referencing should be provided. For example, the organisational structure and the job descriptions are not usually in the same documentation as the detailed working procedures. In such cases, it is recommended that the documented procedures should include an index of cross-references to all such other related information, and the related documentation should be readily available when required.

GM1 21.B.25(a)(2) Management system

ED Decision 2023/014/R

SUFFICIENT PERSONNEL

(a) This GM on the determination of the required personnel is limited to the performance of certification and oversight tasks, excluding any personnel who are required to perform tasks that are subject to any national regulatory requirements.

(b) The elements to be considered when determining who are the required personnel and when planning their availability may be divided into quantitative and qualitative elements:

(1) Quantitative elements

(i) the estimated number of initial certificates to be issued;

(ii) the number of organisations to be certified by the competent authority;

(iii) the estimated number of subcontracted organisations used by certified organisations.

(2) Qualitative elements

(i) the size, nature, and complexity of the activities of certified organisations, taking into account:

(A) the privileges of each organisation;

(B) the types of approval and the scopes of approval;

(C) possible certification to industry standards;

(D) the number of personnel; and

(E) the organisational structure and the existence of subsidiaries;

(ii) the safety priorities identified;

(iii) the results of past oversight activities, including audits, inspections and reviews, in terms of risks and regulatory compliance, taking into account:

(A) the number and the levels of findings;

(B) the time frame for the implementation of corrective actions;

(C) the maturity of the management systems implemented by organisations, and their ability to effectively manage safety risks; and

(iv) the size and complexity of the Member States' aviation industry, and the potential growth of activities in the field of civil aviation, which may be an indication of the number of new applications, and changes to existing certificates to be expected.

(c) Based on existing data from previous oversight planning cycles, and taking into account the situation within the Member State's aviation industry, the competent authority may estimate:

(1) the standard working time required for processing applications for new certificates, approvals, authorisations or letters of agreement;

(2) the number of new certificates, approvals, authorisations or letters of agreement to be issued for each planning period; and

(3) the number of changes to existing certificates, approvals, authorisations or letters of agreement to be processed for each planning period.

(d) In line with the competent authority's oversight policy, the following planning data should be determined:

(1) the standard number of audits to be performed per oversight planning cycle;

(2) the standard duration of each audit;

(3) the standard working time for audit preparation, on-site audit, reporting, and follow-up per inspector;

(4) the standard number of unannounced inspections to be performed;

(6) the standard duration of inspections, including preparation, reporting, and follow-up per inspector; and

(7) the minimum number and the required qualifications of the inspectors for each audit/inspection.

(e) The standard working time could be expressed either in working hours per inspector, or in working days per inspector. All planning calculations should, then, be based on the same units (working hours or days).

(f) The use of a spreadsheet application is recommended to process the data defined under (c) and (d), to assist in determining the total number of working hours/days per oversight planning cycle required for certification, oversight and enforcement activities. This application could also serve as a basis for implementing a system for planning the availability of personnel.

(g) The number of working hours/days per planning period for each qualified inspector that may be allocated for certification, oversight and enforcement activities should be determined, taking into account:

(1) purely administrative tasks not directly related to certification and oversight;

(2) training;

(3) participation in other projects;

(4) planned absences; and

(5) the need to include a reserve for unplanned tasks or unforeseeable events.

(h) The determination of working time available for certification, oversight and enforcement activities should also consider, if applicable:

(1) the use of qualified entities;

(2) cooperation with other competent authorities for approvals that involve more than one Member State; and

(3) oversight activities under a bilateral aviation safety agreement.

(i) Based on the elements listed above, the competent authority should be able to:

(1) monitor the dates when audits and inspections are due, and when they were carried out;

(2) implement a system to plan the availability of personnel; and

(3) identify possible gaps between the number and the qualifications of personnel and the required volume of certification and oversight.

Care should be taken to keep planning data up to date in line with changes in the underlying planning assumptions, with a particular focus on risk-based oversight principles.

AMC1 21.B.25(a)(3) Management system

ED Decision 2023/014/R

QUALIFICATIONS AND TRAINING — GENERAL

(a) It is essential for the competent authority to have the full capability to adequately assess the compliance and performance of an organisation by ensuring that the whole range of activities is assessed by appropriately qualified personnel.

(b) For each inspector, the competent authority should:

(1) define the competencies required to perform the allocated certification and oversight tasks;

(2) define the associated minimum qualifications that are required;

(3) establish initial and recurrent training programmes in order to maintain and to enhance the competency of inspectors at the level that is necessary to perform the allocated tasks; and

(4) ensure that the training provided meets the established standards, and is regularly reviewed and updated as necessary.

(c) The competent authority should ensure that training is provided by qualified trainers with appropriate training skills.

AMC2 21.B.25(a)(3) Management system

ED Decision 2023/014/R

QUALIFICATIONS AND TRAINING — INSPECTORS

(a) Competent authority inspectors should have:

(1) practical experience and expertise in the application of aviation safety standards and safe operating practices;

(2) comprehensive knowledge of:

(i) relevant parts of Regulation (EU) 2018/1139 and its delegated and implementing acts and the related AMC, CSs and GM;

(ii) the competent authority's procedures;

(iii) the rights and obligations of an inspector;

(iv) safety management systems based on the EU management system requirements and ICAO Annex 19, and compliance monitoring;

(v) design or production standards, as applicable;

(vi) design-related or production-related human factors and human performance principles, as appropriate;

(3) training on auditing techniques and assessing and evaluating management systems and safety risk management processes;

(4) 5 years of relevant work experience to be allowed to work without supervision as an inspector. This may include experience gained during training to obtain the qualifications described in point (a)(5) below; and

(5) a relevant engineering degree with additional education. 'Relevant engineering degree' means an engineering degree from aeronautical, mechanical, electrical, electronic, avionics or other studies relevant to the design and production of aircraft/aircraft components.

(b) In addition to technical competency, inspectors should have a high degree of integrity, be impartial in carrying out their tasks, be tactful, and have a good understanding of human nature.

(c) A programme for recurrent training should be developed that ensures that the inspectors remain competent to perform their allocated tasks. As a general policy, it is not desirable for the inspectors to obtain technical qualifications from those entities that are under their direct regulatory oversight.

AMC3 21.B.25(a)(3) Management system

ED Decision 2023/014/R

INITIAL AND RECURRENT TRAINING — INSPECTORS

(a) Initial training programme

The initial training programme for inspectors should include, to an extent appropriate to their role, current knowledge, experience and skills in at least the following:

(1) aviation legislation, organisation, and structure;

(2) the Chicago Convention, the relevant ICAO Annexes and Documents;

(3) Regulation (EU) No 376/2014 on the reporting, analysis and follow-up of occurrences in civil aviation;

(4) overview of Regulation (EU) 2018/1139 and its delegated and implementing acts and the related AMC, CSs, and GM;

(5) Regulation (EU) No 748/2012 as well as any other applicable requirements;

(6) management systems, including the assessment of the effectiveness of a management system, in particular hazard identification and risk assessment, and non-punitive reporting techniques in the context of the implementation of a 'just culture';

(7) auditing techniques;

(8) procedures of the competent authority that are relevant to the inspectors' tasks;

(9) human factors principles;

(10) the rights and obligations of inspecting personnel of the competent authority;

(11) on-the-job training relevant to the inspector's tasks;

(12) technical training that is appropriate to the role and tasks of the inspector, in particular for those areas that require approvals.

NOTE: The duration of the on-the-job training should take into account the scope and complexity of the inspector's tasks. The competent authority should assess whether the required competency has been achieved before an inspector is authorised to perform a task without supervision.

(b) Recurrent training programme

Once qualified, the inspector should undergo training periodically, as well as whenever it is deemed necessary by the competent authority, in order to remain competent to perform the allocated tasks. The recurrent training programme for inspectors should include, as appropriate to their role, at least the following topics:

(1) changes in aviation legislation, the operational environment and technologies;

(2) procedures of the competent authority that are relevant to the inspector's tasks;

(3) technical training that is appropriate to the role and tasks of the inspector; and

(4) results from past oversight.

(c) Assessments of an inspector's competency should take place at regular intervals that do not exceed 3 years. The results of these assessments, as well as any actions taken following these assessments, should be recorded.

AMC1 21.B.25(a)(5) Management system

ED Decision 2023/014/R

SAFETY RISK MANAGEMENT PROCESS

(a) The safety risk management process required by point (a)(5) of point 21.B.25 should be documented. The following should be defined in the related documentation:

(1) means for hazard identification and the related data sources, taking into account data that comes from other competent authorities with which the competent authority interfaces in the State or from the competent authorities of other Member States;

(2) risk management steps including:

(i) analysis (in terms of the probability and the severity of the consequences of hazards and occurrences);

(ii) assessment (in terms of tolerability); and

(iii) control (in terms of mitigation) of risks to an acceptable level;

(3) who holds the responsibilities for hazard identification and risk management;

(4) who holds the responsibility for the follow-up of risk mitigation actions;

(5) the levels of management who have the authority to make decisions regarding the tolerability of risks;

(6) means to assess the effectiveness of risk mitigation actions; and

(7) the link with the compliance monitoring function.

(b) To demonstrate that the safety risk management process is operational, competent authorities should be able to provide evidence that:

(1) the persons involved in internal safety risk management activities are properly trained;

(2) hazards that could impact the authority's capabilities to perform its tasks and discharge its responsibilities have been identified, and the related risk assessment is documented;

(3) regular meetings take place at appropriate levels of management of the competent authority to discuss the risks identified and to decide on the risk tolerability and possible risk mitigations;

(4) in addition to the initial hazard identification exercise, the risk management process is triggered as a minimum whenever changes occur that may affect the competent authority's capability to perform any of the tasks required by Part 21;

(5) a record of the actions taken to mitigate risks is maintained, showing the status of each action and the owner of the action;

(6) there is follow-up on the implementation of all risk mitigation actions;

(7) risk mitigation actions are assessed for their effectiveness;

(8) the results of risk assessments are periodically reviewed to check whether they remain relevant.

GM1 21.B.25(a)(5) Management system

ED Decision 2023/014/R

SAFETY RISK MANAGEMENT PROCESS

The purpose of safety risk management as part of the management system framework for competent authorities is to ensure the effectiveness of the management system. As for any organisation, hazard identification and risk management are expected to contribute to effective decision-making, to guide resource allocation and contribute to organisational success.

The safety risk management process required by point 21.B.25 is intended to address the safety risks that are directly related to the competent authority's organisation and processes, and which may affect its capability to perform its tasks and discharge its responsibilities. This process is not intended to be a substitute for the State safety risk management SARPs defined in ICAO Annex 19, Chapter 3. This does not mean, however, that the competent authority may not use information and data that is obtained through its State Safety Programme (SSP), including oversight data and information, for the purpose of safety risk management as part of its management system.

The safety risk management process is also to be applied to the management of changes (point 21.B.35), which is intended to ensure that the management system remains effective whenever changes occur.

AMC1 21.B.25(d) Management system

ED Decision 2023/014/R

PROCEDURES AVAILABLE TO EASA

(a) Copies of the procedures related to the management system of the competent authority of the Member State, and their amendments, that should be made available to EASA for the purpose of standardisation, should provide at least the following information:

(1) the competent authority's organisational structure for the continuing oversight functions that it undertakes, with a description of the main processes. This information should demonstrate the allocation of responsibilities within the competent authority, and that the competent authority is capable of carrying out the full range of tasks regarding the size and complexity of the Member State's aviation industry. It should also consider the overall proficiency and the scope of authorisation of the competent authority's personnel;

(2) for personnel who are involved in oversight activities, the minimum required professional qualification and amount of experience, and the principles that guide their appointment (e.g. assessment);

(3) how the following are carried out: assessments of applications and evaluations of compliance; the issuance of certificates, approvals, authorisations and letters of agreement; continuing oversight activities; the follow-up of findings; enforcement measures; and the resolution of safety concerns;

(4) the principles used to manage exemptions and derogations;

(5) the processes that are in place to distribute applicable safety information for timely reaction to a safety problem;

(6) the criteria for planning continuing oversight activities (i.e. an oversight programme), including the management of interfaces when conducting continuing oversight activities;

(7) an outline of the initial training of newly recruited oversight personnel (taking future activities into account), and the basic framework for the recurrent training of oversight personnel.

(b) As part of the continuous monitoring of a competent authority, EASA may request details of the working methods used, in addition to a copy of the procedures of the competent authority's management system (and any amendments). These additional details are the procedures and related guidance material that describe the working methods for the personnel of the competent authority who conduct oversight activities.

(c) Information related to the competent authority's management system may be submitted in an electronic format.

21.B.30 Allocation of tasks to qualified entities [applicable until 21 February 2026] / 21.B.30 Allocation of tasks [applicable from 22 February 2026 – Regulation (EU) 2023/203]

Regulation (EU) 2022/203

(a) The competent authority may allocate tasks related to the initial certification or to the continuing oversight of products and parts, as well as of natural or legal persons subject to Regulation (EU) 2018/1139 and its delegated and implementing acts to qualified entities. When allocating tasks, the competent authority shall ensure that it has:

1. put a system in place to initially and continuously assess whether the qualified entity complies with Annex VI to Regulation (EU) 2018/1139. That system and the results of the assessments shall be documented;

2. established a written agreement with the qualified entity, approved by both parties at the appropriate management level, which stipulates:

(i) the tasks to be performed;

(ii) the declarations, reports and records to be provided;

(iii) the technical conditions to be met when performing such tasks;

(iv) the related liability coverage;

(v) the protection given to the information acquired when carrying out such tasks.

(b) The competent authority shall ensure that the internal audit process and safety risk management process established pursuant to point 21.B.25(a)(5) cover all the certification and continuing oversight tasks performed by the qualified entity on its behalf.

(c) For the certification and oversight of the organisation's compliance with points 21.A.139A and 21.A.239A, the competent authority may allocate tasks to qualified entities in accordance with point (a), or to any relevant authority responsible for information security or cybersecurity within the Member State. When allocating tasks, the competent authority shall ensure that:

(1) all aspects related to aviation safety are coordinated and taken into account by the qualified entity or relevant authority;

(2) the results of the certification and oversight activities performed by the qualified entity or relevant authority are integrated in the overall certification and oversight files of the organisation;

(3) its own information security management system established in accordance with point 21.B.25(e) covers all the certification and continuing oversight tasks performed on its behalf.

[point (c) is applicable from 22 February 2026 – Regulation (EU) 2023/203]

GM1 21.B.30 Allocation of tasks to qualified entities

ED Decision 2023/014/R

CERTIFICATION TASKS

The tasks that may be performed by a qualified entity on behalf of the competent authority include those that are related to the initial certification and the continuing oversight of persons and organisations as defined in Part 21.

21.B.35 Changes in the management system

Regulation (EU) 2022/203

(a) The competent authority shall have a system in place to identify the changes that affect its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU) 2018/1139 and its delegated and implementing acts. That system shall enable the competent authority to take action necessary to ensure that its management system remains adequate and effective.

(b) The competent authority shall update in a timely manner its management system to reflect any changes to Regulation (EU) 2018/1139 and its delegated and implementing acts so as to ensure its effective implementation.

(c) The competent authority of the Member State shall notify the Agency of any changes affecting its capability to perform its tasks and discharge its responsibilities as provided for in Regulation (EU) 2018/1139 and its delegated and implementing acts.

21.B.55 Record-keeping

Regulation (EU) 2022/203

(a) The competent authority shall establish a record-keeping system that allows the adequate storage, accessibility and reliable traceability of:

1. the management system's documented policies and procedures;
2. the training, qualifications and authorisation of its personnel;
3. the allocation of tasks, covering the elements required by point 21.B.30, as well as the details of tasks allocated;
4. certification processes and continuing oversight of certified organisations, including:
   - (i) the application for a certificate, approval, authorisation and letter of agreement;
   - (ii) the competent authority's continuing oversight programme, including all the assessments, audits and inspection records;
   - (iii) the certificates, approvals, authorisations and letters of agreement issued, including any changes to them;
   - (iv) a copy of the oversight programme, listing the dates when audits are due and when audits were carried out;
   - (v) copies of all formal correspondence;
   - (vi) recommendations for the issue or continuation of a certificate, an approval authorisation or a letter of agreement, detail of findings and actions taken by the organisations to close those findings, including the date of closure, enforcement actions and observations;
   - (vii) any assessment, audit and inspection report issued by another competent authority pursuant to points 21.B.120(d), 21.B.221(c) or 21.B.431(c);
   - (viii) copies of all the organisation expositions, handbooks or manuals, and of any amendments to them;
   - (ix) copies of any other documents approved by the competent authority;

5. Statements of Conformity (EASA Form 52, see Appendix VIII) and Authorised Release Certificates (EASA Form 1, see Appendix I) that it has validated for organisations that produce products, parts or appliances without a production organisation approval certificate according to Subpart F of Section A of this Annex.

(b) The competent authority shall include in the record-keeping:

1. documents supporting the use of alternative means of compliance

2. safety information in accordance with point 21.B.15 and follow-up measures;

3. the use of safeguard and flexibility provisions in accordance with Articles 70, 71(1) and 76(4) of Regulation (EU) 2018/1139.

(c) The competent authority shall maintain a list of all the certificates, approvals, authorisations and letters of agreement it has issued.

(d) All the records referred to in points (a), (b) and (c) shall be kept for a minimum period of 5 years, subject to applicable data protection law.

(e) All the records referred to in points (a), (b) and (c) shall be made available, upon request, to a competent authorities of another Member State or to the Agency.

GM1 21.B.55 Record-keeping

ED Decision 2023/014/R

DATA RELATED TO DESIGN APPROVALS

This GM specifies the administrative documents to be kept for the various kinds of design approvals. It does not repeat the requirements for design approvals holders to keep records (ref.: point 21.A.55).

(a) Type-certificate

(1) Copy of the TC

(2) Copy of the TCDS

(3) Environmental protection approval data

(4) Documents defining the type-certification basis including information to justify special conditions, equivalent safety findings and exemptions (Certification Review Items or equivalent)

(5) List of approved modifications,

(6) List of the competent authority's approved publications (Flight Manual, Repair Manual, Airworthiness Limitations, Certification Maintenance Requirements)

(7) Airworthiness directives

(8) Master Minimum Equipment List

(9) Maintenance Review Board Report

(b) Supplemental type certificate

(1) Copy the STC

(2) Environmental protection approval data

(3) Documents defining the certification basis including information to justify special conditions, equivalent safety findings and exemptions (Certification Review Items or equivalent)

(4) List of the competent authority's approved documents

(5) Airworthiness directives

(c) JTSO Authorisation

(1) Copy of ETSO authorisation letter

(2) Copy of Declaration of Design and Performance

(3) Statement of compliance with applicable standards

(4) Airworthiness directives

(d) Other part or appliance approvals

(1) Copy of the approval letter,

(2) Copy of the Declaration of Design and Performance or equivalent

(3) Statement of compliance with applicable standards

(4) Airworthiness directives

(e) Changes from non TC or STC holders

(1) Modification approval sheet, or equivalent document

(2) Documents required by point 21.A.5, or equivalent national requirement

Note: Not applicable to design approvals issued under a DOA privilege, for which record-keeping is under the DOA holder responsibility.

(f) Repair design approvals

(1) Repair approval sheet

(2) Documents listed in point 21.A.5

Note: Not applicable to repair designs approved under a DOA privilege, for which record-keeping is under the DOA holder responsibility.

AMC1 21.B.55(a) Record-keeping

ED Decision 2022/021/R

GENERAL

(a) The record-keeping system should ensure that all the records are accessible within a reasonable time whenever they are needed. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.

(b) All the records that contain sensitive data on applicants or organisations should be stored in a secure manner with controlled access, to ensure their confidentiality.

(c) The records should be kept in paper form, or in an electronic format, or a combination of both. Records that are stored on microfilm or optical discs are also acceptable. The records should remain legible and accessible throughout the required retention period. The retention period starts when the record is created.

(d) Paper record systems should use robust material that can withstand normal handling and filing. Computer record systems should have at least one backup system that should be updated within 24 hours of any new entry. Computer record systems should include safeguards to prevent unauthorised personnel from altering the data.

(e) All the computer hardware that is used to ensure the backup of data should be stored in a different location from the one that contains the working data and in an environment that ensures that the data remains in a good condition. When hardware or software changes take place, special care should be taken that all the necessary data continues to be accessible throughout at least the full period that is specified in point 21.B.55(d).

AMC1 21.B.55(a)(1) and (a)(2) Record-keeping

ED Decision 2022/021/R

COMPETENT AUTHORITY MANAGEMENT SYSTEM

The records that are related to the competent authority's management system should include, as a minimum, and as applicable:

(a) the documented policies and procedures;

(b) the personnel files of the competent authority personnel, with the supporting documents related to their training and qualifications;

(c) the results of the competent authority's internal audits and safety risk management processes, including audit findings, as well as any corrective, preventive, and risk mitigation action; and

(d) the contracts that are established with the qualified entities that perform certification or oversight tasks on behalf of the competent authority.

GM1 21.B.55(e) Record-keeping

ED Decision 2022/021/R

TRACEABILITY OF RELEASE CERTIFICATES

The record-keeping of those EASA Forms 52 and 1 that are validated by the competent authority should allow the verification of that validation by the parties concerned, including the recipients of the release certificates.

21.B.65 Suspension, limitation and revocation

Regulation (EU) 2022/203

The competent authority shall:

(a) suspend a certificate, approval, permit to fly, authorisation or letter of agreement when it considers that there are reasonable grounds that such action is necessary to prevent a credible threat to aircraft safety;

(b) suspend, revoke or limit a certificate, approval, permit to fly, authorisation or letter of agreement if such action is required pursuant to points 21.B.125, 21.B.225 or 21.B.433;

(c) suspend or revoke a certificate of airworthiness or a noise certificate upon evidence that some of the conditions specified in points 21.A.181(a) or 21.A.211(a) are not met;

(d) suspend or limit in whole or in part a certificate, approval, permit to fly, authorisation or letter of agreement if unforeseeable circumstances outside the control of the competent authority prevent its inspectors from discharging their oversight responsibilities over the oversight planning cycle.

GM1 21.B.65 Suspension, limitation and revocation

ED Decision 2023/014/R

DEFINTIONS

(a) SUSPENSION

A suspension is a temporary withdrawal of all the privileges of an organisation's approval. No activities that invoke the approval can be made while the suspension is in force. Approval privileges may be reinstated when the circumstances that caused the suspension are corrected and the organisation can once again demonstrate full compliance with the requirements.

(b) LIMITATION

A limitation is an amendment to the certificate, approval, authorisation or letter of agreement that partially limits the privileges of the organisation .

(c) REVOCATION

A revocation is a permanent cancellation of the whole of an approval. All the rights and privileges of the organisation under the approval are withdrawn, and, after revocation, the organisation cannot perform activities that invoke the approval, and must remove all references to the approval from its company documentation.

GM2 21.B.65 Suspension, limitation and revocation

ED Decision 2023/014/R

LINK BETWEEN FINDINGS AND SUSPENSION OR LIMITATION OR REVOCATION

The level 1 findings are those which may lead, if not properly addressed, to suspension, limitation or revocation of the approval. If appropriate, these negative decisions on the approval may be taken immediately, or after the organisation fails to comply within the time period agreed by the competent authority.

The type of the negative decision — i.e. suspension, limitation or revocation — should depend upon the contents and the extent of the level 1 finding. Normally, a limitation or a suspension should be considered first.

SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.B.70 Certification specifications

Regulation (EU) 2019/897

The Agency, in accordance with Article 76(3) of Regulation (EU) 2018/1139, shall issue certification specifications and other detailed specifications, including certification specifications for airworthiness, operational suitability data and environmental protection, that competent authorities, organisations and personnel may use to demonstrate compliance of products, parts and appliances with the relevant essential requirements set out in Annexes II, IV and V to that Regulation, as well as with those for environmental protection set out in Article 9(2) and Annex III of that Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates are to be issued, amended or supplemented.

21.B.75 Special conditions

Regulation (EU) 2019/897

(a) The Agency shall prescribe special detailed technical specifications, named 'special conditions, for a product if the related certification specifications do not contain adequate or appropriate safety standards for the product because:

1. the product has novel or unusual design features relative to the design practices on which the applicable certification specifications are based;
2. the intended use of the product is unconventional; or
3. experience from other similar products in service or products having similar design features or newly identified hazards have shown that unsafe conditions may develop.

(b) Special conditions contain such safety standards as the Agency finds necessary in order to establish a level of safety equivalent to that of the applicable certification specifications.

GM1 21.B.75 Special conditions

ED Decision 2021/001/R

GENERAL

The term 'novel or unusual design features' should be judged in view of the applicable certification basis for the product. A design feature, in particular, should be judged to be a 'novel or unusual design feature' when the certification basis does not sufficiently cover this design.

The term 'unsafe condition' is used with the same meaning as described in GM1 21.A.3B(b).

The term 'newly identified hazards' is intended to address new risks that may be recognised in the design (e.g. questionable features) or its operational characteristics (e.g. volcanic ash) for which there is not yet enough in-service experience.

21.B.80 Type-certification basis for a type-certificate or restricted type-certificate

Regulation (EU) 2019/897

The Agency shall establish the type certification basis and notify it to the applicant for a type-certificate or restricted type-certificate. The type certification basis shall consist of:

(a) the certification specifications for airworthiness designated by the Agency from those applicable to the product at the date of application for that certificate, unless:

1. the applicant chooses to comply, or is required to comply in accordance with point 21.A.15(f), with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or

2. the Agency accepts any alternative to a designated certification specification that cannot be complied with, for which compensating factors have been found that provide an equivalent level of safety; or

3. the Agency accepts or prescribes other means that:

(i) in the case of a type-certificate, demonstrate compliance with the essential requirements of Annex II to Regulation (EU) 2018/1139; or

(ii) in the case of a restricted type-certificate, provide a level of safety adequate with regard to the intended use; and

(b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

GM 21.B.80 Type-certification basis for a type certificate (TC) or restricted type certificate (RTC)

ED Decision 2019/018/R

1. INTRODUCTION

This GM addresses the type-certification basis for a TC or an RTC.

2. APPLICABLE CERTIFICATION SPECIFICATIONS (CSs) (see point 21.B.80(a))

The type-certification basis for a TC or an RTC consists of the airworthiness CSs that were effective on the date of application and were applicable for that certificate.

The effectivity date of the initial application may be changed, as per point 21.A.15(f)(2), when the period of validity of an application for a type certificate is exceeded, or it is evident that it will be exceeded, and the applicant requests an extension; see GM 21.A.15(e) and (f).

The certification basis is then revised accordingly.

3. ELECT TO COMPLY (see point 21.B.80(a)(1))

It is also possible for an applicant to elect to comply with a CS that entered into force after the date on which the applicant has submitted the application.

EASA should assess whether the proposed certification basis is appropriate to ensure that the ‘elect to comply’ proposal includes any other CSs that are ‘directly related’ to one or several of the CSs in it. Directly related CSs are those that are deemed to contribute to the same safety objective by building on each other’s requirements, addressing complementary aspects of the

same safety concern, etc. Typically, they are adopted simultaneously with, or prior to, the CSs with which the applicant has elected to comply.

4. EQUIVALENT LEVEL OF SAFETY (see point 21.B.80(a)(2))

In cases in which the applicable CSs cannot be literally complied with, either fully or in part, EASA may accept a suitable alternative which provides an equivalent level of safety through the use of appropriate compensating factors.

In cases in which the requirements contain not only objectives but also prescriptive parts, an equivalent level of safety may be accepted if:

— the objectives are met by designs or features other than those required in the CSs; or

— suitable compensating factors are proposed.

5. ALTERNATIVE MEANS OF COMPLIANCE (see point 21.B.80(a)(3))

If the intent of the CSs defined in point 21.B.80(a) cannot be met, EASA may accept mitigating factors to the CSs, provided that the safety objective is met.

In the case of a TC, the alternative means should provide a demonstration of compliance with the essential requirements for airworthiness laid down in Annex II to Regulation (EU) 2018/1139.

In the case of an RTC, the alternative means should provide a sufficient level of safety for the intended use.

Note: 'Alternative means of compliance' should not be confused with 'AMC'.

6. SPECIAL CONDITIONS (see point 21.B.75)

EASA may also prescribe special conditions in accordance with point 21.B.75. Guidance on special conditions is provided in GM 21.B.75.

21.B.82 Operational suitability data certification basis for an aircraft type-certificate or restricted type-certificate

Regulation (EU) 2019/897

The Agency shall establish the operational suitability data certification basis and notify it to the applicant for an aircraft type-certificate or restricted type-certificate. The operational suitability data certification basis shall consist of:

(a) the certification specifications for operational suitability data designated by the Agency out of those applicable to the aircraft at the date of the application or at the date of the application supplement for operational suitability data, whichever date is later, unless:

1. the applicant chooses to comply, or in accordance with point 21.A.15(f) is required to comply with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or

2. the Agency accepts or prescribes alternative means to demonstrate compliance with the relevant essential requirements of Annexes II, IV and V to Regulation (EU) 2018/1139.

(b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

GM 21.B.82 Operational suitability data (OSD) certification basis for an aircraft type certificate (TC) or restricted type certificate (RTC)

ED Decision 2019/018/R

1. INTRODUCTION

This GM addresses the OSD certification basis for a TC or an RTC.

2. APPLICABLE CERTIFICATION SPECIFICATIONS (CSs) (see point 21.B.80(a))

The OSD certification basis for a TC or an RTC consists of the OSD CSs that were applicable for that certificate and that were effective on the date of application for the TC or RTC or, if applicable, on the date of the application supplement.

The effectivity date of the initial application for the TC or RTC may be changed, as per point 21.A.15(f)(2), when the period of validity for an application for a type certificate is exceeded, or it is evident that it will be exceeded, and the applicant requests an extension; see GM 21.A.15(e) and (f). As a consequence, the OSD certification basis will be revised accordingly.

3. ELECT TO COMPLY (see point 21.B.82(a)(1))

It is also possible for an applicant to elect to comply with a CS that entered into force after the date on which the applicant has submitted the application.

EASA should assess whether the proposed certification basis is appropriate to ensure that the 'elect to comply' proposal includes any other CSs that are 'directly related' to one or several of the CSs in it.

Directly related CSs are those that are deemed to contribute to the same safety objective by building on each other's requirements, addressing complementary aspects of the same safety concern, etc. Typically, they are adopted simultaneously with, or prior to, the CSs with which the applicant has elected to comply.

4. EQUIVALENT LEVEL OF SAFETY (see point 21.B.82(a)(2))

In cases in which the applicable CS(s) cannot be literally complied with, either fully or in part, EASA may accept a suitable alternative which provides an equivalent level of safety through the use of appropriate compensating factors.

In cases in which the requirements contain not only objectives but also prescriptive parts, an equivalent level of safety may be accepted if:

— the objectives are met by designs or features other than those required in the CSs; or

— appropriate compensating factors are proposed.

5. ALTERNATIVE MEANS OF COMPLIANCE (see point 21.B.82(a)(2))

If the intent of the CSs defined in point 21.B.82(a) cannot be met, EASA may accept mitigating factors to the CSs, provided that the safety objective is met.

In the case of a TC, the alternative means should provide a demonstration of compliance with the essential requirements for airworthiness laid down in Annex II to Regulation (EU) 2018/1139.

In the case of an RTC, the alternative means should provide a sufficient level of safety for the intended use.

Note: 'Alternative means of compliance' should not be confused with 'AMC'.

6. SPECIAL CONDITIONS (see point 21.B.75).

EASA may also prescribe special conditions in accordance with point 21.B.75. Guidance on special conditions is provided in GM 21.B.75.

21.B.85 Designation of applicable environmental protection requirements for a type-certificate or restricted type-certificate

Regulation (EU) 2021/1088

(a) The Agency shall designate and notify to the applicant the applicable environmental protection requirements for a type-certificate or restricted type-certificate for an aircraft or for a type certificate for an engine. The designation and notification shall contain:

1. the applicable noise requirements established in:

(i) Annex 16 to the Chicago Convention, Volume I, Part II, Chapter 1 and:

(A) for subsonic jet aeroplanes, in Chapters 2, 3, 4 and 14;

(B) for propeller-driven aeroplanes, in Chapters 3, 4, 5, 6, 10, and 14;

(C) for helicopters, in Chapters 8 and 11;

(D) for supersonic aeroplanes, in Chapter 12; and

(E) for tilt rotors, in Chapter 13.

(ii) Annex 16 to the Chicago Convention, Volume I:

(A) Appendix 1 for aeroplanes for which Chapters 2 and 12 of Annex 16 to the Chicago Convention, Volume I, Part II are applicable;

(B) Appendix 2 for aeroplanes for which Chapters 3, 4, 5, 8, 13 and 14 of Annex 16 to the Chicago Convention, Volume I, Part II are applicable;

(C) Appendix 3 for aeroplanes for which Chapter 6 of Annex 16 to the Chicago Convention, Volume I, Part II is applicable;

(D) Appendix 4 for aeroplanes for which Chapter 11 of Annex 16 to the Chicago Convention, Volume I, Part II is applicable; and

(E) Appendix 6 for aeroplanes for which Chapter 10 of Annex 16 to the Chicago Convention, Volume I, Part II is applicable;

2. the applicable emissions requirements for preventions of intentional fuel venting for aircraft established in Annex 16 to the Chicago Convention, Volume II, Part II, Chapters 1 and 2;

3. the applicable smoke, gaseous and particulate matter engine emissions requirements established in:

(i) Annex 16 to the Chicago Convention, Volume II, Part III, Chapter 1 and:

(A) for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 2;

(B) for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion at supersonic speeds, in Chapter 3; and

(C) for particulate matter emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 4;

(ii) Annex 16 to the Chicago Convention, Volume II:

(A) Appendix 1 for the measurement of reference pressure ratio;

(B) Appendix 2 for smoke emissions evaluation;

(C) Appendix 3 for instrumentation and measurement techniques for gaseous emissions;

(D) Appendix 4 for specifications for fuel to be used in aircraft turbine engine emissions testing;

(E) Appendix 5 for instrumentation and measurement techniques for gaseous emissions from afterburning gas turbine engines;

(F) Appendix 6 for compliance procedure for gaseous, smoke and particulate matter emissions; and

(G) Appendix 7 for instrumentation and measurement techniques for non-volatile particulate matter;

4. the applicable aeroplane CO_2 emissions requirements established in:

(i) Annex 16 to the Chicago Convention, Volume III, Part II, Chapter 1, and:

(A) for subsonic jet aeroplanes, in Chapter 2; and

(B) for subsonic propeller-driven aeroplanes, in Chapter 2;.

(ii) Annex 16 to the Chicago Convention, Volume III, Appendices 1 and 2, for aeroplanes for which Chapter 2 of Annex 16 to the Chicago Convention, Volume III, Part II is applicable;

5. for engines, the applicable requirements in Annex 16 to the Chicago Convention, Volume II, Part IV and Appendix 8 concerning non-volatile particulate matter assessment for inventory and modelling purposes.

(b) (reserved).

GM1 21.B.85(a) Applicable environmental protection requirements

ED Decision 2021/011/R

1. APPLICABLE ENVIRONMENTAL PROTECTION REQUIREMENTS

The applicable environmental protection requirements are the Standards and Recommended Practices in Volume I, Volume II and Volume III of Annex 16 to the Chicago Convention for aircraft and engines for which the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139 applies. The applicable levels of amendment to Annex 16 to the Chicago Convention are those adopted in the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139.

2. AIRCRAFT NOISE

Guidance material for the application of the certification procedures for aircraft noise is presented in:

(a) Volume I of Annex 16 to the Chicago Convention:

(1) in Attachment A for equations for the calculation of maximum permitted noise levels as a function of take-off mass;

(2) in Attachment D for evaluating an alternative method of measuring helicopter noise during approach;

(3) in Attachment E for applicability of noise certification standards for propeller-driven aeroplanes; and

(4) in Attachment F for guidelines for noise certification of tilt rotors; and

(b) ICAO Doc 9501 'Environmental Technical Manual', Volume I 'Procedures for the Noise Certification of Aircraft', except Chapter 8.

3. FUEL VENTING

Guidance material for the application of the certification procedures for aircraft engine emissions is presented in ICAO Doc 9501 'Environmental Technical Manual' Volume II 'Procedures for the Emissions Certification of Aircraft Engines'.

4. ENGINE EMISSIONS

4.1. Guidance material related to engine emissions requirements

Guidance material for the application of the certification procedures for aircraft engine emissions is presented in:

(a) Attachment E to Appendix 3 to Volume II of Annex 16 to the Chicago Convention for the calculation of the emissions parameters; and

(b) ICAO Doc 9501 'Environmental Technical Manual' Volume II 'Procedures for the Emissions Certification of Aircraft Engines'.

4.2. Engine emissions requirements for inventory and modelling purposes

Aircraft engine manufacturers are required to calculate the nvPM mass and nvPM number system loss correction factors as per Appendix 8 to Volume II of Annex 16 to the Chicago Convention and to report them to the competent authority. The nvPM mass and number system loss correction factors permit an estimation of the nvPM mass and number emissions at the exhaust of the aircraft engine from the nvPM mass and number concentration obtained in accordance with the procedures laid down in Appendix 7 to Volume II of Annex 16 to the Chicago Convention.

5. AEROPLANE CO_2 EMISSIONS

Guidance material for the application of the certification procedures for aeroplane CO_2 emissions is contained in ICAO Doc 9501 'Environmental Technical Manual', Volume III 'Procedures for the CO_2 Emissions Certification of Aeroplanes'.

21.B.100 Level of involvement

Regulation (EU) 2019/897

(a) The Agency shall determine its involvement in the verification of the compliance demonstration activities and data related to the application for a type-certificate, restricted type-certificate, major change approval, supplemental type certificate, major repair design approval or ETSO authorisation for APU. It shall do so on the basis of an assessment of meaningful groups of compliance demonstration activities and data of the certification programme. That assessment shall address:

— the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements; and

— the potential impact of that non-compliance on product safety or environmental protection,

and consider at least the following elements:

1. novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
2. complexity of the design and/or demonstration of compliance;
3. criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and
4. performance and experience of the design organisation of the applicant in the domain concerned.

(b) For the approval of a minor repair design, minor change or ETSO authorisation other than for APU, the Agency shall determine its involvement at the level of the entire certification project, taking into account any novel or unusual features, complexity of the design and/or demonstration of compliance, criticality of the design or technology, as well as the performance and experience of the applicant's design organisation.

(c) The Agency shall notify its level of involvement to the applicant and it shall update its level of involvement when this is warranted by information which has an appreciable impact on the risk previously assessed pursuant to point (a) or (b). The Agency shall notify the applicant about the change in the level of involvement.

AMC 21.B.100(a) and 21.A.15(b)(6) Level of involvement (LoI) in a certification project for a type certificate (TC), a major change to a TC, a supplemental type certificate (STC), a major repair design or European technical standard order (ETSO) authorisation for an auxiliary power unit (APU)

ED Decision 2019/018/R

1. Definitions

Risk: the combination of the likelihood and the potential impact of a non-compliance with part of the certification basis.

Likelihood: a prediction of how likely an occurrence of non-compliance with part of the certification basis is, based on a combination of the novelty and complexity of the proposed

design and its related compliance demonstration activities, as well as on the performance of the design organisation.

Criticality: a measure of the potential impact of a non-compliance with part of the certification basis on product safety or on the environment.

Compliance demonstration item (CDI): a meaningful group of compliance demonstration activities and data of the certification programme, which can be considered in isolation for the purpose of performing a risk assessment.

EASA panel: an EASA panel is composed of one or more experts who are responsible for a particular technical area. Each technical area addressed during product certification is covered by an EASA panel.

EASA discipline: an EAS447

A discipline is a technical subarea of an EASA panel.

EASA's level of involvement (LoI): the compliance demonstration activities and data that EASA retains for verification during the certification process, as well as the depth of the verification.

2. Background

The applicant has to submit a certification programme for their compliance demonstrations in accordance with point 21.A.15(b). The applicant has to break down the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as 'CDIs', and provide their proposal for EASA's LoI.

The applicant should also indicate the EASA panel(s) that is (are) affected by each CDI.

This AMC explains:

(a) how to propose EASA's LoI for each CDI as per points 21.A.15(b)(6), 21.A.93(b)(3)(iii), 21.A.432C(b)(6) as well as 21.A.113(b); and

(b) how EASA will determine its LoI on the basis of the criteria established in point 21.B.100.

EASA will review the proposal and determine its LoI. Both parties, in mutual trust, should ensure that the certification project is not delayed through the LoI proposal and determination.

Additionally, in accordance with point 21.A.20, the applicant has the obligation to update the certification programme, as necessary, during the certification process, and report to EASA any difficulty or event encountered during the compliance demonstration process which may require a change to the LoI that was previously notified to the applicant.

In such a case, or when EASA has other information that affects the assumptions on which the LoI was based, EASA will revisit its LoI determination.

In accordance with points 21.A.33, 21.A.447 and 21.A.615, irrespective of the LoI, EASA has the right to review any data and information related to compliance demonstration.

Note: This AMC should not be considered to be interpretative material for the classification of changes or repairs.

3. Principles and generic criteria for the LoI determination EASA determines its LoI based on the applicant's proposal in view of the risk (the combination of the likelihood of an unidentified non-compliance and its potential impact). This is performed after proper familiarisation with the certification project in three steps:

— Step 1: identification of the likelihood of an unidentified non-compliance,

— Step 2: identification of the risk class, and

— Step 3: determination of EASA's LoI.

This AMC contains criteria, common to all EASA panels, for the determination of:

— any novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;

— the complexity of the design and/or compliance demonstration;

— the performance and experience of the design organisation of the applicant in the domain concerned;

— the criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and

— the data and activities to be retained by EASA.

Note: Additional panel-specific criteria are available in further informative material published by EASA[1]. This material should not be considered to be AMC.

For CS-23 commuter (or CS-23 level 4 airplanes as defined in CS-23 Amdt 5), CS-25, CS-27 and CS-29 aircraft, all the panel-specific additional criteria should be considered. For the other products, the panel-specific criteria should only be considered for CDIs that affect noise, propulsion, development assurance and safety assessment (DASA), operational suitability data (OSD) and software and airborne electronic hardware.

The criteria used to determine the likelihood and the potential impact of an unidentified non-compliance generally allow a proportionate approach to be applied, in particular in order to differentiate between CS-25 and general aviation (GA) aircraft projects.

3.1. LoI determination at CDI level

The determination of EASA's LoI is performed at the level of the CDI (please refer to AMC 21.A.15(b)(5)).

The applicant should demonstrate that all the affected elements of the type-certification basis as specified in point 21.B.80, of the OSD certification basis as specified in point 21.B.82, and of the environmental protection requirements as specified in 21.B.85, the corresponding means and methods of compliance, as well as the corresponding certification activities and data, are fully covered by the proposed CDIs. If the provided data does not clearly show that this is the case, the applicant should clearly state to EASA that all the above-mentioned elements are fully covered.

Note: There could be different ways to 'clearly show' that all the elements of the certification basis are included in at least one CDI. For instance, this could be achieved by means of a 'CDI reference' column added in the table that lists all the elements of the certification basis.

[1] Such additional criteria are contained as an attachment to the EASA Certification Memorandum (CM) CM-21.A/21.B-001, available at: https://www.easa.europa.eu/document-library/product-certification-consultations/cm-21a21b-001.

3.2. Method for determining the likelihood of an unidentified non-compliance

3.2.1. Principle The likelihood of an unidentified non-compliance is assessed on the basis of the following criteria:

— novelty,

— complexity, and

— the performance of the design organisation.

3.2.2. Novelty

For the purpose of risk class determination, the following simplification has been made: a CDI may be either novel or non-novel.

Whether or not a CDI is novel is based on the extent to which the respective elements of the certification project, as well as the related requirement or means of compliance, are new/novel to either the industry as a whole, or to the applicant, including their subcontractors, or from an EASA panel perspective.

The determination that a CDI is novel may be driven by the use of new technology, new operations, new kind of installations, the use of new requirements or the use of new means of compliance.

When an applicant utilises a type of technology for the first time, or when that applicant is relatively unfamiliar with the technology, this technology is considered to be 'novel', even if other applicants may be already familiar with it. This also means that a type of technology may no longer be novel for one applicant, while it may still be novel for other applicants.

The following list includes some examples:

— new materials or combinations of materials;

— a new application of materials or combinations of materials;

— new manufacturing processes;

— a new or unusual aircraft configuration and/or system architecture;

— a novel reconfiguration of systems;

— a new interface or interaction with other parts or systems;

— the unusual location of a part or a system, or an unusual construction;

— a new or unusual use;

— new functions;

— new kinds of operations;

— the potential for new failure modes;

— the introduction of a new threat (e.g. new threats regarding fire, fuel, hydrogen, energy storage devices, etc.) or a new prevention/detection/mitigation method;

— new maintenance techniques;

— novel operating conditions or limitations;

— a new human-machine interface (HMI); or

— new flight or cabin crew tasks.

Another consideration is the extent to which the requirements, means of compliance or guidance have changed or need to be adapted due to particular novel features of the design.

The following list includes some examples:

— recently issued or amended CSs with which the applicant has little or no experience;

— new or adapted special conditions;

— new or adapted equivalent safety findings;

— new or adapted deviations;

— new or adapted guidance or interpretative material;

— new or adapted means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices), e.g. the replacing of tests by simulation, numerical models or analytical methods;

— the use of new or adapted industry standards or in-house methods, as well as EASA's familiarity with these standards and methods;

— a change in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs; or

— novelty in the interpretation of the results of the compliance demonstration, e.g. due to in-service occurrences (compliance demonstration results are interpreted differently from the past).

Additional new guidance/interpretative material in the form of new certification memoranda (CM) may be considered for the determination of novelty if its incorrect application/use may lead to an unidentified non-compliance. In the context of novelty, the time between the last similar project and the current project of the applicant should also be considered.

Regardless of the extent of an organisation's previous experience in similar projects, a CDI may be classified as novel if there are specific discontinuities in the process for transferring information and know-how within the organisation.

3.2.3. Complexity For the purpose of risk class determination, the following simplification has been made: a CDI may be either complex or non-complex. For each CDI, the determination of whether it is complex or not may vary based on factors such as the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), interpretation of the results of the compliance demonstration, interfaces with other technical disciplines/CDIs, and the requirements. The compliance demonstration may be considered to be

'complex' for a complex (or highly integrated) system, which typically requires more effort from the applicant. The following list includes some examples:

— Compliance demonstration in which challenging assessments are required, e.g.:
  — for requirements of a subjective nature, i.e. they require a qualitative assessment, and do not have an explicit description of the means of compliance with that requirement, or the means of compliance are not a common and accepted practice; this is typically the case where the requirement uses terms such as 'subjective', 'qualitative', 'assessment' or 'suitable'/'unsuitable'
  — in contrast, engineering judgement for a very simple compliance demonstration should not be classified as 'complex';
  — a test for which extensive interpretation of the results may be anticipated;
  — an analysis that is sensitive to assumptions and could potentially result in a small margin of safety;
  — the classification of structures, depending on the conservatism of the method;
  — an advanced analysis of dynamic behaviour;
  — a multidisciplinary compliance demonstration in which several panels are involved and interface areas need to be managed (e.g. sustained engine imbalance, extended-range twin-engine operation performance standards (ETOPS), 2X.1309 assessment, flight in known icing conditions, full authority digital engine control (FADEC)-controlled engines, etc.);
  — when the representativeness of a test specimen is questionable, e.g. due to its complexity;
— the introduction of complex work-sharing scheme with system or equipment suppliers.

For major changes, the complexity of the change should be taken into account, rather than the complexity of the original system.

Whether or not a CDI is complex should be determined in a conservative manner if this cannot be determined at an early stage of the certification project. When greater clarity has been achieved, the complexity may be re-evaluated and the LoI adapted accordingly.

3.2.4. Performance of the design organisation

The assessment of the level of performance of the design organisation takes into account the applicant's experience with the applicable certification processes, including their performance on previous projects and their degree of familiarity with the applicable certification requirements.

For approved design organisations, EASA uses relevant data to consider the design organisation's expected performance at an organisational, panel or discipline level, depending on the availability of data[1].

This data stems from design organisation audits, the applicant's measured level of performance on previous projects, and their performance during the familiarisation phase. EASA shares this data with the respective design organisations (in the form of the design organisation approval (DOA) dashboard).

For each CDI proposed by the applicant, the DOA holder's performance associated with the affected disciplines or panels is to be considered.

If one CDI affects more panels or disciplines than the others, a conservative approach should be followed in selecting the lower performance level. As an alternative, that CDI may be assessed separately for each affected EASA panel or discipline.

If, for a well-established organisation, there is no shared performance data available at the panel level, it may be acceptable to propose the overall DOA holder's performance. If the organisation or its scope are fundamentally new, the 'unknown' level of performance should be conservatively proposed by the applicant.

The determination of the performance of the design organisation may also take into consideration information that is more specific or more recent than the information on the DOA holder's dashboard, e.g. experience gained during technical familiarisation with the current certification project, the performance of compliance verification engineers and of the affected technical areas, as well as the performance of the design organisation in overseeing subcontractors and suppliers.

The performance of some applicants' organisations is not known if:

— EASA has agreed in accordance with point 21.A.14(b) that the applicants may use procedures that set out specific design practices, as an alternative means to demonstrate their capability (excluding European technical standard order (ETSO) applicants for other than APU, covered by point 21.B.100(b)); or

— the applicants demonstrate their capability by providing EASA with the certification programme in accordance with point 21.A.14(c).

In these cases, the assumed level of performance is 'unknown'.

Exceptionally, EASA may consider a higher level of performance for a specific CDI if that is proposed and properly justified by the applicant.

The following list includes some examples:

— a CDI with which EASA is fully familiar and satisfied (from previous similar projects) regarding the demonstration of compliance proposed by the applicant;

— if the applicant fully delegates the demonstration of compliance to a supplier that holds a DOA, the performance level of the supplier may be proposed.

[1] The ultimate objective is to define the organisation's performance at the discipline level.

3.2.5. Likelihood of an unidentified non-compliance

Assessing the likelihood of an unidentified non-compliance is the first step that is necessary to determine the risk class.

The likelihood of an unidentified non-compliance should not be confused with the likelihood of occurrence of an unsafe condition as per AMC 21.A.3B(b). In fact, that AMC provides EASA's confidence level that the design organisation addresses all the details of the certification basis for the CDI concerned, and that a non-compliance will not occur.

The likelihood of an unidentified non-compliance is established as being in one of four categories (very low, low, medium, high), depending on the level of performance of the design organisation as assessed by EASA, and on whether the CDI is novel or complex, as follows:

Step 1 — Likelihood of an unidentified non-compliance			
CDI Performance level of the DOAH	No novel aspects, no complex aspects	No novel aspects, but complex ones; Novel aspects, but no complex ones	Novel and complex aspects
High	Very low	Low	Medium
Medium	Low	Medium	High
Low or unknown	Medium	High	High

3.3. Criticality

The second step that is necessary to determine the risk class is the assessment of the potential impact of a non-compliance on part of the certification basis regarding the airworthiness or the environmental protection of the product. For the purpose of risk class determination, the following simplification has been made: the impact of a non-compliance can be either critical or non-critical.

Some of the guidance below has been derived from GM 21.A.91, not due to a major/minor change classification, but because the same considerations may be applied to determine the effect of a non-compliance on the airworthiness or environmental protection at the CDI level. It is therefore normal that some of the CDIs of a major change that consists of several CDIs may be critical, and others may be non-critical.

The potential impact of a non-compliance within a CDI should be classified as critical if, for example:

— a function, component or system is introduced or affected where the failure of that function, component or system may contribute to a failure condition that is classified as hazardous or catastrophic at the aircraft level, for instance for 'equipment, systems and installations', e.g. where applicable as defined in 2X.1309;

— a CDI has an appreciable effect on the human–machine interface (HMI) (displays, approved procedures, controls or alerts);

— airworthiness limitations or operating limitations are established or potentially affected;

— a CDI is affected by an existing airworthiness directive (AD), or affected by an occurrence (or occurrences) potentially subject to an AD, a known in-service issue or by a safety information bulletin (SIB); or

— a CDI affects parts that are classified as critical as per CS 27.602/29.602, CS-E 515, or that have a hazardous or catastrophic failure consequence (e.g. a principal structural element as per CS 25.571).

If the classification of the potential impact of a non-compliance within a CDI as critical is based on the criterion that the CDI is affected by an AD, then the impact of a non-compliance within that CDI may be reclassified by EASA as non-critical due to the involvement of EASA in the continued-airworthiness process.

During the early stages of a project, the criticality in terms of the potential safety consequence of a failure may not always be known, but should be conservatively estimated and the LoI should be subsequently re-evaluated, if appropriate. 3.4. Method for the determination of risk classes The risk is determined as a combination of the potential impact of an unidentified non-compliance with part of the certification basis (vertical axis) and of the likelihood of the unidentified non-compliance (horizontal axis) using the following matrix. As a consequence, four qualitative risk classes are established at the CDI level.

Step 2 — Risk classes				
Likelihood (see Section 3.2.5) Criticality (see Section 3.3)	Very low	Low	Medium	High
Non-critical	Class 1	Class 1	Class 2	Class 3
Critical	Class 1	Class 2	Class 3	Class 4

The various inputs and the resulting risk class determination are of a continuous nature, rather than consisting of discrete steps. The selected risk class provides the order of magnitude of EASA's involvement and is used as a qualitative indicator for the determination of EASA's involvement described in Section 3.5 below.

Under specific circumstances, the risk class that is determined on the basis of the above criteria may be reduced or increased on the basis of justified and recorded arguments. For a reused and well-proven item of compliance demonstration for which:

— the CDI is independent of the affected product type or model; and

— the design, operation, qualification, and installation of the product are basically the same; and

— the certification process is identical to one that was used in a modification already approved by EASA,

the CDI may be accepted as being similar, resulting in reduced LoI, as the likelihood of an unidentified non-compliance is low. Furthermore, when an identical CDI is reused for the compliance demonstration in a new project, there is no involvement in the compliance demonstration verification, as the likelihood of an unidentified non-compliance is very low.

3.5. Determination of EASA's LoI

EASA's LoI in the verification of compliance demonstration is proposed by the applicant and determined by EASA in Step 3 on the basis of the qualitative risk class identified per CDI in Step 2, as well as by applying sound engineering judgement.

EASA's LoI is reflected in a list of activities and data, in which EASA retains the verification of compliance demonstration (e.g. review and acceptance of compliance data, witnessing of tests, etc.), as well as the depth of the verification. The depth of the verification for individual compliance reports, data, test witnessing, etc., may range from spot checks to extensive reviews. EASA always responds to those retained compliance demonstration activities and data with corresponding comments or a 'statement of no objection'.

In addition, some data that is not retained for verification may be requested for information. In this case, no 'statement of no objection' will be provided.

It is recommended that an LoI should be proposed for each of the EASA disciplines involved. Depending on the risk classes determined in Section 3.4 above, EASA's LoI in:

(a) compliance demonstration verification data; and

(b) compliance demonstration activities (witnessing of tests, audits, etc.),

may be as follows:

— risk Class 1: there is no EASA involvement in verifying the compliance data/activities performed by the applicant to demonstrate compliance at the CDI level;

— risk Class 2: EASA's LoI is typically limited to the review of a small portion of the compliance data; there is either no participation in the compliance activities, or EASA participates in a small number of compliance activities (witnessing of tests, audits, etc.);

— risk Class 3: in addition to the LoI defined for Class 2, EASA's LoI typically comprises the review of a large amount of compliance data, as well as the participation in some compliance activities (witnessing of tests, audits, etc.); and

— risk Class 4: in addition to the LoI defined for Class 3, EASA's LoI typically comprises the review of a large amount of compliance data, the detailed interpretation of test results, and the participation in a large number of compliance activities (witnessing of tests, audits, etc.).

By default, the following activities require EASA's involvement in all cases:

— initial issues of, and changes to, a flight manual (for those parts that require EASA approval and that do not fall under the DOA holder's privilege);

— classification of failure cases that affect the handling qualities and performance, when:

  — performed through test (in flight or in a simulator); and

  — initial issues of, and non-editorial changes to, airworthiness limitations.

If the risk assessment (Steps 1 and 2 above) is made on the level of a compliance demonstration activity or on the level of a document, the risk class provides an indication for the depth of the involvement, i.e. the verification may take place only for certain compliance data within a compliance document.

4. Documentation of the LoI

The LoI proposal in the certification programme should include the applicant's proposal regarding the compliance demonstration verification activities and data that would be retained by EASA, as well as the data on which the LoI proposal has been based. For this purpose, the applicant should appropriately document the analysis per CDI, considering the above criteria.

In cases where the rationale for the assessment is obvious, it is considered to be sufficient for the applicant to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

EASA documents the LoI determination by accepting the certification programme or, if it deviates from the proposal, by recording its analysis regarding the deviations from the proposal, and notifies the applicant accordingly.

5. Sampling during surveillance of the DOA holder

It should be noted that all the previously defined risk classes may be complemented by the sampling of project files during surveillance of the DOA holder, independently from the ongoing certification project. This is necessary in order to maintain confidence in the DOA system and to constantly monitor its performance.

AMC No 1 to 21.B.100(b) Level of involvement (LoI) in projects for minor changes and minor repairs

ED Decision 2019/018/R

In contrast to 21.B.100(a), the assessment of the LoI for minor repair designs and minor changes is performed by EASA at the level of the certification project.

EASA reviews the information provided by the applicant in accordance with point 21.A.93(b) for novel or unusual features, the complexity of the design and/or the compliance demonstration, as well as the criticality of the design or technology.

An application for EASA's approval of a minor change implies that the applicant either does not hold a design organisation approval (DOA) or that the change is outside the DOA holder's terms of approval. However, EASA takes into account the performance and experience of the applicant with similar design changes, for which data may be already available at EASA. The applicant may be also requested to present its experience with similar design changes if insufficient information is available at EASA.

By definition (see point 21.A.91), a minor change has no appreciable effect on the airworthiness of the product. Therefore, the potential impact of a non-compliance with part of the certification basis regarding the airworthiness or environmental protection aspects of the product should, in most cases, be non-critical.

This facilitates the assessment of the likelihood of an unidentified non-compliance.

A process similar to the one described in AMC 21.B.100(a) and 21.A.15(b)(6) should be used to justify and document EASA's LoI.

Following a first assessment of the criticality of the described design or technology, EASA evaluates the existence of any novel or unusual features, as well as the complexity of the design and/or the compliance demonstration.

Depending on the results of this evaluation, and based on the table below, EASA determines its LoI as follows:

		Risk class	
Non-critical	Non-novel and non-complex	Class A	Class A
	Novel and/or complex	Class B	Class C
Critical	All cases	Class C	Class C
		Level of experience: high or medium	**Level of experience: low or unknown**

— Class A: EASA's involvement is limited to the review of the information that summarises the main results of the compliance demonstration, without any participation in compliance activities (witnessing of tests, audits, etc.).

— Class B: in addition to the LoI defined for risk Class A, EASA's involvement is limited to the review of those compliance elements that are related to the identified novel or unusual features, complexity of the design and/or compliance demonstration. EASA may exceptionally participate in the related compliance activities (by witnessing tests, audits, etc.).

— Class C: EASA's involvement is limited to the review of all the compliance documents that are related to the identified criticality of the design or technology, if applicable, or to the identified novel or unusual features. EASA may participate in the related compliance activities (by witnessing tests, audits, etc.).

AMC No 2 to 21.B.100(b) Level of involvement (LoI) in European technical standard order authorisation (ETSOA) projects

ED Decision 2019/018/R

The applicant for an ETSOA is required to demonstrate its capability by obtaining EASA's agreement for the use of procedures that incorporate its specific design practices.

The assessment by EASA that these procedures are properly applied is performed solely through the various ETSOA projects of the applicant. No regular audits of the organisation are performed by EASA outside the ETSOA projects.

A properly completed Form 34 and the certification programme, including a technical description of the proposed design of the ETSO article, are the basis for the determination of EASA's initial LoI.

EASA assesses the compliance of the proposed ETSO article with the ETSO requirements as defined in the applicable CS-ETSO standards, as well as compliance with Part 21 Subpart O (e.g. the declaration of design and performance (DDP), ETSO marking, rating of performance, etc.). The ETSOA applicant should deliver a complete data package per point 21.A.605.

EASA's LoI is further reassessed and adapted throughout the certification project until the ETSOA is issued, depending on the applicant's data, as well as on the ETSO project changes regarding the applicant's compliance demonstration (e.g. methods, design changes, deviations, limitations, problem reports, etc.).

1. Principles

EASA's LoI in ETSO projects is defined based both on the responsibility of EASA to assess the applicant's demonstration of compliance, and on the risk evaluated, according to the following criteria:

— the applicant's level of experience in the ETSO process and scope of work;

— the applicant's level of performance in the ETSO scope of work;

— the use of novelties in the technology/design or in the means of compliance; and

— the complexity of the ETSO article.

1.1. Applicant's experience in the ETSOA process and scope of work

This Section addresses the experience of the applicant's organisation in the ETSOA process, as well as in the scope of the certification basis of the ETSO article, and of the related requirements. The presence of any of the following aspects contributes to EASA's identification of the risk related to the level of experience of the applicant in the ETSOA process, or to the scope of work of the article:

— the applicant is new and has just applied for the acceptance of its procedures by EASA, or it is the first project of the applicant after EASA has accepted such procedures;

— the organisation has changed significantly the agreed procedures; and

— the scope of work of the ETSOA project (ETSO standards) is new to the applicant.

1.2. ETSOA applicant's performance within its scope of work

The ETSOA applicant's level of performance within its scope of work is evaluated using criteria that enable EASA to identify risks in the applicant's performance due to the following situations:

— the applicant has deficiencies in the procedures that it uses to demonstrate compliance with the certification requirements;

— the applicant has changed its methods or procedures to demonstrate compliance with the certification requirements;

— the assessment of the applicant's compliance on previous projects in the same ETSO scope of work has revealed significant issues in complying with the certification requirements, in the completion of data, or in the repetition of errors;

— the scope of work is new to the applicant's team at the facilities where the project is developed, or the team had significant issues on preceding projects;

— EASA has not conducted an ETSOA project assessment of the applicant in the same ETSO scope of work for a long period (i.e. 2 or 3 years); and

— the applicant did not regularly report minor changes or occurrences in a timely manner.

1.3. Novelty in the technology or in the means of compliance

A 'novelty' is understood to be the use of new technology, new sensors, new material, the use of new requirements or the use of new means of compliance. When an applicant is faced with a technology for the first time, or when that applicant is relatively unfamiliar with the technology, this is considered to be 'novel' even if other applicants may be already familiar with that technology.

Also related to novelty is the extent to which requirements, means of compliance or guidance need to be adapted due to particular novel features of the design. The following list includes some examples:

— recently issued CS-ETSO standards, with which the applicant has limited experience;

— novel deviations;

— new guidance;

— new means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices);

— the use of new industry standards or new in-house methods, as well as EASA's familiarity with these new standards and methods;

— changes in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs.

Technology or means of compliance may be new/novel either from a global industry, applicant or EASA perspective.

1.4. Complexity

Complexity may result from the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), as well as from the variety of ETSOs with which the applicant intends to comply, and their possible interactions.

The demonstration of compliance may be 'complex' for complex (or highly integrated) equipment, so it typically requires more effort from the applicant.

1.5. Criticality of the design and of the technology

The criticality levels of the design and of the technology of the ETSO article are considered, but have a minor impact on the definition of EASA's LoI. The main reasons are:

— the assessment of ETSO compliance is as important for an ETSO article that hosts a critical function as it is for equipment that host less critical functions (e.g. flight data recorders); and

— the criticality of the design or technology is not always defined for an ETSO article, and it may depend on the installation of the design or technology (e.g. a multifunction display), which may only occur later.

2. Determination of EASA's LoI

EASA's LoI in the assessment of the applicant's compliance demonstration is determined by EASA on the basis of the qualitative risk class and EASA's responsibilities in assessing the ETSO project certification data package, together with the procedures for compliance with the ETSO requirements (Part 21 Subpart O, and CS-ETSO).

EASA's LoI is defined in the following paragraph 2.1 and, as per point 21.B.100(c), the EASA's LoI that is applicable to each project is notified to the applicant.

To every LoI class corresponds a list of activities that govern EASA's involvement. By means of these activities, EASA verifies the demonstration of compliance (e.g. by document review and acceptance, test witnessing, sampling on the applicant's site, desktop assessments, etc.).

The ETSO applicant is responsible for providing a complete ETSO certification data package.

2.1. Definition of the LoI classes

EASA's LoI for an ETSO certification project is classified as one of the following:

— class high,

— class high reduced,

— class medium, or

— class basic.

Class 'high reduced' is, by default, EASA's initial LoI in an ETSO project.

The following is a description of each LoI class:

— High

EASA evaluates and samples/checks in an extensive manner all the compliance data to assess the applicant's demonstration of compliance with the applicable ETSO standards. EASA assesses the applicant's DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews, as well as on-site assessments of compliance demonstrations. This occurs when design and verification evidence is available.

— High reduced

EASA assesses all the compliance data; sampling/checking is significant and adapted to the likelihood of an unidentified non-compliance. The sampling rate may be reduced if the content of the life cycle data provides confidence in compliance and is focused in the area where confidence needs to be gained. EASA assesses the DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews, as well as an on-site assessment of the applicant's compliance demonstration. This occurs when design and verification evidence is available.

— Medium

EASA assesses all the compliance data, but for some compliance data, it performs no or limited sampling/checking. EASA adapts its sampling and focuses on the likelihood of an unidentified non-compliance, taking into account the level of complexity and novelty of the project. EASA assesses the DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews and may perform an on-site assessment of the applicant's compliance demonstration.

— Basic

EASA assesses the DDP and general compliance with Part 21 Subpart O, and verifies the completeness of the data package.

Generally, EASA performs a desktop assessment.

3. The process of determining EASA's LoI

The determination of EASA's LoI is captured as a process. This process is performed mainly in three steps and is illustrated in the following figure:

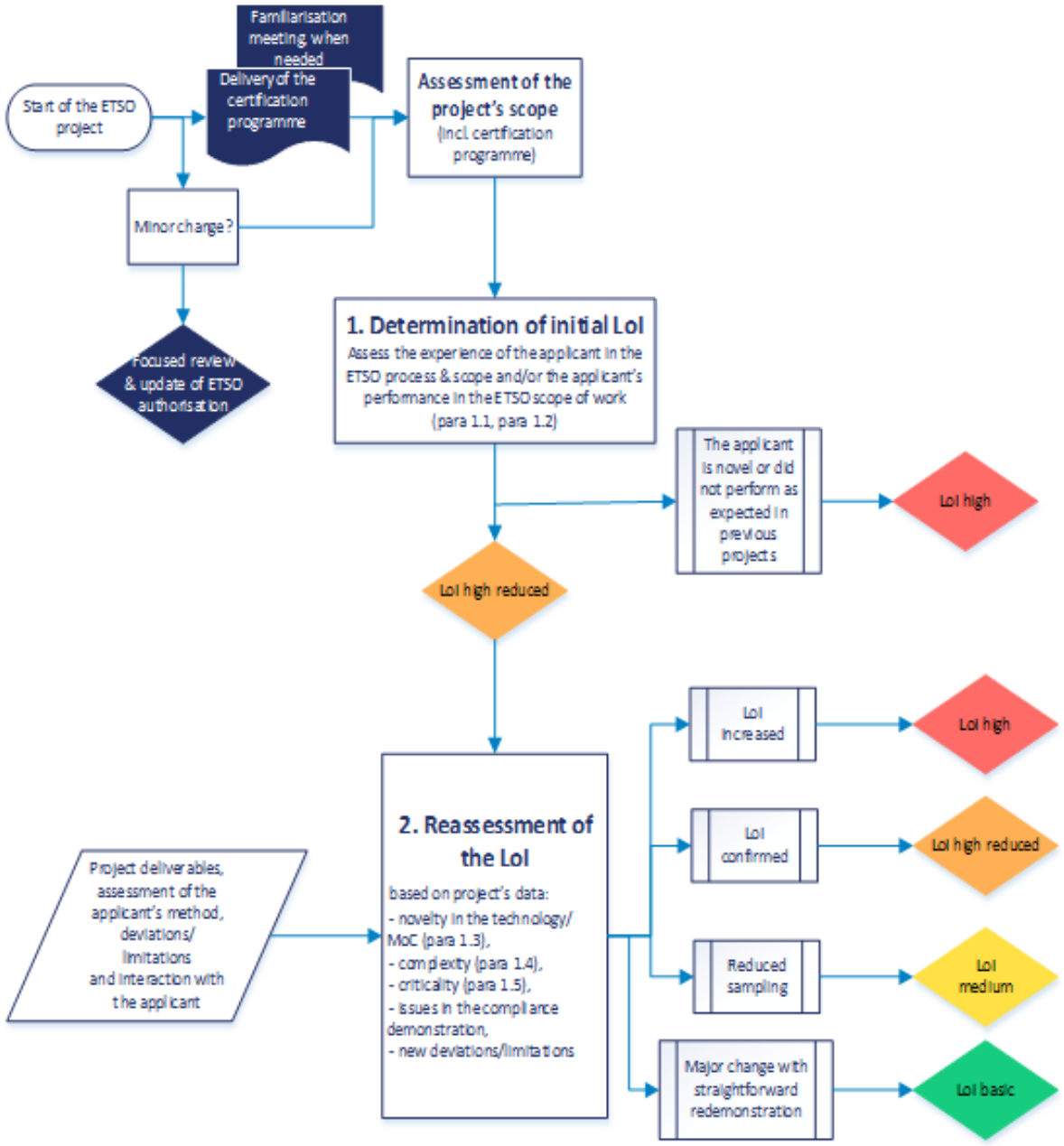


Figure 1: Process of determination of EASA's LoI in ETSO certification projects

Step 1 consists of the initial LoI determination which EASA evaluates by assessing:

- the applicant's experience in the ETSOA process and scope of work according to Section 1.1 above, and
- the ETSOA applicant's performance within its scope of work according to Section 1.2 above.

The result of this determination of EASA's initial LoI is either high or high reduced.

Step 2 consists of reassessing EASA's LoI. Throughout the ETSO project, EASA receives project deliverables (e.g. plans, reports), means of compliance, requests for deviations, limitations, etc., and interacts with the applicant.

If EASA's LoI has been initially set to high reduced, EASA re-evaluates it considering:

— the novelty in the technology or in the means of compliance according to Section 1.3 above, and

— the complexity of the ETSO project according to Section 1.4 above.

The result of this reassessment may vary from high to medium according to the following table:

Assessment results	LoI adaptation
The ETSO article is novel and complex or a significant issue is detected during the compliance demonstration.	LoI is increased to high.
The ETSO article is novel or complex or a new deviation is requested ([1]).	LoI is confirmed as high reduced.
The ETSO article is non-novel and non-complex, no issue is detected during the compliance demonstration or method, and no novel deviation or new limitation is requested.	LoI is decreased to medium.
There is a major change with straightforward redemonstration of the ETSO compliance ([2]).	LoI is reduced to basic.

1 It refers to deviations from ETSO minimum operational performance standards (MOPSs), excluding deviations for requesting compliance with a new revision of an industry MOPS standard.

2 When EASA agrees that a major change only requires a straightforward redemonstration of the ETSO compliance using previous methods, without any identified risk, then EASA's LoI is reduced to basic. Please note that this may only be defined after a minimum assessment of the applicant's compliance demonstration methods.

Note: For a minor change, this process does not apply; in that case, EASA's LoI consists of an assessment of the minor change classification, an update of the certificate, and, when needed, an assessment of the DDP.

21.B.103 Issuance of a type-certificate or a restricted type-certificate

Regulation (EU) 2022/201

(a) The Agency shall issue an aircraft, engine or propeller type-certificate or an aircraft restricted type-certificate, provided that:

1. the applicant has complied with point 21.A.21;

2. the Agency, through verifications of the demonstration of compliance in accordance with its involvement determined pursuant to point 21.B.100, has not found any non-compliance with the type-certification basis, the operational suitability data certification basis where applicable in accordance with point 21.B.82, and the environmental protection requirements; and

3. no feature or characteristic has been identified that may make the product unsafe for the uses for which the certification is requested.

(b) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

(SUBPART C — NOT APPLICABLE)

SUBPART D — CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.B.105 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a major change to a type-certificate

Regulation (EU) 2019/897

The Agency shall establish the applicable type-certification basis, the environmental protection requirements, and in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a major change to a type certificate.

21.B.107 Issuance of an approval of a change to a type-certificate

Regulation (EU) 2022/201

(a) The Agency shall issue an approval of a change to a type-certificate provided that:

1. the applicant for an approval has complied with:

   (i) point 21.A.95 for a minor change; or

   (ii) point 21.A.97 for a major change;

2. the Agency, through its verification of the demonstration of compliance in accordance with the level of its involvement determined pursuant to point (a) or (b) of point 21.B.100 has not found any non-compliance with the type-certification basis, operational suitability data certification basis where applicable in accordance with point 21.B.82, and environmental protection requirements; and

3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(b) In the case of a change affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may approve a change to an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(c) The approval of the changes to the operational suitability data shall be included in the approval of the change to the type-certificate.

(d) The approval of a change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

GM 21.B.107 and 21.B.111 Operational suitability data (OSD) considerations for the approval of changes to type certificates (TCs) or supplemental type certificates (STCs)

ED Decision 2019/018/R

The requirement for EASA in points 21.B.107(c) or 21.B.111(c) are applicable to necessary changes to the OSD as foreseen by 21.A.95(b) Section 2 for minor changes, 21.A.97(b) Section 2 for major changes, and 21.A.115(b) Section 3 for STCs. By analogy, these requirements should also be considered by design organisation approval (DOA) holders that approve changes or issue supplemental type certificates (STCs) under their privileges (without EASA's involvement), as stated in the GM to A.21.A.90A.

Changes to TCs can comprise several interrelated changes to the TC. For example, a change to the cockpit design may trigger a necessary change to the flight crew data, which is part of the OSD, and is, therefore, included in the TC.

Interrelated changes (e.g. type design changes and necessary changes to the MMEL and/or flight crew data) should be approved together under a single approval.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES

21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type-certificate

Regulation (EU) 2019/897

The Agency shall establish the applicable type-certification basis, the environmental protection requirements and, in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a supplemental type-certificate.

21.B.111 Issuance of a supplemental type-certificate

Regulation (EU) 2022/201

(a) The Agency shall issue a supplemental type-certificate, provided that:

1. the applicant has complied with point 21.A.115(b);
2. the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement established pursuant to point 21.B.100(a), has not found any non-compliance with the type-certification basis, operational suitability data certification basis where applicable in accordance with point 21.B.82, and environmental protection requirements; and
3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(b) In the case of a supplemental type-certificate affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue a supplemental type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(c) The approval of the changes to the operational suitability data shall be included in the supplemental type-certificate.

(d) The supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.

GM 21.B.107 and 21.B.111 Operational suitability data (OSD) considerations for the approval of changes to type certificates (TCs) or supplemental type certificates (STCs)

ED Decision 2019/018/R

The requirement for EASA in points 21.B.107(c) or 21.B.111(c) are applicable to necessary changes to the OSD as foreseen by 21.A.95(b) Section 2 for minor changes, 21.A.97(b) Section 2 for major changes, and 21.A.115(b) Section 3 for STCs. By analogy, these requirements should also be considered by design organisation approval (DOA) holders that approve changes or issue

supplemental type certificates (STCs) under their privileges (without EASA's involvement), as stated in the GM to A.21.A.90A.

Changes to TCs can comprise several interrelated changes to the TC. For example, a change to the cockpit design may trigger a necessary change to the flight crew data, which is part of the OSD, and is, therefore, included in the TC.

Interrelated changes (e.g. type design changes and necessary changes to the MMEL and/or flight crew data) should be approved together under a single approval.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

21.B.115 Means of compliance

Regulation (EU) 2022/203

(a) The Agency shall develop acceptable means of compliance ('AMC') that may be used to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(b) Alternative means of compliance may be used to establish compliance with this Regulation.

(c) Competent authorities shall inform the Agency of any alternative means of compliance used by organisations under their oversight or by themselves for establishing compliance with this Regulation.

GM1 21.B.115 and 21.B.215 Means of compliance

ED Decision 2022/021/R

ALTERNATIVE MEANS OF COMPLIANCE — GENERAL

(a) A competent authority may establish means to comply with the regulation, which are different from the AMC that are established by EASA.

In that case, the competent authority is responsible for demonstrating how those alternative means of compliance (AltMoC) establish compliance with the regulation.

(b) AltMoC that are used by a competent authority, or by an organisation under its oversight, may be used by other competent authorities, or another organisation, only if they are processed by those authorities in accordance with point 21.B.115 or 21.B.215, and by that organisation in accordance with point 21.A.124A or 21.A.134A.

(c) AltMoC that are issued by the competent authority may cover the following cases:

(1) AltMoC to be used by organisations under the oversight of the competent authority and which are made available to those organisations; and

(2) AltMoC to be used by the authority itself to discharge its responsibilities.

AMC1 21.B.115(b),(c) and 21.B.215(b),(c) Means of compliance

ED Decision 2022/021/R

PROCESSING THE ALTERNATIVE MEANS OF COMPLIANCE

To meet the objective of points (b) and (c) of points 21.B.115 and 21.B.215:

(a) the competent authority should establish the means to consistently evaluate over time that all the AltMoC that are used by itself or by organisations under its oversight allow for the establishment of compliance with the regulation;

(b) if the competent authority issues AltMoC for itself or for the organisations under its oversight, it should:

(1) make them available to all relevant organisations; and

(2) notify EASA of the AltMoC as soon as it is issued, including the information that is described in point (d) of this AMC;

(c) the competent authority should evaluate the AltMoC that is proposed by an organisation by analysing the documentation provided and, if considered necessary, by inspecting the organisation; when the competent authority finds that the AltMoC is in accordance with the Regulation, it should:

(1) notify the applicant that the AltMoC is approved;

(2) indicate that this AltMoC may be implemented, and agree when the production organisation exposition (POE) is to be amended accordingly; and

(3) notify EASA of the AltMoC approval as soon as it is approved, including the information that is described in point (d) of this AMC; and

(d) the competent authority should provide EASA with the following information:

(1) a summary of the AltMoC;

(2) the content of the AltMoC;

(3) a statement that compliance with the regulation is achieved; and

(4) in support of that statement, an assessment that demonstrates that the AltMoC reaches an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding EASA AMC.

(e) All these elements that describe the AltMoC are an integral part of the records to be kept, which are managed in accordance with point 21.B.55.

GM1 21.B.115(b) and (c) and 21.B.215(b) and (c) Means of Compliance

ED Decision 2022/021/R

CASES IN WHICH THERE IS NO CORRESPONDING EASA AMC

When there is no EASA AMC to a certain requirement in the regulation, the competent authority may choose to develop national guides or other types of documents to assist the organisations under its oversight in compliance demonstration. The competent authority may inform EASA so that such guides or other documents may be later considered for incorporation into an AMC that is published by EASA using the EASA rulemaking process.

21.B.120 Initial certification procedure

Regulation (EU) 2022/203

(a) Upon receiving an application for the issue of a letter of agreement for the purpose of demonstrating conformity of the individual products, parts and appliances, the competent authority shall verify the applicant's compliance with the applicable requirements.

(b) The competent authority shall record all the findings issued, closure actions as well as recommendations for the issue of the letter of agreement.

(c) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the letter of agreement can be issued.

(d) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the letter of agreement (EASA Form 65, see Appendix XI).

(e) The letter of agreement shall contain the scope of the agreement, a termination date and, where applicable, the appropriate limitations.

(f) The duration of the letter of agreement shall not exceed 1 year.

GM1 21.A.139, 21.A.239, 21.B.120, 21.B.140, 21.B.220, and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2022/021/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

AMC1 21.B.120(a) Initial certification procedure

ED Decision 2023/014/R

INVESTIGATION TEAM AND PROCEDURES

(a) The competent authority should appoint a team for each applicant for, or holder of, a letter of agreement. This team is responsible for conducting all the relevant tasks related to the issuance of the letter of agreement. The team should consist of a team leader to manage and lead the team, and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).

(b) The competent authority should perform sufficient investigation activities for an applicant for, or holder of, a letter of agreement, to justify the recommendations for the issuance, maintenance, amendment, suspension, limitation or revocation of the letter of agreement.

(c) The competent authority should prepare procedures for the investigation of applicant for, or a holder of, a letter of agreement, as part of the documented procedures that cover at least the following elements:

(1) evaluation of the application received;

(2) appointment of the investigation team;

(3) preparation and planning of the investigation;

(4) evaluation of the documentation (manual, procedures, etc.);

(5) auditing;

(6) follow-up of corrective actions; and

(7) recommendations for the issuance, amendment, suspension, limitation or revocation of a letter of agreement; and

(8) oversight.

AMC2 21.B.120(a) Initial certification procedure

ED Decision 2023/014/R

The competent authority should ensure that the team leader and team members have received appropriate training in the relevant Subparts of Part 21 and in the related competent authority documentation before performing investigations in accordance with AMC1 21.B.25(a)(3). They should also have knowledge and experience at the appropriate level in aviation production and inspection activities related to the particular application for a letter of agreement.

AMC3 21.B.120(a) Initial certification procedure

ED Decision 2023/014/R

EVALUATION OF APPLICATIONS

(a) General

When applying Part 21 Section A, Subpart F and Section B, Subpart F, the competent authority should consider that these Subparts are only alternatives for production to Part 21 Section A, Subpart G and Section B, Subpart G. To meet the ICAO airworthiness obligations and to issue a certificate of airworthiness for an individual aircraft in a practical and efficient way, the competent authority should use a system of approval of production organisations (POA) under

Part 21 Section A, Subpart G and Section B, Subpart G, providing to the competent authority the necessary confidence in the technical standards. The consistent standards of these approvals will also support the standardisation efforts by EASA. Nevertheless, it is recognised that it is not always practical, economical and/or advisable to use the POA.

Considering the ICAO airworthiness obligations as well, Part 21 Section A, Subpart F and Section B, Subpart F are provided for such a case on the basis of the following principles:

(1) Subpart F should be considered as an alternative option for particular cases.

(2) Its adoption should be done on an individual basis, as a consequence of an assessment by the competent authority (see point 21.A.121, and its associated AMC and GM).

(b) Application

The competent authority should receive an application for a letter of agreement on an EASA Form 60 (see AMC1 21.A.124) completed by the applicant. The eligibility of the application should be verified in relation to the competent authority procedures, based on point 21.A.121 and its associated AMC and GM. The applicant should be advised accordingly about the acceptance or rejection of the application.

An application may be accepted from:

— an individual applying on his or her own behalf; or

— in the case of an organisation, an individual with the authority to make agreements on behalf of the organisation.

(c) Location of the applicant

The location of the applicant seeking acceptance for production under Part 21 Section A, Subpart F determines which competent authority is responsible for issuing the letter of agreement.

AMC4 21.B.120(a) Initial certification procedure

ED Decision 2023/014/R

INVESTIGATION PREPARATION AND PLANNING

Following acceptance of an application for a letter of agreement and before commencing an investigation, the competent authority should:

(a) identify the site locations that they need to investigate;

(b) liaise with the competent authority of a Member State where the investigation of the organisation should include a facility in that Member State for one of the following reasons:

(1) where a production organisation has contracted part of the production to another organisation holding a POA and a need arises to ensure that the contract has the same meaning for all the parties to the contract, and the local competent authority of the Member State agrees;

(2) to inspect a product (or part or appliance) under production where the subcontractor does not hold a POA.

(c) coordinate with the competent authority of a third country and/or EASA where the investigation of the organisation should include a facility in that country for one of the following reasons:

(1) where a production organisation has contracted part of the production to another organisation holding a POA issued by EASA or accepted through a recognition agreement in accordance with Article 68 of Regulation (EU) 2018/1139, and a need arises to ensure that the contract has the same meaning for all the parties to the contract, and EASA and/or the competent authority agrees;

(2) to inspect a product (or part or appliance) under production where the subcontractor does not hold a POA.

GM1 21.B.120(c) Initial certification procedure

ED Decision 2023/014/R

During its investigation process, the competent authority may raise findings which should then be recorded. These may be non-conformities to the requirements, the manual as supplied by the production organisation describing its inspection procedures or non-conformities related to the items under inspection. The manner in which the findings will be handled by the competent authority before and during the validity of the letter of agreement, should be detailed in its procedures.

AMC1 21.B.120(d) Initial certification procedure

ED Decision 2023/014/R

ISSUE OF THE LETTER OF AGREEMENT

(a) Unless otherwise agreed by the competent authority, no production before the issue of the letter of agreement may be accepted under Part 21 Section A, Subpart F.

(b) The agreement should include or reference a predefined plan of inspection points established as part of the production inspection system and agreed with the competent authority to be used as a basis for the inspections described in points 21.A.129 and 21.B.120(a) and their associated AMC and GM. The plan should clearly identify the inspection points, places, inspection subjects (materials, processes, tooling documentation, human resources, etc.), as well as the focal points and the method of communication between the production organisation and the competent authority.

(c) The competent authority should detail the method by which it will assure itself that the production organisation is working in accordance with the manual and the agreed inspection procedures during the validity period of the agreement. For a renewal of this validity period, the procedure as defined in point 21.B.140 should be used.

(d) Any conditions under which the agreement will expire (such as the termination date and/or number of units to produce) should be clearly stated in the letter of agreement.

21.B.125 Findings and corrective actions; observations

Regulation (EU) 2022/203

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when any significant non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the terms of the letter of agreement which lowers safety or seriously endangers flight safety.

Level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;
2. obtaining the letter of agreement or maintaining its validity by falsification of the submitted documentary evidence; and
3. any evidence of malpractice or fraudulent use of the letter of agreement.

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the terms of the letter of agreement, which is not classified as a level 1 finding.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance(s) identified. Where a level 1 finding directly relates to an aircraft, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, it shall take action to revoke the letter of agreement or to limit or suspend it in whole or in part, depending on the extent of the level 1 finding, until successful corrective action has been taken by the organisation.
2. If there are any level 2 findings, the competent authority shall:
   (i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. The period shall commence from the date of the written communication of the finding to the organisation, requesting corrective action to address the non-compliance identified. At the end of that period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed with the competent authority;
   (ii) assess the corrective action plan and implementation plan proposed by the organisation, and if the assessment concludes that they are sufficient to address the non-compliance, accept them;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (f)(1)(i).

(e) The competent authority may issue observations for any of the following cases not requiring level 1 or level 2 findings:

1. for any item whose performance has been assessed to be ineffective;
2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c);
3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.

GM1 21.B.125(b) Findings and corrective actions; observations

ED Decision 2023/014/R

EXAMPLES OF LEVEL 1 FINDINGS

Examples of level 1 findings are non-compliance with any of the following points, which may affect the safety of the aircraft:

— point 21.A.126;

— point 21.A.127;

— point 21.A.128; and

— point 21.A.129.

It should be anticipated that non-compliance with those points is only considered a level 1 finding if there is objective evidence that that finding is uncontrolled non-compliance that could affect the safety of the aircraft.

GM1 21.B.125(b) and 21.B.225(b) Findings and corrective actions; observations

ED Decision 2023/014/R

SIGNIFICANT NON-COMPLIANCE

Significant non-compliance includes uncontrolled non-compliance with applicable design data, which is non-compliance that:

(a) cannot be discovered through systematic analysis; or

(b) prevents the identification of the affected products, parts, appliances, or material.

GM2 21.B.125(b) and 21.B.225(b) Findings and corrective actions; observations

ED Decision 2023/014/R

EVIDENCE

A finding can only be raised on the basis of evidence.

Evidence is a fact that is, or can be, documented based on observations, measurements, or tests that can be verified. Evidence generally comes from the following:

(a) documents or manuals;

(b) examination of equipment/products; and

(c) information from interview questions and from observations of an organisation's activities, as applicable.

AMC1 21.B.125(d) and 21.B.225(d) Findings and corrective actions; observations

ED Decision 2023/014/R

NOTIFICATION OF FINDINGS

In the case of a level 1 finding, confirmation should be obtained in a timely manner that the accountable manager has taken note of the finding and its details.

A finding requires effective oversight by the competent authority to monitor the timely completion of the corrective action. That oversight may include intermediate communication, such as letters, as necessary, to remind the approval holder to verify that the corrective action plan is followed.

GM1 21.B.125(e) and 21.B.225(e) Findings and corrective actions; observations

ED Decision 2023/014/R

DIFFERENCE BETWEEN A 'LEVEL 2 FINDING' AND AN 'OBSERVATION'

(a) 'Findings' are issued for non-compliance with the regulation, with the organisation's procedures and manuals, or with the certificate including the terms of approval, whereas 'observations' may be issued to an organisation that remains compliant with the regulation, while additional input to the organisation may be considered for continuous improvement (see points (1), (2), and (3) of point 21.B.125(e)).

The competent authority may decide to issue a 'level 2 finding' when the 'observations' process is not managed correctly or is overlooked (see points 21.A.125B(c) and 21.A.158(c)).

(b) Examples to help differentiate between a 'level 2 finding' and an 'observation' are provided below, based on the requirements for the control and calibration of tools in accordance with point 21.A.139(b)(1)(vii).

Example of a 'level 2 finding':

The organisation could not demonstrate compliance with some elements of point 21.A.145(a) regarding the control register of the tools and equipment, as evidenced by the fact that:

(a) some sampled tools that are physically available in the tool store were missing in the tool control register that is managed by the organisation; or

(b) one tool was not correctly identified (e.g. incorrect part number or serial number) in the tool control register.

Examples of 'observations':

(a) Accumulation of tools in the tool store, which have not been yet sent for calibration. This situation may have some consequences regarding the availability of tools and the operational capabilities during a peak of activities (ineffectiveness of the process).

(b) The process for managing the tool control register through the dedicated software is not detailed enough (potential to cause a 'level 2 finding').

(c) The colour of the 'unserviceable' tag of the tools may generate some confusion. The organisation should consider changing the colour of that unserviceable tag to better alert its staff to the particular status of the unserviceable tools (potential improvement).

21.B.135 Maintenance of the letter of agreement

Regulation (EU) No 748/2012

The competent authority shall maintain the letter of agreement as long as:

(a) the manufacturer is properly using the EASA Form 52 (see Appendix VIII) as a statement of conformity for complete aircraft, and the EASA Form 1 (see Appendix I) for products other than complete aircraft, parts and appliances; and

(b) inspections performed by the competent authority of the Member State before validation of the EASA Form 52 (see Appendix VIII) or the EASA Form 1 (see Appendix I), as per point 21.A.130(c) did not reveal any findings of non-compliance with the requirements or the procedures as contained in the manual provided by the manufacturer, or any non-conformity of the respective products, parts or appliances. These inspections shall check at least that:

1. the agreement covers the product, part or appliance being validated, and remains valid;
2. the manual described in point 21.A.125A(b) and its change status referred in the letter of agreement is used as basic working document by the manufacturer. Otherwise, the inspection shall not continue and therefore the release certificates shall not be validated;
3. production has been carried out under the conditions prescribed in the letter of agreement and satisfactorily performed;
4. inspections and tests (including flight tests, if appropriate), as per points (b)(2) and/or (b)(3), have been carried out under the condition prescribed in the letter of agreement and satisfactorily performed;
5. the inspections by the competent authority described or addressed in the letter of agreement have been performed and found acceptable;
6. the statement of conformity complies with point 21.A.130, and the information provided by it does not prevent its validation; and

(c) any termination date for the letter of agreement has not been reached.

21.B.140 Amendment of a letter of agreement

Regulation (EU) No 748/2012

(a) The competent authority shall investigate, as appropriate, in accordance with point 21.B.120 any amendment of the letter of agreement.

(b) When the competent authority is satisfied that the requirements of Section A, Subpart F continue to be complied with, it shall amend the letter of agreement accordingly.

AMC 21.B.140 Amendment of a letter of agreement

ED Decision 2023/014/R

The competent authority must be satisfied that any change affecting a letter of agreement complies with the shows of Section A Subpart F before implementation can start. A plan for the change should be agreed with the applicant in accordance with AMC1 21.B.120(d). If the change affects the content of the letter of agreement, a new application should be filed, and an amended/revised letter of agreement should be obtained subsequently.

GM1 21.A.139, 21.A.239, 21.B.120, 21.B.140, 21.B.220, and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2022/021/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— ‘remote audit’ means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the ‘remote audit’ concept;

— ‘auditing entity’ means the competent authority or organisation that performs the remote audit;

— ‘auditee’ means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools

employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

SUBPART G — PRODUCTION ORGANISATION APPROVAL

21.B.215 Means of compliance

Regulation (EU) 2022/203

(a) The Agency shall develop acceptable means of compliance ('AMC') that may be used to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(b) Alternative means of compliance may be used to establish compliance with this Regulation.

(c) Competent authorities shall inform the Agency of any alternative means of compliance used by organisations under their oversight or by themselves for establishing compliance with this Regulation.

GM1 21.B.115 and 21.B.215 Means of compliance

ED Decision 2022/021/R

ALTERNATIVE MEANS OF COMPLIANCE — GENERAL

(a) A competent authority may establish means to comply with the regulation, which are different from the AMC that are established by EASA.

In that case, the competent authority is responsible for demonstrating how those alternative means of compliance (AltMoC) establish compliance with the regulation.

(b) AltMoC that are used by a competent authority, or by an organisation under its oversight, may be used by other competent authorities, or another organisation, only if they are processed by those authorities in accordance with point 21.B.115 or 21.B.215, and by that organisation in accordance with point 21.A.124A or 21.A.134A.

(c) AltMoC that are issued by the competent authority may cover the following cases:

(1) AltMoC to be used by organisations under the oversight of the competent authority and which are made available to those organisations; and

(2) AltMoC to be used by the authority itself to discharge its responsibilities.

AMC1 21.B.115(b),(c) and 21.B.215(b),(c) Means of compliance

ED Decision 2022/021/R

PROCESSING THE ALTERNATIVE MEANS OF COMPLIANCE

To meet the objective of points (b) and (c) of points 21.B.115 and 21.B.215:

(a) the competent authority should establish the means to consistently evaluate over time that all the AltMoC that are used by itself or by organisations under its oversight allow for the establishment of compliance with the regulation;

(b) if the competent authority issues AltMoC for itself or for the organisations under its oversight, it should:

(1) make them available to all relevant organisations; and

(2) notify EASA of the AltMoC as soon as it is issued, including the information that is described in point (d) of this AMC;

(c) the competent authority should evaluate the AltMoC that is proposed by an organisation by analysing the documentation provided and, if considered necessary, by inspecting the organisation; when the competent authority finds that the AltMoC is in accordance with the Regulation, it should:

(1) notify the applicant that the AltMoC is approved;

(2) indicate that this AltMoC may be implemented, and agree when the production organisation exposition (POE) is to be amended accordingly; and

(3) notify EASA of the AltMoC approval as soon as it is approved, including the information that is described in point (d) of this AMC; and

(d) the competent authority should provide EASA with the following information:

(1) a summary of the AltMoC;

(2) the content of the AltMoC;

(3) a statement that compliance with the regulation is achieved; and

(4) in support of that statement, an assessment that demonstrates that the AltMoC reaches an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding EASA AMC.

(e) All these elements that describe the AltMoC are an integral part of the records to be kept, which are managed in accordance with point 21.B.55.

GM1 21.B.115(b) and (c) and 21.B.215(b) and (c) Means of Compliance

ED Decision 2022/021/R

CASES IN WHICH THERE IS NO CORRESPONDING EASA AMC

When there is no EASA AMC to a certain requirement in the regulation, the competent authority may choose to develop national guides or other types of documents to assist the organisations under its oversight in compliance demonstration. The competent authority may inform EASA so that such guides or other documents may be later considered for incorporation into an AMC that is published by EASA using the EASA rulemaking process.

21.B.220 Initial certification procedure

Regulation (EU) 2022/203

(a) Upon receiving an application for the initial issue of a production organisation approval certificate, the competent authority shall verify the applicant's compliance with the applicable requirements.

(b) A meeting with the accountable manager of the applicant shall be convened at least once during the investigation for initial certification to ensure that this person understands his or her role and accountability.

(c) The competent authority shall record all the findings issued, closure actions as well as the recommendations for the issue of the production organisation approval certificate.

(d) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the certificate can be issued.

(e) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the production organisation approval certificate (EASA Form 55, see Appendix X).

(f) The certificate reference number shall be included on the EASA Form 55 in a manner specified by the Agency.

(g) The certificate shall be issued for an unlimited duration. The privileges and the scope of the activities that the organisation is approved to conduct, including any limitations as applicable, shall be specified in the terms of approval attached to the certificate.

AMC1 21.B.220 Initial certification procedure

ED Decision 2023/014/R

INVESTIGATION TEAM AND PROCEDURES

(a) The competent authority should appoint a production organisation investigation team for each applicant for a production organisation approval. This team is responsible for conducting all the relevant tasks related to the approval. The team should consist of a team leader to manage and lead the approval team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).

(b) The competent authority should perform sufficient investigation activities for an applicant for a production organisation approval, to justify the recommendations for the issuance of the approval.

(c) The competent authority should prepare procedures for the investigation of a production organisation as part of the documented procedures that cover at least the following elements:

(1) evaluation of the application received;

(2) appointment of the investigation team;

(3) preparation and planning of the investigation;

(4) evaluation of the documentation (production organisation exposition, procedures, etc.);

(5) auditing;

(6) follow-up of corrective actions;

(7) recommendation for the issuance of a POA; and

(8) continued surveillance.

AMC1 21.B.220 Initial certification procedure

ED Decision 2023/014/R

VERIFICATION OF COMPLIANCE — INITIAL CERTIFICATION AUDITS

(a) In order to verify the organisation's compliance with the applicable requirements, the investigation by the competent authority should include one or more audits of the organisation, together with interviews of the personnel, carried out at the organisation's facilities.

(b) The competent authority should only conduct such an audit if it is satisfied that the application and supporting documentation are in compliance with the applicable requirements.

(c) The audit should focus on the following areas:

(1) the detailed management structure, notably its adequacy;

(2) the personnel: the adequacy of the number of staff, and of their qualifications and experience with regard to the intended terms of approval and the associated privileges;

(3) the processes used for safety risk management and compliance monitoring;

(4) the facilities and their adequacy regarding the organisation's intended terms of approval including its scope of work; and

(5) the documentation based on which the approval should be granted.

(d) If an application for an approval is refused, the applicant should be informed of the right of appeal that exists under national or EU law.

AMC2 21.B.220 Initial certification procedure

ED Decision 2023/014/R

INVESTIGATION PREPARATION AND PLANNING

Following the acceptance of the application for a POA and before commencing an investigation, the competent authority should, for the preparation and planning of the investigation:

(a) identify the site locations that they need to investigate taking into account the scope of any other POA issued by a Member State, which are valid in the circumstances;

(b) establish any necessary liaison arrangement with other competent authorities;

(c) agree the size and composition of the investigation team and any specialist tasks likely to be covered and to select suitable team members from all involved competent authorities; and

(d) liaise with the competent authority of a Member State where the investigation of the organisation should include a facility in that Member State for one of the following reasons:

(1) where a production organisation has subcontracted production to another organisation and therefore a need arises to ensure that the contract has the same meaning for all the parties to the contract, and the competent authority agrees;

(2) to perform the audit of the production of a product, part, appliance, or material at the approved organisation facilities in that Member State.

AMC3 21.B.220 Initial certification procedure

ED Decision 2023/014/R

INVESTIGATION TEAM

(a) Type of team

The competent authority should appoint a production organisation approval team leader (POATL) and members appropriate to the nature and scope of the applicant's organisation.

Where the facilities of the applicant are located in more than one Member State, the competent authority of the country of manufacture should liaise with the other involved competent authorities to agree and appoint a POATL and members appropriate to the nature and scope of the applicant's organisation.

(b) Team leader selection

The team leader should satisfy all of the criteria for a team member and will be selected by considering the following additional criteria:

(1) the capability to lead and manage a team;

(2) the capability to prepare reports and be diplomatic;

(3) experience in approval team investigations (not necessarily only Part 21 Section A Subpart G);

(4) a knowledge of production and quality systems for aircraft and related products and parts; and

(5) a knowledge of management systems of production organisations.

(c) Team member selection

The competent authority should determine the size of the team and the specialisations to be covered taking into account the scope of work and the characteristics of the applicant. Team members should be selected by considering the following criteria:

(1) training, which is mandatory, for Part 21 Section A, Subparts A and G and Section B, Subparts A and G;

(2) education and experience, to cover appropriate aviation knowledge, audit practices and approval procedures, and

(3) the ability to verify that an applicant's organisation conforms to its own procedures, and that its key personnel are competent.

GM1 21.A.139, 21.A.239, 21.B.120, 21.B.140, 21.B.220, and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2022/021/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

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— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM1 21.B.220(a) Initial certification procedure

ED Decision 2023/014/R

ORGANISATION APPROVAL — GENERAL

(a) Purpose of the procedures

The purpose of the procedures is to investigate the applicant's production organisation for compliance with Part 21 in relation to the requested terms of approval. When appropriate, these procedures should also be used to investigate significant changes or applications for variations in the scope of approval.

(b) Initiation

The team leader initiates the procedure by:

(1) arranging a meeting with the team members to review the information provided in accordance with the application (according to point 21.A.134 and to take account of any other information available within the competent authority about the applicant;

(2) collecting information from other investigation or oversight teams of competent authorities or EASA on the functioning of the applicant's organisation;

(3) arranging a meeting with the applicant in order to:

(i) enable the applicant to make a general presentation of its organisation and products, parts or appliances;

(ii) ensure that the accountable manager understands his or her role and accountability when signing the statement specified in point 21.A.143(a)(1);

(iii) enable the investigation team to describe the proposed investigation process; and

(iv) enable the investigation team to confirm to the applicant the identity of those managers nominated in accordance with Part 21 Subpart G, Section A.

(c) Preparation

The investigation team:

(1) studies the information gathered in the initiation phase;

(2) establishes an investigation plan which:

(i) takes account of the location of the applicant's facility as identified per GM3 21.B.65(c);

(ii) defines areas of coverage and work-sharing between team members taking account of their individual expertise;

(iii) defines areas where more detailed investigation is considered necessary;

(iv) establishes the need for external advice to team members where expertise may be lacking within the team;

(v) includes completion of a comprehensive plan for the investigation in order to present it to the applicant; and

(vi) recognises the need to:

(A) review the documentation and procedures;

(B) verify compliance and implementation; and

(C) audit a sample of products, parts, and appliances;

(3) coordinates with the appropriate design organisation approval teams sufficiently for both parties to have confidence in the applicant's coordination links with the holder of the approval of the design (as required by point 21.A.133; and

(4) establishes liaison with the applicant to plan mutually suitable dates and times for audits or inspections at each location needing investigation, and also to agree the investigation plan and approximate time scales with the applicant.

(d) Investigation

The investigation team:

(1) makes a check of the exposition for compliance with Part 21;

(2) audits the organisation, its organisational structure, working procedures and processes for compliance with Part 21, using internal compliance checklist and at the end of the investigation, prepares the EASA Form 56 as a summary document;

(3) checks that the exposition standard reflects the organisation, its procedures, practices and the requirements defined in point 21.A.143. Having checked and agreed an exposition issue or subsequent amendment, the competent authority should have a clear procedure to indicate its acceptance or rejection;

(4) performs sample audits at working level to verify that:

(i) work is performed in accordance with the system described in the exposition;

(ii) products, parts, appliances or material produced by the organisation are in conformity with the applicable design data;

(iii) facilities, working conditions, equipment and tools are in accordance with the exposition and appropriate for the work being performed;

(iv) competency and numbers of personnel are appropriate for the work being performed; and

(v) coordination between production and design is satisfactory; and

(5) at an advanced stage of the investigation, conducts an interim team review of audit results and matters arising, in order to determine any additional areas requiring investigation.

Each investigation team should be accompanied during the process by company representatives who are knowledgeable of the applicant's organisation and procedures. This will ensure that the organisation is aware of the audit progress and problems as they arise. Access to information will also be facilitated.

The team leader should coordinate the work of the team members for an efficient investigation process, which will provide a consistent and effective investigation and reporting standards.

(e) Conclusions

(1) The team leader holds a team meeting to review the findings and observations so as to produce a final agreed report of findings.

(2) The team leader, on completion of the investigation, holds a meeting to verbally present the report to the applicant.

The team leader should be the chair of this meeting, but individual team members may present their own findings and observations.

(3) The meeting should agree the findings, corrective action time scales, and preliminary arrangements for any follow-up that may be necessary.

(4) Some items may as a result of this meeting be withdrawn by the team leader but if the investigation has been correctly performed, at this stage there should be no disagreement over the facts presented.

(5) Inevitably there will be occasions when the team leader/member carrying out the audit may find situations in the applicant or approval holder where he or she is unsure about compliance. In this case, the organisation is informed about possible non-compliance at the time and advised that the situation will be reviewed within the competent authority before a decision is made. The organisation should be informed of the decision without undue delay. Only if the decision results in a confirmation of non-compliance, this is recorded in the audit report, eventually in Part 4 of EASA Form 56 at the end of investigation, if not solved before.

(6) Completion of the audit report includes the need to record findings, observations, comments, etc. and this should reflect any problems found during the audit and should be the same as the ones made to the organisation during the debrief at the end of each audit. Under no circumstances should additional findings, observations, comments etc. be included in the audit report, unless the applicant or approval holder has previously been made aware of such comments.

An applicant may need to take corrective action and amend the proposed exposition before the competent authority is able to conclude its investigation. Such corrective actions should be described in a corrective action plan submitted by the organisation and agreed by the investigation team, so that there is a common understanding of the actions necessary before approval can be granted.

(7) Findings raised during the investigation are communicated at the last day of the audit to the organisation. The final version of the audit report is confirmed in writing to the organisation within 2 weeks of each audit. The reason for confirmation in writing is that many organisations take a considerable time to establish compliance. As a result, it is too easy to establish a position of confusion where the organisation claims it was not aware of the findings that prevented the issue of an approval.

(8) At the end of the investigation, the team leader will prepare the final report through an EASA Form 56 and in accordance with the competent authority internal procedures. The report will include the recommendations and any open finding or observation, together with the supporting documentation e.g. audit reports, corrective action plan, closure of findings, minutes of meetings held during the investigation, etc.

The intention of Part 4 of the EASA Form 56 is to provide a summary report of open findings, observations and outstanding items at the end of initial investigation or significant changes to recommend the issue of the approval, or the issue of the significant change approval.

(f) Management involvement

The investigation team should meet the accountable manager at least once during the investigation process and preferably twice, because he or she is ultimately responsible for ensuring compliance with the requirements for the initial granting and subsequent maintenance of the production organisation approval. Two is the preferred number of meetings with the accountable manager, with the first being conducted at the beginning of the investigation to explain the investigation process, and the second, at the end, to debrief on the results of the investigation.

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL
ISSUE / CONTINUATION / VARIATION / SIGNIFICANT CHANGE

PART 1 OF 5: **BASIC DETAILS OF THE ASSESSMENT**

Name of the organisation:

Approval reference:_____

Address(es) of the facilities surveyed:

Main Part 21 Subpart G activities at facilities surveyed:

Date(s) of survey:

Names and positions of the organisation's senior management attended during survey:

Names of the competent authority staff:

Office: EASA Form 56 completion date:

Note: If it is determined that a recommendation for issue/continuation/variation/significant change of approval cannot be made because of a non-compliance with Part 21 Subpart G, the reasons for the non-compliance need to be identified in Part 4 of the report. A copy of Part 1 and Part 4, or at least the information included in these parts, must be given to the organisation to ensure that the organisation, in failing to obtain Part 21 Subpart G approval, even if only temporarily, has the same information as that in the files of the competent authority.

EASA Form 56 Issue 4 — POAT Recommendation Audit Report — Part 1 of 5, Page 1 of 1 MONTH YEAR

Competent authority
of an EU Member State or
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RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART 2 OF 5: **Part 21 SUBPART G COMPLIANCE**

Name of organisation:

Approval of organisation:

Approval reference: _____ Survey reference:

Note A: This form has been compiled according to those points of Part 21 Subpart G which are relevant to an organisation trying to demonstrate compliance.

Note B: The right-hand part of each box must be completed with one of the following three indicators:

1. a tick (✓) which means compliance;)
2. NR which means that the requirement is NOT RELEVANT to the activity at the address surveyed; (the reason for NR should be stated in Part 4 of the report, unless the reason is obvious)
3. a number relating to a comment which must be recorded in Part 4 of the report.

The left-hand part of each box is optional for use by the competent authority.

21.A.3A Reporting system

(a) N/A

(b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person that holds or has applied for a production organisation approval certificate under Subpart G of this Section, or that produces a product, part or appliance under Subpart F of this Section, shall:

(1) ☐ establish and maintain a system for collecting and assessing occurrence reports, including reports on errors, near misses and hazards, in order to identify adverse trends or to address deficiencies and extract occurrences whose reporting is mandatory in accordance with points 2 and 3 and those which are reported voluntarily. For organisations that have their principal place of business in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts;

(2) ☐ report to the responsible design approval holder all the cases where products, parts or appliances have been released by the production organisation and possible deviations from the applicable design data have been subsequently identified, and investigate with the design approval holder to identify those deviations which could lead to an unsafe condition;

(3) ☐ report to the competent authority of the Member State responsible in accordance with point 21.1 and the Agency the deviations that have been identified in accordance with point 21.A.3A(b)2 and which could lead to an unsafe condition;

(4) ☐ if the production organisation acts as a supplier to another production organisation, also report to that other organisation all the cases where it has released products, parts or appliances to that organisation and possible deviations from the applicable design data have been subsequently identified.

(c) ☐ Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person, when reporting in accordance with points (a)(3), (b)(2), (b)(3) and (b)(4), shall appropriately protect the confidentiality of the person who reports and of the person(s) mentioned in the report.

(d) ☐ Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person shall make the reports referred to in points (a)(3) and (b)(3) in a form and manner established by the Agency or the competent authority, respectively, and dispatch them as soon as practicable and in any case not later than 72 hours after the natural or legal person has identified that the occurrence may lead to a possible unsafe condition, unless exceptional circumstances prevent this.

(e) ☐ Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, if an occurrence reported under point (a)(3) or under point (b)(3) results from a deficiency in the design or a production deficiency, the holder of the type certificate, restricted type certificate, supplemental type certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall investigate the reason for the deficiency and report to the competent authority of the Member State responsible in accordance with point 21.1 and to the Agency the results of its investigation and any action it intends to take or proposes to be taken to correct that deficiency.

(f) ☐ If the competent authority finds that action is required to correct the deficiency, the holder of the type certificate, restricted type certificate, supplemental type certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall submit the relevant data to the competent authority upon its request.

21.A.5 Record-keeping

All natural or legal persons that hold or have applied for a type certificate, restricted type certificate, supplemental type certificate, ETSO authorisation, design or repair approval, permit to fly, production organisation approval certificate or letter of agreement under this Regulation shall:

(a) N/A

(b) when they produce a product, part or appliance, record the details of the production process relevant to the conformity of the product, part or appliance with the applicable design data, and the requirements imposed on their partners and suppliers, and make that data available to their competent authority in order to provide the information that is necessary to ensure the continuing airworthiness of the product, part or appliance;

(c) with regard to permits to fly:

(1) ☐ maintain the documents that are produced to establish and justify the flight conditions, and make them available to the Agency and to their competent authority of the Member State in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

(2) ☐ when they issue a permit to fly under the privilege of approved organisations, maintain the documents associated with it, including inspection records and documents that support the approval of the flight conditions and the issuance of the permit to fly itself, and make them available to the Agency and to their competent authority of the Member State responsible for the oversight of the organisation in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

(d) ☐ retain records of the competence and qualifications, referred to in points 21.A.139(c), 21.A.145(b), 21.A.145(c), 21.A.139(c), 21.A.145(a) or 21.A.145(e)(1), of the personnel that are involved in the following functions:

(1) ☐ design or production;

(2) ☐ independent monitoring of the compliance of the organisation with the relevant requirements;

(3) ☐ safety management;

(e) ☐ retain records of the authorisation of personnel, when they employ personnel that:

(1) ☐ exercise the privileges of the approved organisation pursuant to points 21.A.163 and/or 21.A.263, as appropriate;

(2) ☐ carry out the independent function to monitor the compliance of the organisation with the relevant requirements pursuant to points 21.A.139(e) and/or 21.A.139(e), as appropriate;

(3) ☐ carry out the independent verification function of the demonstration of compliance pursuant to point 21.A.139(d)(2).

21.A.9 Access and investigation

Any natural or legal person that holds or has applied for a type certificate, restricted type certificate, supplemental type certificate, ETSO authorisation, design change or repair approval, certificate of airworthiness, noise certificate, permit to fly, design organisation approval, production organisation approval certificate or letter of agreement under this Regulation, shall:

(a) ☐ grant the competent authority access to any facility, product, part and appliance, document, record, data, process, procedure or to any other material in order to review any report, make any inspection, or perform or witness any flight and ground test, as necessary, in order to verify the initial and continued compliance of the organisation with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;

(b) ☐ make arrangements to ensure the competent authority has access, as provided for in point (a), also in respect of the natural or legal person's partners, suppliers and subcontractors.

21.A.133 Eligibility

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart. The applicant shall:

(a) ☐ justify that, for a defined scope of work, an approval under this Subpart is appropriate for the purpose of showing conformity with a specific design; and

(b) ☐ hold or have applied for an approval of that specific design; or

(c) ☐ have ensured, through an appropriate arrangement with the applicant for, or holder of, an approval of that specific design, satisfactory coordination between production and design.

21.A.134 Application

Each application for a production organisation approval shall be made to the competent authority in a form and manner established by that authority, and shall include an outline of the information required by point 21.A.143 and the terms of approval requested to be issued under point 21.A.151.

PART 2 OF 5 (CONTINUED):	SURVEY REFERENCE:

21.A.139 Production management system

(a) ☐ The production organisation shall establish, implement and maintain a production management system that includes a safety management element and a quality management element, with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The production management system shall:

(1) ☐ correspond to the size of the organisation, and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities;

(2) ☐ be established, implemented and maintained under the direct accountability of a single manager appointed pursuant to point 21.A.145(c)(1).

(c) As part of the safety management element of the production management system, the production organisation shall:

(1) ☐ establish, implement and maintain a safety policy and the corresponding related safety objectives;

(2) ☐ appoint key safety personnel in accordance with point 21.A.145(c)(2);

(3) ☐ establish, implement and maintain a safety risk management process to identify safety hazards entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness;

(4) ☐ establish, implement and maintain a safety assurance process that includes:

(i) ☐ the measurement and monitoring of the organisation's safety performance;

(ii) ☐ the management of changes in accordance with point 21.A.147; and

(iii) ☐ the principles for the continuous improvement of the safety management element;

(5) ☐ promote safety in the organisation through:

(i) ☐ training and education;

(ii) ☐ communication;

(6) ☐ establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.

(d) As part of the quality management element of the production management system, the production organisation shall:

(1) ☐ ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in condition for safe operation, thus enabling the exercise of the privileges set out in point 21.A.163;

(2) ☐ establish, implement, and maintain, as appropriate, within the scope of the approval, control procedures for:

(i) ☐ document issue, approval or change;

(ii) ☐ vendor and subcontractor assessment, audit and control;

(iii) ☐ verifying that incoming products, parts, materials and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;

(iv) ☐ identification and traceability;

(v) ☐ manufacturing processes;

(vi) ☐ inspection and testing, including production flight tests;

(vii) ☐ the calibration of tools, jigs, and test equipment;

(viii) ☐ non-conforming item control;

(ix) ☐ airworthiness coordination with the applicant for, or holder of, the design approval;

(x) ☐ the completion and retention of records;

(xi) ☐ the competence and qualifications of personnel;

(xii) ☐ the issue of airworthiness release documents;

(xiii) ☐ handling, storage and packing;

(xiv) ☐ internal quality audits and the resulting corrective actions;

(xv) ☐ work within the terms of approval performed at any location other than the approved facilities;

(xvi) ☐ work performed after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;

(xvii) ☐ the issue of a permit to fly and approval of associated flight conditions;

(3) ☐ include specific provisions in the control procedures for any critical parts.

(e) The production organisation shall establish, as part of the production management system, an independent monitoring function to verify compliance of the organisation with the relevant requirements of this Annex as well as compliance with and adequacy of the production management system. Monitoring shall include feedback to the person or group of persons referred to in point 21.A.145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where necessary, the implementation of corrective actions.

(f) If the production organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the production management system may be integrated with that required under the additional certificate(s) held.

PART 2 OF 5 (CONTINUED):	SURVEY REFERENCE:

21.A.143 Production organisation exposition

(a) The production organisation shall establish and maintain a production organisation exposition (POE) that provides directly or by cross reference the following information related to the production management system as described in point 21.A.139:

(1) ☐ a statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Subpart will be complied with at all times;

(2) the title(s) and names of managers accepted by the competent authority in accordance with point 21.A.145(c)(2);

(3) the duties and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation;

(4) an organisational chart showing associated chains of responsibility of the managers as required by point 21.A.145(c)(1) and (2);

(5) a list of certifying staff as referred to in point 21.A.145(d);

(6) a general description of man-power resources;

(7) a general description of the facilities located at each address specified in the production organisation's certificate of approval;

(8) a general description of the production organisation's scope of work relevant to the terms of approval;

(9) the procedure for the notification of organisational changes to the competent authority;

(10) the amendment procedure for the production organisation exposition;

(11) a description of the production management system, the policy, processes and procedures as provided for in point 21.A.139(c);

(12) a list of the outside parties referred to in point 21.A.139(d)(1);

(13) if flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test. The flight test operations manual shall include:

(i) ☐ a description of the organisation's processes for flight test, including the flight test organisation involvement into the permit to fly issuance process;

(ii) ☐ crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex I (Part 21), where applicable;

(iii) ☐ procedures for the carriage of persons other than crew members and for flight test training, when applicable;

(iv) ☐ a policy for risk and safety management and associated methodologies;

(v) ☐ procedures to identify the instruments and equipment to be carried;

(vi) ☐ a list of documents that need to be produced for flight test.

(b) ☐ The initial issue of the POE shall be approved by the competent authority.

(c) ☐ The POE shall be amended as necessary so that it remains an up-to-date description of the organisation. Copies of any amendments shall be supplied to the competent authority.

21.A.145 Resources

The production organisation shall demonstrate that:

(a) ☐ the facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and general organisation are adequate to discharge its obligations under point 21.A.165;

(b) with regard to all necessary airworthiness, and environmental protection data:

(1) ☐ the production organisation holds all data it needs to determine conformity with the applicable design data. Such data may originate from the Agency and from the holder of, or applicant for, the type certificate, restricted type certificate or design approval, and may include any exemption granted from the environmental protection requirements;

(2) ☐ the production organisation has established a procedure to ensure that the airworthiness and environmental protection data are correctly incorporated in its production data;

(3) ☐ such data are kept up to date and made available to all personnel that need access to such data to perform their duties;

(c) with regard to management and staff:

(1) an accountable manager has been appointed by the production organisation with the authority to ensure that, within the organisation, all production is performed to the required standards and that the production organisation is continuously in compliance with the requirements of the production management system referred to in point 21.A.139, and the data and procedures identified in the POE referred to in point 21.A.143;

(2) ☐ a person or group of persons has/have been nominated by the accountable manager to ensure that the organisation is in compliance with the requirements of this Annex, and are identified, together with the extent of their authority; such person or group of persons shall be responsible to the accountable manager and have direct access to him. The person or group of persons shall have the appropriate knowledge, background and experience to discharge their responsibilities;

(3) ☐ staff at all levels have been given the appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the production organisation in respect of airworthiness and environmental protection data matters;

(d) with regard to certifying staff authorised by the production organisation to sign the documents issued under point 21.A.163 within the scope of the terms of approval:

(1) ☐ they have the appropriate knowledge, background (including other functions in the organisation) and experience to discharge their allocated responsibilities;

(2) ☐ they are provided with evidence of the scope of their authorisation.

PART 2 OF 5 (CONTINUED): **SURVEY REFERENCE:**

21.A.147 Changes in the production management system

☐ After the issue of a production organisation approval certificate, each change in the production management system that is significant for the demonstration of conformity or the airworthiness and environmental protection characteristics of the product, part or appliance, shall be approved by the competent authority before being implemented. The production organisation shall submit an application for approval to the competent authority demonstrating that it will continue to comply with this Annex.

21.A.148 Changes of location

☐ A change of the location of the manufacturing facilities of the approved production organisation shall be deemed of significance and therefore shall comply with point 21.A.147.

21.A.149 Transferability

☐ Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.147, a production organisation approval is not transferable.

21.A.151 Terms of approval

☐ The terms of approval shall identify the scope of work, the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise the privileges under point 21.A.163.

Those terms shall be issued as part of a production organisation approval.

21.A.153 Changes to the terms of approval

☐ Each change to the terms of approval shall be approved by the competent authority. An application for a change to the terms of approval shall be made in a form and manner established by the competent authority. The applicant shall comply with the applicable requirements of this Subpart.

21.A.163 Privileges

Pursuant to the terms of approval issued under point 21.A.135, the holder of a production organisation approval may:

(a) perform production activities under this Annex I (Part 21);

(b) in the case of complete aircraft and upon presentation of a statement of conformity (EASA Form 52) under point 21.A.174, obtain an aircraft certificate of airworthiness and a noise certificate without further showing;

(c) in the case of other products, parts or appliances, issue authorised release certificates (EASA Form 1) without further showing;

(d) maintain a new aircraft that it has produced and issue a certificate of release to service (EASA Form 53) in respect of that maintenance;

(e) under procedures agreed with its competent authority for production, for an aircraft it has produced, and when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight, to issue a permit to fly in accordance with point 21.A.711(c) including approval of the flight conditions in accordance with point 21.A.710(b).

PART 2 OF 5 (CONTINUED):	SURVEY REFERENCE:

21.A.165 Obligations of the holder

The holder of a production organisation approval shall:

(a) ☐ ensure that the production organisation exposition furnished in accordance with point 21.A.143 and the documents to which it refers, are used as basic working documents within the organisation;

(b) ☐ maintain the production organisation in conformity with the data and procedures approved for the production organisation approval;

(c) (1) ☐ determine that each completed aircraft conforms to the type design and is in condition for safe operation prior to submitting statements of conformity to the competent authority; or

(2) ☐ determine that other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1 to certify conformity to approved design data and condition for safe operation;

(3) ☐ Additionally, in the case of environmental requirements, determine that:

(i) the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine; and

(ii) the completed aeroplane is in compliance with the applicable CO_2 emissions requirements on the date its first certificate of airworthiness is issued;

(4) ☐ determine that other products, parts or appliances conform to the applicable data before issuing an EASA Form 1 as a conformity certificate;

(d) ☐ provide assistance to the holder of the type certificate or other design approval in dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced;

(e) ☐ where, under its terms of approval, the holder of a production organisation approval intends to issue a certificate of release to service, determine, prior to issuing the certificate, that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation;

(f) ☐ where applicable, under the privilege set out in point 21.A.163(e), determine the conditions under which a permit to fly can be issued;

(g) ☐ where applicable, under the privilege set out in point 21.A.163(e), establish compliance with points 21.A.711 (c) and (e) before issuing an aircraft with a permit to fly;

(h) ☐ comply with Subpart A of this Section.

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART 3 OF 5: Part 21 SUBPART G EXPOSITION COMPLIANCE

Name of organisation:

Approval of organisation:

Approval reference: _____ Survey reference:

Note A: Each box must be completed with one of the three following indicators:

1. a tick (✓) which means compliance;
2. NR which means that the requirement is NOT RELEVANT to the activity at the address surveyed; (The reason for NR should be stated in Part 4 of the report unless the reason is obvious.);
3. a number relating to a comment which must be recorded in Part 4 of the report.

Note B: The exposition may be compiled in any subject order as long as all applicable subjects are covered.

Note C: If the organisation holds another Part approval requiring an exposition or handbook, it is acceptable to use this index as a supplement to the existing exposition or handbook and to cross-refer each subject to the position in the existing exposition or handbook.

Production organisation exposition
Revision status:
(Content as required by point 21.A.143v(a))

(1) a statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Annex will be complied with at all times;

(2) the title(s) and names of the managers accepted by the competent authority in accordance with point 21.A.145(c)(2);

(3) the accountability and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation;

(4) an organisational chart showing the associated chains of accountability and responsibility of the managers as required by points 21.A.145 (c)(1) and (c)(2);

(5) a list of certifying staff as referred to in point 21.A.145(d);

[Note: a separate document may be referenced]

(6) a description of man-power resources;

PART 3 OF 5 (CONTINUED):	**SURVEY REFERENCE:**
(7)	a general description of the facilities located at each address specified in the production organisation's certificate of approval;
(8)	a general description of the production organisation's scope of work that is relevant to the terms of approval;
(9)	the procedure for the notification of organisational changes to the competent authority;
(10)	the amendment procedure for the production organisation exposition;
(11)	a description of the production management system and the policy, processes and procedures as required by point 21.A.139(b)(1);
(12)	a list of those outside parties referred to in point 21.A.139(d)(1); and [Note: a separate document may be referenced]
(13)	if flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test.

EASA Form 56 Issue 4 — POAT Recommendation Report POA Audit Report — Part 3 of 5, Page 2 of 2 ***MONTH YEAR***

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART 4 OF 5: FINDINGS ON Part 21 SUBPART G COMPLIANCE STATUS

Name of organisation:

Approval reference: _____ Survey reference: _____

Note A: Each finding must be identified by a number and the number must cross-refer to the same number in a box in Parts 2 or 3 of the Part 21 Subpart G survey report.

Note B: As stated in Part 1, any comments recorded in this Part 4 should be copied to the organisation surveyed, together with Part 1.

Note C: In the case of a partial clearance of a finding with some outstanding actions remaining, these actions have to be identified.

NO:	FINDING	LEVEL	OUTSTANDING ACTION	CLEARANCE	
				DATE	REP.REF.

NAME & SIGNATURE OF INSPECTOR: Date:

PART 4 OF 5 (CONTINUED): Sheet ___ of ___

SURVEY REFERENCE:

NO:	FINDING	LEVEL	OUTSTANDING ACTION	CLEARANCE	
				DATE	REP.REF.

NAME & SIGNATURE OF INSPECTOR: Date:

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART 5 OF 5: Part 21 SUBPART G APPROVAL RECOMMENDATION

Name of organisation:

Approval reference: _____ Survey reference: _____

Recommendation for issue / variation of approval/significant change:

The following Part 21 Subpart G terms of approval are recommended for the above organisation at the address(es) specified in Part 1 of this report:

or

Recommendation for continuation of existing approval:

It is recommended that the Part 21 Subpart G terms of approval identified in EASA Form 55 referenced

_____ be continued.

☐ Reporting performed according to the procedure for authority surveillance of suppliers of a POA holder located in other Member States, if applicable. (Strict confidentiality to be observed)

Name of the competent authority inspector making the recommendation:

Signature of the competent authority inspector:

Competent authority office: Date:

GM2 21.B.220 Initial certification procedure

ED Decision 2023/014/R

APPLICATION RECEIVED FROM ORGANISATIONS WITH FACILITIES/PARTNERS/SUPPLIERS/SUBCONTRACTORS LOCATED IN A THIRD COUNTRY

The obligations of the applicant are totally independent from the surveillance exercised by the competent authority. It is not acceptable that the applicant relies on the surveillance activities of the competent authority to simplify its tasks.

Facilities located in a third country

When any part of the production facilities of an applicant for a POA is located outside the Member States, then the location will be treated in all aspects as part of the applicant's POA organisation.

Therefore, the investigating competent authority will include the facilities outside the Member States:

(a) fully in their investigation and surveillance activities for the applicant for, or holder of, the POA;

(b) in the terms of approval of the EASA Form 55 (see Part 21 Appendix X) when issuing the POA.

Partners/suppliers/subcontractors located in a third country

The competent authority should define, on the basis of Part 21 and its associated AMC and GM, a clear procedure on supplier control. This procedure should include the control of partners/suppliers/subcontractors of the applicant for, or holder of, a POA that are located outside the Member States.

In respect of the applicant for, or holder, of the POA, the competent authority should:

(1) investigate, for the initial approval and consequent continued surveillance, the production organisation, and its partners/suppliers/subcontractors at the necessary level, to ensure that the organisation can comply with the requirements of Part 21;

(2) in accordance with the competent authority procedure, assess and accept the documented procedure for supplier control as part of the POA holder's quality system, and changes to that procedure prior to implementation; and

(3) in accordance with the competent authority procedure, assess the necessary level of surveillance to be exercised by the production organisation on partners / suppliers / subcontractors and check the audit plan of the production organisation against this level.

The level of cooperation between the competent authority and the competent authority of the third country where a partner/supplier/subcontractor of the production organisation is located may influence the authorities' activities concerning this partner/supplier/subcontractor. Cooperation with the competent authority of the third country should be based on the capability and goodwill of that authority, and a complete interchange of necessary information.

The involvement of this competent authority of the third country in the surveillance of the partner/supplier/subcontractor will be based on the following principles:

(a) A recognition agreement under Article 68 of Regulation EU) 2018/1139 covering production subjects has been concluded:

  (1) The competent authority in accordance with GM1 21.A.139(d)(1) may decide that direct surveillance of the POA holder activities at the foreign location may not be necessary.

  (2) In any other case, provisions of the recognition agreement on the subject apply (technical assistance, etc.).

(b) If a recognition agreement has not been concluded, or it does not cover production subjects, it may be necessary that the competent authority of the Member State, EASA, and the competent authority of a third country enter into a specific working arrangement addressing the following matters:

(1) acceptance by the competent authority of the third country of conducting surveillance of the relevant production activities on behalf of the competent authority, under the respective quality standards defined by the competent authority.

(2) tasks to be performed; and

(3) practical methods.

These arrangements are between authorities and do not relieve the applicant of its obligations.

— In all cases, even though surveillance tasks are delegated to the competent authority of the third country, the competent authority remains the responsible authority and may consequently exercise direct surveillance if necessary.

— If it is not possible to delegate surveillance tasks to the competent authority of the third country, the competent authority will have to establish a direct surveillance programme in accordance with its procedure concerning supplier control as part of the overall surveillance of the POA holder.

GM3 21.B.220 Initial certification procedure

ED Decision 2023/014/R

COMPETENT AUTHORITY SURVEILLANCE OF SUPPLIERS OF A POA HOLDER LOCATED IN OTHER MEMBER STATES

(a) The aviation legislation identifies specific State obligations in relation to complete products.

The State of manufacture, as used in ICAO Annex 8, normally identifies the country where the final assembly and the final determination of airworthiness is made. However, sub-assemblies and parts may be produced by POA holders in other countries and Form 1 - Authorised Release Certificate will identify those countries as the locations for production.

Among Member States, the obligations of the State of manufacture may be discharged through the use of the Part 21 POA system.

According to Part 21 Section A, Subpart G, each POA holder must have established and documented in its POE a system for its own control of suppliers/supplies. Surveillance of this system is part of the responsibility of the competent authority of the POA holder wherever the suppliers are located.

This surveillance may be exercised through the POA holder and/or at supplier level especially in the cases where the supplier would be eligible for its own POA.

The purpose of this procedure is to ensure the completeness of the chain of responsibilities so that no separate technical agreement between these competent authorities is necessary, and when necessary to establish a means of communication between the involved competent authorities of the Member States.

(b) Principle to organise competent authority supplier surveillance between Member States

In order to avoid duplication and to take the best advantage of Regulation (EU) 2018/1139(EC) No 216/2008 that establishes under Article 67 mutual recognition of certificates issued by production organisations approved in accordance with Part 21 Section A, Subpart G by a Member State, the principle for the competent authority surveillance of the suppliers of a POA holder located in other Member States is for the responsible competent authority to delegate surveillance activities to the other competent authority of the supplier.

This applies between Member States and for suppliers holding a Part 21 POA.

Delegation of surveillance tasks does not imply a delegation of the overall responsibility, therefore the competent authority of the contractor always retains the right of direct supervision at the supplier location especially when serious quality problems are encountered. In such a case, there will be coordination between both competent authorities.

This delegation of surveillance is to be considered automatic as soon as the supplier holds a Part 21 POA, provided that the intended supply is included in the approved scope of work. Evidence of that approval will normally be found through the release of the supplied parts with a Form 1. In addition, the competent authority of the supplier should immediately inform the competent authority of the contractor in any case of a serious quality problem.

In the cases where the competent authority of the contractor considers that it is necessary to establish closer ties with the competent authority of the supplier (i.e., critical or significant parts), the exchange of information between the competent authorities should be organised as follows:

(1) Tasks of the competent authority of the POA contractor

The competent authority of the contractor should inform in writing the competent authority of the subcontractor of the following:

(i) The identification (and location) of the contractor;

(ii) The identification (and location) of the subcontractor;

(iii) The identification of the subcontracting (parts, contract No, etc.);

(iv) A reference to the quality requirements attached to the contract;

(v) The name and address of the competent authority office/person in charge of the POA;

(vi) Whether direct delivery authorisation (DDA) applies;

(vii) Any specific action item/requirement from the competent authority; and

(viii) A request for a bi-annual reporting (both ways).

EASA Form 58A is provided for the convenience of the competent authority for this purpose.

The competent authority of the contractor should require the contract/order from the contractor to the subcontractor to indicate that it is placed under the surveillance of its competent authority on behalf of the competent authority of the contractor, and should address the subject to the payment of the possible surveillance fees.

(2) Tasks of the competent authority of the supplier (subcontractor)

On receipt of the information from the competent authority of the contractor, the competent authority of the subcontractor should:

(i) verify that the scope of work of the POA of the supplier covers the intended supply (or envisage extending it in liaison with the supplier).

(ii) verify that the specific quality requirements for the parts have been introduced into the quality system of the supplier.

(iii) confirm to the competent authority of the contractor that the procurement is included in the POA of the supplier and that their surveillance will cover this activity; and

(iv) indicate the name and address of the competent authority's office/person in charge of the POA.

If the supplier has no POA under Part 21, or does not want to extend it, and/or if its competent authority cannot conduct surveillance on behalf of the other competent authority, the competent authority of the supplier will inform the competent authority of the contractor in order for it to decide on the appropriate actions.

(3) Exchange of information between the competent authorities

This information should normally take two forms:

— Immediate exchange of information between both competent authorities in case of serious quality problems;

— A bi-annual exchange of information on a given date in order to guarantee proper ongoing control of the subcontract by both competent authorities.

This information should cover in a concise form:

(i) for the competent authority of the contractor:

— a résumé of the quality problems encountered by the contractor, on receipt inspection, on installation on aircraft or on in service aircraft; and

— a status of the reference documents.

(ii) For the competent authority of the subcontractor:

— a résumé of at least the following subjects:

— changes in organisation and qualification of the subcontractor.(in case of impact on the procurement);

— quality problems encountered during manufacture;

— corrective actions following problems encountered earlier on the procurement;

— findings from competent authorities surveillance that may have an impact on the procurement; and

— quality problems related to the contractor procurement (materials, documentation, procedures, processes).

Any exchange of information between competent authorities according to this procedure is strictly confidential and should not be disclosed to other parties.

It is recommended to plan at least every 5 years a meeting between industry and the two competent authorities to review each major subcontract to verify that there is proper management by the various parties involved.

3. Miscellaneous

(a) Release documentation

The release of parts by the POA subcontractor to the contractor will be accompanied by an 'Authorised Release Certificate EASA Form 1' issued for 'Airworthiness' or for 'Conformity ' as appropriate.

(b) Subsubcontracting

If the subcontractor wants itself to subcontract, it is up to the competent authority of the subcontractor to verify that this is done in accordance with the conditions of the contract, to organise as necessary the related authority surveillance and to inform the competent authority of the contractor.

(c) Language

Except if it is agreed otherwise, it is recommended to use the English language for the exchange of information between the competent authorities.

Competent authority *of an EU Member State or* *EASA* **REQUEST FOR REPORTING ON SUBCONTRACTOR SURVEILLANCE**	
Document reference number:	*<REQUEST REF. NO.>*
As competent authority which issued a POA to:	*<CONTRACTOR COMPANY>*
With approval reference:	*<CONTRACTOR POA REF. NO..>*
The *<COMPETENT AUTHORITY>* has determined that there is a need for direct authority supplier surveillance of:	*<SUBCONTRACTOR COMPANY>*
With approval reference:	*<SUBCONTRACTOR POA REF.NO.>*
Which is situated in:	*<COUNTRY OF SUBCONTRACTOR COMPANY>*
As part of the surveillance as required for the Part 21 Section A, Subpart G approved production organisation, according to GM3 21.B.220, the competent authority of the subcontractor is requested to perform authority surveillance on the specific sub-assemblies and parts as details and requirements are defined below.	
Identification of subcontracting (parts, contract No., etc.):	
Reference to the quality requirements attached to the contract between contractor and subcontractor:	
Name and address of the requesting competent authority office/person in charge of the POA:	
Direct delivery authorisation (DDA) applies:	☐ Yes ☐ No
Specific action item/requirement from the competent authority of the contractor:	
Request and details required for a bi-annual reporting (both ways) according to GM3 21.B.220 (Strict confidentiality to be observed):	
Name and signature of the competent authority person making the request:	
Competent authority office:	**Date:**

EASA Form 58A – Request for reporting on subcontractor surveillance, Page x of x

Competent authority
of an EU Member State or
EASA

REPORT ON SUBCONTRACTOR SURVEILLANCE

Document reference number:	*<REPORT REF. NO.>*
Reporting request reference number:	*< REQUEST REF. NO >*
As responsible competent authority the *<COMPETENT AUTHORITY>* issued a POA to and is performing direct authority surveillance of:	*<SUBCONTRACTOR COMPANY>*
With approval reference:	*<SUBCONTRACTOR POA REF. NO..>*
Which is a subcontracted supplier of:	*<CONTRACTOR COMPANY>*
With approval reference :	*<CONTRACTOR POA REF.NO.>*
Which is situated in:	*<COUNTRY OF CONTRACTOR COMPANY>*
According to GM No. 4 to 21.B.220(c) and on request of the competent authority of the contractor company the <COMPETENT AUTHORITY> reports on the results of its authority surveillance on the specific parts and appliances defined below:	
Identification of subcontracting (parts, contract No., …):	
Identification of attachments to this report (if needed):	
Date and identification of the previous report:	
Résumé of surveillance results:	
Changes in organisation and qualification of the subcontractor (in case of impact on the procurement):	
Quality problems encountered during manufacture:	
Corrective actions following problems encountered earlier in the procurement:	
Findings from competent authority surveillance that may have an impact on the procurement:	
Quality problems related with the contractor procurement (materials, documentation, procedures, processes):	
Note: the exchange of information between competent authorities according to this procedure is strictly confidential and should not be disclosed to other parties.	
Name and signature of the competent authority person reporting:	
Competent authority office:	**Date:**

EASA Form 58B – Report on subcontractor surveillance, Page x of x

AMC1 21.B.220(e) Initial certification procedure

ED Decision 2023/014/R

ISSUE OF THE CERTIFICATE

(a) The competent authority should base its decision to issue a POA on the recommendation report (EASA Form 56, see GM1 21.B.220) of the investigation team submitted by the POA team leader. EASA Form 56 includes a proposal by the investigation team for the scope and terms of approval that define the products, parts and appliances for which the approval is to be granted, with appropriate limitations.

(b) When the competent authority issues the approval, a final controlled copy of an acceptable exposition for the organisation should be supplied to the competent authority.

(c) A record should be kept by the competent authority and should upon request be brought to the attention of EASA for standardisation purposes.

21.B.221 Oversight principles

Regulation (EU) 2022/203

(a) The competent authority shall verify:

1. compliance with the requirements that are applicable to organisations, prior to issuing the production organisation approval certificate;
2. continued compliance with the applicable requirements of the organisations it has certified;
3. the implementation of appropriate safety measures mandated by the competent authority according to points 21.B.20(c) and (d).

(b) This verification shall:

1. be supported by documentation specifically intended to provide personnel responsible for oversight with guidance to perform their functions;
2. provide the organisations concerned with the results of oversight activities;
3. be based on assessments, audits, inspections and, if needed, unannounced inspections;
4. provide the competent authority with the evidence needed in case further action is required, including the measures provided for in point 21.B.225.

(c) The competent authority shall establish the scope of the oversight defined in points (a) and (b) taking into account the results of past oversight activities and the safety priorities.

(d) If the facilities of an organisation are located in more than one State, the competent authority, as defined in point 21.1, may agree to have the oversight tasks performed by the competent authority(ies) of the Member State(s) where the facilities are located, or by the Agency for facilities that are located outside a territory for which Member States are responsible under the Chicago Convention. Any organisation that is subject to such an agreement shall be informed of its existence and of its scope.

(e) For any oversight activities that are performed at facilities located in a Member State other than where the organisation has its principal place of business, the competent authority, as defined in point 21.1, shall inform the competent authority of that Member State before performing any on-site audit or inspection of the facilities.

(f) The competent authority shall collect and process any information deemed necessary for performing oversight activities.

(g) With regard to the certification and oversight of the organisation's compliance with point 21.A.139A, in addition to complying with points (a) to (f), the competent authority shall review any approval granted under point IS.I.OR.200(e) of this Regulation or point IS.D.OR.200(e) of Delegated Regulation (EU) 2022/1645 following the applicable oversight audit cycle and whenever changes are implemented in the scope of work of the organisation.

[point (g) is applicable from 22 February 2026 – Regulation (EU) 2023/203]

AMC1 21.B.221 Oversight principles

ED Decision 2023/014/R

OVERSIGHT TEAM AND PROCEDURES

(a) The competent authority should appoint a production organisation oversight team for each holder of a production organisation approval. This team is responsible for conducting all the relevant tasks related to the approval. The team should consist of a team leader to manage and lead the oversight team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).

(b) The competent authority should perform sufficient oversight activities for the holder of a production organisation approval, to justify the recommendations for the maintenance, amendment, limitation, suspension or revocation of the approval.

(c) The competent authority should prepare procedures for the oversight of a production organisation as part of the documented procedures that cover at least the following elements:

(1) appointment of the production organisation oversight team;

(2) review of result of past oversight activities;

(3) appointment of the production organisation oversight team;

(4) preparation and planning of the oversight;

(5) evaluation of the documentation (production organisation exposition, procedures, etc.)

(6) auditing;

(7) follow-up of corrective actions;

(8) recommendation for the amendment, limitation, suspension or revocation of a production organisation approval; and

(9) continued surveillance.

AMC2 21.B.221 Oversight principles

ED Decision 2023/014/R

MANAGEMENT SYSTEM ASSESSMENT

(a) As part of the initial certification of an organisation in accordance with point 21.B.220, the competent authority should assess the organisation's management system and its processes to make sure that all the required enablers of a functioning management system are present and suitable.

(b) As a result of their oversight, the competent authority should be satisfied as to the effectiveness of the organisation's management system and processes.

(c) When significant changes take place in the organisation, the competent authority should determine whether there is a need to review the existing assessment to ensure that it is still valid.

AMC1 21.B.221(f) Oversight principles

ED Decision 2023/014/R

INFORMATION DEEMED NECESSARY FOR OVERSIGHT

This information should include, as a minimum:

(a) any occurrence reports received by the competent authority;

(b) the results of the following types of inspections and surveys if they indicate an issue that originates from a Part 21 Section A, Subpart G organisation:

(1) ramp inspections performed in accordance with Subpart RAMP of Annex II (Part-ARO)

(2) product audits conducted pursuant to point 21.B.222(b)(1); and

(3) results from other POA Investigations.

21.B.222 Oversight programme

Regulation (EU) 2022/203

(a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required by point 21.B.221(a).

(b) The oversight programme shall take into account the specific nature of the organisation, the complexity of its activities, the results of past certification and/or oversight activities, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including, as appropriate:

(i) management system assessments and process audits;

(ii) product audits of a relevant sample of the products, parts and appliances that are within the scope of the organisation;

(iii) sampling of the work performed; and

(iv) unannounced inspections;

2. meetings convened between the accountable manager and the competent authority to ensure that both parties remain informed of all significant issues.

(c) The oversight planning cycle shall not exceed 24 months.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;

2. the organisation has continuously demonstrated compliance with points 21.A.147 and 21.A.148 and it has full control over all changes to the production management system;

3. no level 1 findings have been issued;

4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as defined in point 21.B.225.

Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions provided in points (1) to (4) above, the organisation has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(e) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(f) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the approval, reflecting the results of the oversight.

AMC1 21.B.222 Oversight programme

ED Decision 2023/014/R

ANNUAL REVIEW

(a) The oversight planning cycle and the related oversight programme for each organisation should be reviewed annually to ensure that they remain adequate regarding any changes in the nature of the organisation, the complexity of its activities or the safety performance of the organisation.

(b) When reviewing the oversight planning cycle and the related oversight programme, the competent authority should also consider any relevant information collected in accordance with points 21.A.3A and 21.B.215(d).

AMC1 21.B.222(a) and (b) Oversight programme

ED Decision 2023/014/R

OVERSIGHT PLANNING

(a) When defining the oversight programme, the competent authority should assess the risks related to the activity and set-up of each organisation and adapt the oversight to the level of risk identified and to the effectiveness of the organisation's management system, in particular its ability to effectively manage safety risks.

(b) The competent authority should establish a schedule of assessments, audits and inspections that is appropriate to each organisation. The planning of assessments, audits and inspections should take into account the results of the hazard identification and risk assessment conducted and maintained by the organisation as part of the organisation's management system. Inspectors should work in accordance with the schedule provided to them.

(c) When the competent authority, having regard to the level of risk identified and the effectiveness of the organisation's management system, varies the frequency of an audit or inspection, it should ensure that all the aspects of the organisation's activities are audited and inspected within the applicable oversight planning cycle.

AMC1 21.B.222(b) Oversight programme

ED Decision 2023/014/R

SPECIFIC NATURE OF THE ORGANISATION AND COMPLEXITY OF ITS ACTVITIES — RESULTS OF PAST OVERSIGHT ACTIVITIES

When determining the oversight programme, including a relevant sample of production activities under the scope of the organisation as product audits, the competent authority should consider in particular the following elements, as applicable:

(a) the effectiveness of the organisation's management system in identifying and addressing non-compliances and safety hazards;

(b) the implementation by the organisation of any industry standards that are directly relevant to the organisation's activity subject to Part 21;

(b) the procedures for the management and the scope of non-significant changes;

(c) any specific procedures implemented by the organisation that are related to any alternative means of compliance used;

(d) the number of approved locations and the activities performed at each location;

(e) the number and scope of subcontractors that perform production activities; and

(f) the volume of activity for each product or parts.

AMC2 21.B.222(b) Oversight programme

ED Decision 2023/014/R

SUBCONTRACTED ACTIVITIES

If a production organisation subcontracts production activities, the competent authority should determine whether the subcontracted organisations need to be audited and include this in the oversight programme, taking into account the specific nature and complexity of the subcontracted activities, the results of previous oversight activities of the production organisation, and assessment of the associated risks.

For such an audit, the competent authority inspectors should ensure that they are accompanied throughout the audit by a representative of the production organisation.

NOTE: If a production organisation subcontracts production activities, the competent authority should verify that the production organisation has sufficient control over the subcontracted activities and manages the related risks.

AMC1 21.B.222(b)(1) Oversight programme

ED Decision 2023/014/R

ASSESSMENTS, AUDIT AND INSPECTIONS

(a) The oversight programme should indicate which aspects of the approval will be covered by each assessment, audit or inspection.

(b) Audits may be complemented by a review of the independent monitoring function results related to the topic of the audit.

(c) At the conclusion of the assessment, audit or inspection, the POA team should complete a report that identifies the areas and processes that were covered and includes all the findings and observations that were raised.

(d) At the completion of each oversight planning cycle, the POATL responsible for the POA should complete an EASA Form 56 (see GM1 21.B.220) as a summary report for the continued surveillance, including the recommendation for a continuation of the POA, as applicable. EASA Form 56 should be countersigned by the person responsible within the competent authority for the acceptance. At this stage, there is no limitation on the number of level 2 findings that may be open, provided that they are within the time limits of the respective corrective action plans.

GM1 21.B.222(b)(1)(ii) Oversight programme

ED Decision 2023/014/R

GUIDE TO THE CONDUCT OF MONITORING PRODUCTION STANDARDS

(a) Point 21.B.222(b)(1)(ii) identifies the need for a sample investigation of products, parts or appliances, their associated conformity determinations and the certifications made by a POA holder. For this to be performed effectively and efficiently, the competent authority should integrate a sampling plan as part of the planning of the investigation and continued surveillance activities that are appropriate to the scope and size of the relevant applicant.

(b) The sample investigation could, for example, include:

(1) a modification (or change);

(2) the installation, testing, or operation of a major part or system;

(3) the accuracy and generation of the flight test report data;

(4) the accuracy and generation of the weighing report data;

(5) an engine test bed run;

(6) the traceability of records;

(7) the accuracy and generation of the statement of conformity data and the associated safe operation determination; and

(8) the accuracy and generation of EASA Form 1 data.

AMC1 21.B.222(c) Oversight programme

ED Decision 2023/014/R

OVERSIGHT PLANNING CYCLE — AUDIT

(a) For each organisation approved by the competent authority, all applicable requirements including processes should be audited at periods that do not exceed the applicable oversight planning cycle. The beginning of the first oversight planning cycle is normally determined by the date of issue of the first approval. If the competent authority wishes to align the oversight planning cycle with the calendar year, it should shorten the first oversight planning cycle accordingly.

(b) The oversight planning should include at least one on-site audit within each oversight planning cycle. For organisations that carry out their regular activities at more than one site, the determination of the sites and the requirements to be audited at these sites should consider the results of past oversight activities and the volume of activity at each site, as well as the main risk areas identified.

(c) For organisations that hold more than one approval under Regulation (EU) 2018/1139, the competent authority may define an integrated oversight schedule to include all the applicable audit items. In order to avoid any duplication of audits, credit may be granted for any specific audit items already completed during the current oversight planning cycle, provided that:

(1) the specific audit item is the same for all the approvals under consideration;

(2) there is satisfactory evidence on record that the specific audit items were carried out and that all corrective actions have been implemented to the satisfaction of the competent authority; and

(3) the competent authority should be satisfied that there is no evidence that standards have deteriorated regarding those specific audit items for which credit is granted.

GM1 21.B.222(c) Oversight programme

ED Decision 2023/014/R

STANDARD OVERSIGHT PLANNING CYCLE

The expression ‘shall not exceed 24 months’ does not imply that 24 months is a minimum duration for the oversight cycle. Based on the elements specified in 21.B.221(c) and 21.B.222(b) (e.g. safety priorities, assessment of the risks, complexity of activities), the competent authority may decide to apply a cycle of less than 24 months (e.g. 12 months).

AMC1 21.B.222(d) and (e) Oversight programme

ED Decision 2023/014/R

EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS

(a) Regardless of planning cycle length, the competent authority should perform at least one focused inspection of the organisation (inspection of a specific area, element or aspect of the organisation) within each 12-month segment of the applicable oversight planning cycle, to support the determined length of the planning cycle.

(b) If the oversight planning was beyond 24 months and the results of the focused inspection indicate a decrease in the safety performance of the organisation, the competent authority should revert to a 24-month (or shorter) oversight planning cycle and review the oversight programme accordingly.

(c) In order to be able to apply an oversight planning cycle of up to 36 months, the competent authority should agree on the format and contents of the continuous reporting to be made by the organisation on its safety performance and regulatory compliance.

(d) To enable the competent authority to apply an oversight planning cycle of up to 48 months, the competent authority should establish, implement and maintain a methodology to evaluate the safety performance of the organisation, focusing on the organisation's ability to effectively identify aviation safety hazards and manage the associated risks.

GM1 21.B.222(d)(2) Oversight programme

ED Decision 2023/014/R

ORGANISATION'S CONTROL OVER THE CHANGES

For the purpose of extending the oversight planning beyond 24 months, the continuous compliance of the organisation with 21.A.147 and 21.A.148, and the full control over all changes referred to in point 21.B.222(d)(2), includes in particular the ability of the organisation to manage adequately the changes not requiring prior approval foreseen in 21.A.147 and 21.A.148.

21.B.225 Findings and corrective actions; observations

Regulation (EU) 2022/203

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when any significant non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval which lowers safety or seriously endangers flight safety.

The level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;
2. obtaining the production organisation approval certificate or maintaining its validity by falsification of the submitted documentary evidence;
3. any evidence of malpractice or fraudulent use of the production organisation approval certificate; and
4. failure to appoint an accountable manager pursuant to point 21.A.245(a)/

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval, which is not classified as a level 1 finding.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance(s) identified. Where a level 1 finding directly relates to an aircraft, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, it shall take action to revoke the production organisation approval certificate or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

   (i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. The period shall commence from the date of the written communication of the finding to the organisation requesting corrective action to address the non-compliance identified. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed by the competent authority;

   (ii) assess the corrective action and implementation plan proposed by the organisation, and if the assessment concludes that they are sufficient to address the non-compliance, accept them;

   (iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (d)(1).

(e) The competent authority may issue observations for any of the following cases not requiring level 1 or level 2 findings:

1. for any item whose performance has been assessed to be ineffective; or

2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c); or

3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.

GM 21.B.225(a) Objective evidence

ED Decision 2012/020/R

Objective evidence is a fact which is, or can be documented, based on observations, measurements or tests that can be verified. Objective evidence generally comes from the following:

a) documents or manuals

b) examination of equipment/products

c) information from interview questions and observations of POA activities.

AMC 21.B.225(a) Notification of findings

ED Decision 2012/020/R

In case of a level one finding confirmation must be obtained in a timely manner that the accountable manager received the letter containing details of the level one finding and the approval suspension details.

A level two finding requires timely and effective handling by the competent authority to ensure completion of the corrective action. This includes intermediate communication, including reminding letters as necessary, with the POA holder to verify that the corrective action plan is followed.

GM1 21.B.225(b) Findings and corrective actions; observations

ED Decision 2023/014/R

EXAMPLE OF A LEVEL 1 FINDING

The production organisation cannot demonstrate compliance with 21.A.139(d)2.(xii) and 21.A.163(c), as evidenced by:

The POA holder released the 'critical' Part No XXX, Serial Number YYY with EASA Form 1 No ZZZZ having ticked the box *'Certifies that the items identified above were manufactured in conformity to: approved design data and are in a condition for safe operation';* while:

(a) the released part is not included in the organisation's capability list/scope of work; and/or

(b) the POA holder could not demonstrate that the released part is covered by an EASA approved/accepted type design.

Consequently, the released part is not eligible for installation on in-service type-certificated aircraft.

GM1 21.B.125(b) and 21.B.225(b) Findings and corrective actions; observations

ED Decision 2023/014/R

SIGNIFICANT NON-COMPLIANCE

Significant non-compliance includes uncontrolled non-compliance with applicable design data, which is non-compliance that:

(a) cannot be discovered through systematic analysis; or

(b) prevents the identification of the affected products, parts, appliances, or material.

GM2 21.B.125(b) and 21.B.225(b) Findings and corrective actions; observations

ED Decision 2023/014/R

EVIDENCE

A finding can only be raised on the basis of evidence.

Evidence is a fact that is, or can be, documented based on observations, measurements, or tests that can be verified. Evidence generally comes from the following:

(a) documents or manuals;

(b) examination of equipment/products; and

(c) information from interview questions and from observations of an organisation's activities, as applicable.

AMC1 21.B.125(d) and 21.B.225(d) Findings and corrective actions; observations

ED Decision 2023/014/R

NOTIFICATION OF FINDINGS

In the case of a level 1 finding, confirmation should be obtained in a timely manner that the accountable manager has taken note of the finding and its details.

A finding requires effective oversight by the competent authority to monitor the timely completion of the corrective action. That oversight may include intermediate communication, such as letters, as necessary, to remind the approval holder to verify that the corrective action plan is followed.

GM1 21.B.125(e) and 21.B.225(e) Findings and corrective actions; observations

ED Decision 2023/014/R

DIFFERENCE BETWEEN A 'LEVEL 2 FINDING' AND AN 'OBSERVATION'

(a) 'Findings' are issued for non-compliance with the regulation, with the organisation's procedures and manuals, or with the certificate including the terms of approval, whereas 'observations' may be issued to an organisation that remains compliant with the regulation, while additional input to the organisation may be considered for continuous improvement (see points (1), (2), and (3) of point 21.B.125(e)).

The competent authority may decide to issue a 'level 2 finding' when the 'observations' process is not managed correctly or is overlooked (see points 21.A.125B(c) and 21.A.158(c)).

(b) Examples to help differentiate between a 'level 2 finding' and an 'observation' are provided below, based on the requirements for the control and calibration of tools in accordance with point 21.A.139(b)(1)(vii).

Example of a 'level 2 finding':

The organisation could not demonstrate compliance with some elements of point 21.A.145(a) regarding the control register of the tools and equipment, as evidenced by the fact that:

(a) some sampled tools that are physically available in the tool store were missing in the tool control register that is managed by the organisation; or

(b) one tool was not correctly identified (e.g. incorrect part number or serial number) in the tool control register.

Examples of 'observations':

(a) Accumulation of tools in the tool store, which have not been yet sent for calibration. This situation may have some consequences regarding the availability of tools and the operational capabilities during a peak of activities (ineffectiveness of the process).

(b) The process for managing the tool control register through the dedicated software is not detailed enough (potential to cause a 'level 2 finding').

(c) The colour of the 'unserviceable' tag of the tools may generate some confusion. The organisation should consider changing the colour of that unserviceable tag to better alert its staff to the particular status of the unserviceable tools (potential improvement).

21.B.240 Changes in production management system

Regulation (EU) 2022/203

(a) Upon receiving an application for a significant change to the production management system, the competent authority shall verify the organisation's compliance with the applicable requirements of this Annex before issuing the approval.

(b) The competent authority shall establish the conditions under which the organisation may operate during the evaluation of a change unless the competent authority determines that the production organisation approval certificate needs to be suspended.

(c) When it is satisfied that the organisation complies with the applicable requirements, the competent authority shall approve the change.

(d) Without prejudice to any additional enforcement measures, if the organisation implements a significant change to the production management system without having received the approval of the competent authority pursuant to point (c), the competent authority shall consider the need to suspend, limit or revoke the organisation's certificate.

(e) For non-significant changes to the production management system, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles set forth in point 21.B.221. If any non-compliance is found, the competent authority shall notify the organisation, request further changes and act in accordance with point 21.B.225.

AMC1 21.B.240 Changes in production management system

ED Decision 2023/014/R

APPLICATION FOR SIGNIFICANT CHANGES OR A VARIATION OF SCOPE AND TERMS OF THE POA

(a) The competent authority should have adequate control over any changes to the personnel specified in points 21.A.145 (c)(1) and (c)(2). Such changes in personnel will require an amendment to the exposition.

(b) When an organisation submits the name of a new nominee for any of the personnel specified in points 21.A.145 (c)(1) and (c)(2), the competent authority may require the organisation to produce a written résumé of the proposed person. The competent authority should reserve the right to interview the nominee or call for additional evidence of their suitability before deciding upon the nominee being acceptable.

(c) For changes requiring prior approval, in order to verify the organisation's compliance with the applicable requirements, the competent authority should conduct an audit of the organisation, limited to the extent of the changes, and determine whether the organisation needs to provide a safety risk assessment.

(d) If required for verification, the audit may include interviews and inspections carried out at the organisation's facilities.

(e) The competent authority should receive an application for any significant changes or for a change to the terms of approval of the POA on an EASA Form 51 completed by the applicant.

(f) The applicable part(s) of EASA Form 56 should be used to document the assessment of any changes to the POA.

GM1 21.A.139, 21.A.239, 21.B.120, 21.B.140, 21.B.220, and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2022/021/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

21.B.240A Changes to the information security management system

Regulation (EU) 2023/203

(a) For changes managed and notified to the competent authority in accordance with the procedure set out in point IS.D.OR.255(a) of the Annex (Part-IS.D.OR) to Delegated Regulation (EU) 2022/1645, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles laid down in point 21.B.221. If any non-compliance is found, the competent authority shall notify the organisation thereof, request further changes and act in accordance with point 21.B.225.

(b) For other changes requiring an application for approval in accordance with point IS.D.OR.255(b) of the Annex (Part-IS.D.OR) to Delegated Regulation (EU) 2022/1645:

(1) upon receiving the application for the change, the competent authority shall check the organisation's compliance with the applicable requirements before issuing the approval;

(2) the competent authority shall establish the conditions under which the organisation may operate during the implementation of the change;

(3) if it is satisfied that the organisation complies with the applicable requirements, the competent authority shall approve the change.

[applicable from 22 February 2026 – Regulation (EU) 2023/203]

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

21.B.320 Investigation

Regulation (EU) No 748/2012

(a) The competent authority of the Member State of registry shall perform sufficient investigation activities for an applicant for, or holder of, an airworthiness certificate to justify the issuance, maintenance, amendment, suspension or revocation of the certificate or permit.

(b) The competent authority of the Member State of registry shall prepare evaluation procedures covering at least the following elements:

1. evaluation of eligibility of the applicant;
2. evaluation of the eligibility of the application;
3. classification of airworthiness certificates;
4. evaluation of the documentation received with the application;
5. inspection of aircraft;
6. determination of necessary conditions, restrictions or limitations to the airworthiness certificates.

GM 21.B.320(b)(6) Investigation

ED Decision 2012/020/R

1. Determination of necessary conditions, restrictions and/or limitations on the airworthiness certificate issued by a Member State

The competent authority of the Member State of registry may issue under its own legislation a document to list and identify all necessary conditions, restrictions and limitations that result from the investigation by the Agency and/or from the legislation of the competent authority of the Member State of registry. This document could take the form of an addendum to the approved flight manual or operating instruction or comparable document and should be referenced in Block 5 (limitations/remarks) of the appropriate certificate of airworthiness.

21.B.325 Issuance of airworthiness certificate

Regulation (EU) 2022/203

(a) The competent authority of the Member State of registry shall issue or change a certificate of airworthiness (EASA Form 25, see Appendix VI) without undue delay when it is satisfied that the requirements of point 21.B.326 and the applicable requirements of Section A of Subpart H of this Annex I (Part 21) are met.

(b) The competent authority of the Member State of registry shall issue or change a Restricted certificate of airworthiness (EASA Form 24, see Appendix V) without undue delay when it is satisfied that requirements of point 21.B.327 and the applicable requirements of Section A of Subpart H of this Annex I (Part 21) are met.

(c) For new aircraft, and used aircraft originating from a non-member State, in addition to the appropriate airworthiness certificate referred to in point (a) or (b), the competent authority of the Member State of registry shall issue:

1. for aircraft subject to Annex I (Part-M) to Commission Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15a, Appendix II);

2. for new aircraft subject to Annex Vb (Part-ML) to Commission Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15c, Appendix II);

3. for used aircraft originating from a non-member State and subject to Annex Vb (Part-ML) to Commission Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15c, Appendix II), when the competent authority has performed the airworthiness review.

GM 21.B.325(a) Airworthiness certificates

ED Decision 2012/020/R

1. Completion of the certificate of airworthiness by a Member State

Block 5: Insert restrictions developed in accordance with Part 21, including any reference to limitations as indicated in GM 21.B.320(b)(6).

2. Completion of the restricted certificate of airworthiness by a Member State

Block 5: Insert restrictions developed in accordance with Part 21, including any reference to limitations as indicated in GM 21.B.320(b)(6).

GM 21.B.325(b) Completion of the Airworthiness Review Certificate by a Member State

ED Decision 2012/020/R

1. Purpose

In accordance with the applicable continuing airworthiness requirements a certificate of airworthiness is valid only if a valid airworthiness review certificate is attached to it. For new aircraft, the competent authority will issue the airworthiness review certificate when issuing the certificate of airworthiness.

21.B.326 Certificate of airworthiness

Regulation (EU) 2020/570

The competent authority of the Member State of registry shall issue a certificate of airworthiness for:

(a) new aircraft:

1. upon presentation of the documentation required by point 21.A.174(b)(2);

2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry; and

3. where the competent authority of the Member State of registry is satisfied that the aircraft is in compliance with the applicable CO_2 emissions requirements on the date on which the certificate of airworthiness is first issued.

(b) used aircraft:

1. upon presentation of the documentation required by point 21.A.174(b)(3) demonstrating that:

(i) the aircraft conforms to a type design approved under a type-certificate and any supplemental type- certificate, change or repair approved in accordance with this Annex I (Part 21) and;

(ii) the applicable airworthiness directives have been complied with and;

(iii) the aircraft has been inspected in accordance with the provisions of Annex I (Part-M) or Annex Vb (Part-ML) of Regulation (EU) No 1321/2014, as appropriate;

(iv) the aircraft was in compliance with the applicable CO_2 emissions requirements on the date on which the certificate of airworthiness was first issued;

2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry and

3. where the competent authority of the Member State of registry is satisfied that the aircraft was in compliance with the applicable CO_2 emissions requirements on the date on which the certificate of airworthiness was first issued.

21.B.327 Restricted certificate of airworthiness

Regulation (EU) 2020/570

(a) The competent authority of the Member State of registry shall issue a restricted certificate of airworthiness for:

1. new aircraft:

(i) upon presentation of the documentation required by point 21.A.174(b)(2);

(ii) when the competent authority of the Member State of registry is satisfied that the aircraft conforms to a design approved by the Agency under a restricted type-certificate or in accordance with specific airworthiness specifications, and is in a condition for safe operation. This may include inspections by the competent authority of the Member State of registry;

2. used aircraft:

(i) upon presentation of the documentation required by point 21.A.174(b)(3) demonstrating that:

(A) the aircraft conforms to a design approved by the Agency under a restricted type-certificate or in accordance with specific airworthiness specifications and any supplemental type-certificate change or repair approved in accordance with this Annex I (Part 21); and

(B) the applicable airworthiness directives have been complied with; and

(C) the aircraft has been inspected in accordance with the provisions of Annex I (Part-M) or Annex Vb (Part-ML) of Regulation (EU) No 1321/2014, as appropriate.

(ii) when the competent authority of the Member State of registry is satisfied that the aircraft conforms to the approved design and is in a condition for safe operation. This may include inspections by the competent authority of the Member State of registry.

(b) For an aircraft that cannot comply with the essential requirements referred to in Regulation (EC) No 216/2008 and which is not eligible for a restricted type-certificate, the Agency shall, as necessary to take account of deviations from these essential requirements:

1. issue and check compliance with specific airworthiness specifications ensuring adequate safety with regard to the intended use, and

2. specify limitations for use of this aircraft.

(c) Limitations for use will be associated with restricted certificates of airworthiness, including airspace restrictions, as necessary to take account of deviations from essential requirements for airworthiness laid down in Regulation (EC) No 216/2008.

SUBPART I — NOISE CERTIFICATES

21.B.420 Investigation

Regulation (EU) No 748/2012

(a) The competent authority of the Member State of registry shall perform sufficient investigation activities for an applicant for, or holder of, a noise certificate to justify the issuance, maintenance, amendment, suspension or revocation of the certificate.

(b) The competent authority of the Member State of registry shall prepare evaluation procedures as part of the documented procedures covering at least the following elements:

1. evaluation of eligibility;
2. evaluation of the documentation received with the application;
3. inspection of aircraft.

21.B.425 Issuance of noise certificates

Regulation (EU) 2022/201

The competent authority of the Member State of registry shall, as applicable, issue, or amend noise certificates (EASA Form 45, see Appendix VII) without undue delay when it is satisfied that the applicable requirements of Section A, Subpart I are met.

GM 21.B.425(a) Noise certificates

ED Decision 2016/003/R

1. Completion of the noise certificate by a Member State

1.1 Completion instructions

Block 1. State of registry

The name of the State issuing the noise certificate. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 2. Noise certificate

The title of the EASA Form 45 is ‘Noise Certificate’

Block 3. Document No

A unique number, issued by the State of registry that identifies this particular document in their administration. Such a number will facilitate any enquiries with respect to the document.

Block 4. Registration marks

The nationality or common mark and registration marks as issued by the State of registry in accordance with Annex 7 to the Chicago Convention[1]. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 5. Manufacturer and manufacturer's designation of aircraft

The type and model of the subject aircraft. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 6. Aircraft serial No

The aircraft serial number as given by the manufacturer of the aircraft. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 7. Engine

The designation of the installed engine(s) for identification and verification of the aircraft configuration. It should contain the type and model of the subject engine(s). The designation should be in accordance with the type certificate or supplemental type certificate for the subject engine(s).

Block 8. Propeller

The designation of the installed propeller(s) for identification and verification of the aircraft configuration. It should contain the type and model of the subject propeller(s). The designation should be in accordance with the type certificate or supplemental type certificate for the subject propeller(s). This item is included only in noise certification documentation for propeller driven aeroplanes.

Block 9. Maximum take-off mass (kg)

The maximum take-off mass associated with the certificated noise levels of the aircraft in kilograms. The unit (kg) should be specified explicitly in order to avoid misunderstanding. If the primary unit of mass for the State of manufacture of the aircraft is different from kilograms, the conversion factor used should be in accordance with Annex 5 to the Chicago Convention.

Block 10. Maximum landing mass (kg)

The maximum landing mass associated with the certificated noise levels of the aircraft in kilograms. The unit (kg) should be specified explicitly in order to avoid misunderstanding. If the primary unit of mass for the State of manufacture of the aircraft is different from kilograms, the conversion factor used should be in accordance with Annex 5 to the Chicago Convention. This item will only be included in the noise certification documentation for noise certificates issued under Chapter 2, 3, 4, 5, 12 and 14.

[1] The Convention on International Civil Aviation on 7 December 1944

Block 11. Noise certification standard

The chapter to which the subject aircraft is noise certificated. For Chapters 2, 8, 10 and 11, the section specifying the noise limits should also be included.

Block 12. Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards

This item should contain as a minimum all additional modifications to the basic aircraft as defined by Blocks 5, 7 and 8 that are essential in order to meet the requirements of the chapter to which the aircraft is certificated as given under Block 11. Other modifications that are not essential to meet the stated chapter but are needed to attain the certificated noise levels as given may also be included at the discretion of the certificating authority. The additional modifications should be given using unambiguous references, such as supplemental type certificate (STC) numbers, unique part numbers or type/model designators given by the manufacturer of the modification.

Block 13. Lateral/full-power noise level

The lateral/full-power noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB) of the noise level and the noise level should be stated to the nearest tenth of a decibel (dB). This item is included only in noise certification documentation for aircraft certificated to Chapters 2, 3, 4, 5, 12 and 14.

Block 14. Approach noise level

The approach noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 2, 3, 4, 5, 8, 12, 13 and 14.

Block 15. Flyover noise level

The flyover noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 2, 3, 4, 5, 12 and 14.

Block 16. Overflight noise level

The overflight noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB or dB(A)) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 6, 8, 11 and 13. For tilt-rotors certificated according to Chapter 13 only the overflight noise level established in vertical take-off and landing (VTOL)/conversion mode needs to be stated.

Block 17. The take-off noise level

The take-off noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB or dB(A)) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 8, 10 and 13.

Block 18. Statement of compliance, including reference to Annex 16 to the Chicago Convention, Volume I

The statement is provided in EASA Form 45.

Block 19. Date of issue

The date on which the document was issued.

Block 20. Signature

The signature of the officer issuing the noise certificate. Other items may be added such as seal, stamp etc.

Additional information:

1. Logo and name of the issuing authority

In order to facilitate recognition the logo or symbol and the name of the issuing authority may be added in the box ‘For use by the State of registry’.

2. Language

States issuing their noise certification documentation in a language other than English should provide an English translation.

SUBPART J — DESIGN ORGANISATION APPROVAL

21.B.430 Initial certification procedure

Regulation (EU) 2022/201

(a) Upon receiving an application for the initial issue of a design organisation approval, the competent authority shall verify the applicant's compliance with the applicable requirements,

(b) A meeting with the head of the design organisation shall be convened at least once during the investigation for initial certification to ensure that this person understands their role and accountability.

(c) The competent authority shall record all the findings issued, closure actions as well as recommendations for the issue of the design organisation approval.

(d) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the design organisation approval can be issued.

(e) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the design organisation approval.

(f) The certificate reference number shall be included in the design organisation approval in a manner specified by the Agency.

(g) The certificate shall be issued for an unlimited period of time. The privileges and the scope of the activities that the design organisation is approved to perform, including any limitations as applicable, shall be specified in the terms of approval attached to the design organisation approval.

AMC1 21.B.430 Initial certification procedure

ED Decision 2023/014/R

VERIFICATION OF COMPLIANCE — INITIAL CERTIFICATION AUDITS

(a) In order to verify the organisation's compliance with the applicable requirements, the investigation by the competent authority should include one or more audit(s) of the organisation, together with interviews of the personnel, typically carried out at the organisation's facilities.

(b) The competent authority should only conduct such an audit if it is satisfied that the application and supporting documentation are in compliance with the applicable requirements.

(c) The audit(s) should address the following areas:

(1) the organisation's core processes;

(2) the detailed management structure, notably its adequacy;

(3) the personnel: the adequacy of the number of staff, and of their qualifications and experience with regard to the intended terms of approval and the associated privileges;

(4) the processes used for safety risk management and compliance monitoring (independent monitoring function);

(5) the facilities and their adequacy regarding the organisation's intended terms of approval including its scope of work; and

(6) the documentation based on which the approval should be granted.

AMC2 21.B.430 Initial certification procedure

ED Decision 2023/014/R

INVESTIGATION TEAM AND PROCEDURES

(a) The competent authority should appoint a design organisation investigation team for each applicant for a DOA. This team is responsible for conducting all the relevant tasks related to the initial certification. The team should consist of a team leader to manage and lead the team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).

(b) The competent authority should perform sufficient investigation activities for an applicant for a DOA to justify the recommendations for the issuance of the approval.

(c) The competent authority should prepare procedures for the investigation of a design organisation as part of the documented procedures that cover at least the following elements:

(1) evaluation of the application received;

(2) appointment of the investigation team;

(3) preparation and planning of the investigation;

(4) evaluation of the documentation (design organisation handbook, procedures, etc.);

(5) auditing;

(6) follow-up of corrective actions;

(7) recommendation for the issuance of a design organisation approval; and

(8) oversight.

AMC3 21.B.430 Initial certification procedure

ED Decision 2023/014/R

ALTERNATIVE MEANS OF COMPLIANCE

The competent authority should have a procedure for formally recording the proposal, discussion and disposition of alternative means of compliance (deviations from existing AMC). This procedure is necessary to record satisfaction by the competent authority that the use of alternative means provides for compliance with the applicable requirements. The alternative means of compliance should only be allowed to be used by the organisation once agreement has been found with the competent authority. For those alternative means of compliance where previously no formal satisfaction was recorded, a pragmatic approach should be followed on both organisation and competent authority side as to the need to formally record acceptance of such an alternative means of compliance.

Note: EASA Management Board Decisions 03-2004 (Section 2, Article 2, Paragraph 2) and 12-2007 (Section 2, Article 3, Paragraph 2) already required a formal process on the handling of deviations from AMC.

AMC1 21.B.430(a) Initial certification procedure

ED Decision 2023/014/R

INVESTIGATION TEAM SELECTION

(a) Team leader selection

The team leader should satisfy all of the criteria for a team member and will be selected by considering the following additional criteria:

(1) the capability to lead and manage a team;

(2) the capability to prepare reports and be diplomatic;

(3) experience in investigations (not necessarily only Part 21 Section A, Subpart J); and

(4) a knowledge of design management systems.

(b) Team member selection

The competent authority should determine the size of the team and the specialisations to be covered, taking into account the scope of work and the characteristics of the applicant. Team members should be selected by considering the following criteria:

(1) training for Part 21;

(2) education and experience, to cover the appropriate aviation knowledge, investigation practices; and

(3) the ability to verify that an applicant's organisation conforms to its own procedures, and that its key personnel are competent.

AMC1 21.B.430(e) Initial certification procedure

ED Decision 2023/014/R

ISSUE OF THE CERTIFICATE

(a) The competent authority should base its decision to issue a DOA on the recommendation in the DOA investigation report submitted by the DOA team leader. The report includes a proposal by the DOA team for the certificate and terms of approval that define the products, technical scope and privileges for which the approval is to be granted, with appropriate limitations.

(b) When the competent authority issues the approval, a final controlled copy of an acceptable handbook for the organisation should be supplied to the competent authority. Alternatively, when no physical handbook exists, the organisation should provide access to equivalent data.

(c) In some cases, it may be acceptable for some actions to not be fully closed because work is still in progress. The competent authority may decide according to the following principles:

(1) Actions may not represent a non-compliance with the rule. Such non-compliances should be findings and need to be resolved before the approval can be issued.

(2) Actions still to be taken by the organisation which do not prevent the design organisation from working properly in the period when the action is open, can remain open at the time of the approval when an action plan, including timescales, is found to be acceptable.

(3) Recommendations only need acknowledgement of receipt by the organisation at the time of the approval.

21.B.431 Oversight principles

Regulation (EU) 2022/201

The competent authority shall verify whether certified organisations continue to comply with the applicable requirements

(a) The verification shall:

1. be supported by documentation specifically intended to provide personnel responsible for oversight with guidance to perform their functions;
2. provide the organisations concerned with the results of oversight activities;
3. be based on assessments, audits, inspections and, if needed, unannounced inspections;
4. provide the competent authority with the evidence needed in case further action is required, including the measures provided for in point 21.B.433.

(b) The competent authority shall establish the scope of the oversight set out in point (a) taking into account the results of past oversight activities and the safety priorities.

(c) The competent authority shall collect and process any information deemed necessary for performing oversight activities.

(d) For the certification and oversight of the organisation's compliance with point 21.A.239A, in addition to complying with points (a) to (c), the competent authority shall comply with the following principles:

(1) the competent authority shall review the interfaces and associated risks identified in accordance with point IS.D.OR.205(b) of the Annex (Part-IS.D.OR) to Delegated Regulation (EU) 2022/1645 by each organisation subject to its oversight;

(2) if discrepancies are found in the mutual interfaces and associated risks identified by different organisations, the competent authority shall review them with the affected organisations and, if necessary, raise appropriate findings to ensure the implementation of corrective actions;

(3) where the documentation reviewed under point (2) reveals the existence of significant risks associated with interfaces with organisations subject to the oversight of a different competent authority within the same Member State, this information shall be communicated to the corresponding competent authority.

[point (d) is applicable from 22 February 2026 – Regulation (EU) 2023/203]

AMC1 21.B.431 Oversight principles

ED Decision 2023/014/R

OVERSIGHT TEAM AND PROCEDURES

(d) The competent authority should appoint a design organisation oversight team for each holder of a DOA. This team is responsible for conducting all the relevant tasks related to the oversight. The team should consist of a team leader to manage and lead the team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).

(e) The competent authority should perform sufficient oversight activities for a holder of a DOA to justify the recommendations for the maintenance, amendment, limitation, suspension or revocation of the approval.

(f) The competent authority should prepare procedures for the oversight of a design organisation as part of the documented procedures that cover at least the following elements:

(1) appointment of the investigation team;

(2) review of results of past oversight activities;

(3) preparation and planning of the investigation;

(4) evaluation of the documentation (design organisation handbook, procedures, etc.);

(5) auditing;

(6) follow-up of corrective actions;

(7) recommendation for the amendment, limitation, suspension or revocation of a design organisation approval; and

(8) continued surveillance.

AMC2 21.B.431 Oversight principles

ED Decision 2023/014/R

OVERSIGHT TEAM SELECTION

(c) Team leader selection

The team leader should satisfy all of the criteria for a team member and will be selected by considering the following additional criteria:

(5) the capability to lead and manage a team;

(6) the capability to prepare reports and be diplomatic;

(7) experience in oversight (not necessarily only Part 21 Section A, Subpart J); and

(8) a knowledge of design management systems.

(d) Team member selection

The competent authority should determine the size of the team and the specialisations to be covered, taking into account the scope of work and the characteristics of the applicant. Team members should be selected by considering the following criteria:

(4) training for Part 21;

(5) education and experience, to cover the appropriate aviation knowledge, investigation practices; and

(6) the ability to verify that an applicant's organisation conforms to its own procedures, and that its key personnel are competent.

AMC3 21.B.431 Oversight principles

ED Decision 2023/014/R

MANAGEMENT SYSTEM ASSESSMENT

(a) As a result of the oversight, the competent authority should be satisfied as to the effectiveness of the organisation's management system and processes.

(b) When significant changes take place in the organisation, the competent authority should determine whether there is a need to review the existing assessment to ensure that it is still valid.

AMC4 21.B.431 Oversight principles

ED Decision 2023/014/R

ALTERNATIVE MEANS OF COMPLIANCE

The competent authority should have a procedure for formally recording the proposal, discussion and disposition of alternative means of compliance (deviations from existing AMC). This procedure is necessary to record satisfaction by the competent authority that the use of alternative means provides for compliance with the applicable requirements. The alternative means of compliance should only be allowed to be used by the organisation once agreement has been found with the competent authority. For those alternative means of compliance where previously no formal satisfaction was recorded, a pragmatic approach should be followed on both organisation and competent authority side as to the need to formally record acceptance of such an alternative means of compliance.

Note: EASA Management Board Decisions 03-2004 (Section 2, Article 2, Paragraph 2) and 12-2007 (Section 2, Article 3, Paragraph 2) already required a formal process on the handling of deviations from AMC.

21.B.432 Oversight programme

Regulation (EU) 2022/201

(a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required to comply with point 21.B.431(a).

(b) The oversight programme shall take into account the specific nature of the organisation, the complexity of its activities, the results of past certification or oversight activities, or both, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including, where appropriate:
   - (i) management system assessments and process audits;
   - (ii) product audits of a relevant sample of the design and certification of the products, parts and appliances that are within the scope of work of the organisation;
   - (iii) sampling of the work performed;
   - (iv) unannounced inspections;
2. meetings convened between the head of the design organisation and the competent authority to ensure that both parties remain informed of all significant issues.

(c) The oversight planning cycle shall not exceed 24 months.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;

2. the organisation has continuously demonstrated compliance with point 21.A.247 and has full control over all changes to the design management system;

3. no level 1 findings have been issued;

4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as provided for in point 21.B.433(d).

Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions laid down in points (d)(1) to (d)(4), the organisation has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(e) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(f) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the approval, reflecting the results of the oversight.

AMC1 21.B.432 Oversight programme

ED Decision 2023/014/R

ANNUAL REVIEW

(a) The oversight planning cycle and the related oversight programme for each organisation should be reviewed annually to ensure that they remain adequate regarding any changes in the nature of the organisation, the complexity of its activities or the safety performance of the organisation.

(b) When reviewing the oversight planning cycle and the related oversight programme, the competent authority should also consider any relevant information collected in accordance with point 21.B.431(c).

AMC1 21.B.432(a) and (b) Oversight programme

ED Decision 2023/014/R

OVERSIGHT PLANNING

(a) When defining the oversight programme, the competent authority should assess the risks related to the activity and set-up of each organisation, and adapt the oversight to the level of risk identified and to the effectiveness of the organisation's management system, in particular its ability to effectively manage safety risks.

(b) The competent authority should establish a schedule of assessments, audits and inspections that is appropriate to each organisation. The planning of assessments, audits and inspections should take into account the results of the hazard identification and the risk assessment conducted and maintained by the organisation as part of the organisation's management system.

AMC1 21.B.432(b) Oversight programme

ED Decision 2023/014/R

SPECIFIC NATURE OF THE ORGANISATION AND COMPLEXITY OF ITS ACTIVITIES — RESULTS OF PAST OVERSIGHT ACTIVITIES

When determining the oversight programme, including a relevant sample of design activities under the scope of the organisation as product audits, the competent authority should consider in particular the following elements, as applicable:

(a) the effectiveness of the organisation's management system in identifying and addressing non-compliances and safety hazards;

(b) the implementation by the organisation of any industry standards that are directly relevant to the organisation's activity subject to Part 21;

(c) the procedure for the management and the scope of non-significant changes;

(d) the number of locations and the activities performed at each location;

(e) the number and scope of subcontractors that perform design activities; and

(f) the overall volume of activity and, as applicable, per specific product.

AMC2 21.B.432(b) Oversight programme

ED Decision 2023/014/R

SUBCONTRACTED ACTIVITIES

If a design organisation subcontracts design activities, the competent authority should determine whether the subcontracted organisations need to be audited and include this in the oversight programme, taking into account the specific nature and complexity of the subcontracted activities, the results of previous oversight activities of the design organisation, and assessment of the associated risks.

For such an audit, the competent authority inspectors should ensure that they are accompanied throughout the audit by a representative of the design organisation.

NOTE: If a design organisation subcontracts design activities, the competent authority should verify that the design organisation has sufficient control over the subcontracted activities and manages the related risks.

AMC1 21.B.432(b)(1) Oversight programme

ED Decision 2023/014/R

ASSESSMENTS, AUDITS AND INSPECTIONS

(a) The oversight programme should indicate which aspects of the approval will be covered by each assessment, audit or inspection.

(b) Audits may be complemented by a review of the independent monitoring function results related to the topic of the audit.

(c) At the conclusion of the assessment, audit, or inspection, the DOA team should complete a report that identifies the areas and processes that were covered and includes all the findings and observations that were raised.

AMC2 21.B.432(c) Oversight programme

ED Decision 2023/014/R

OVERSIGHT PLANNING CYCLE — AUDIT

(a) The beginning of the first oversight planning cycle is determined by the date of issue of the first approval.

(b) The oversight planning should include at least one on-site audit within each oversight planning cycle. For organisations that carry out their regular activities at more than one site, the determination of the sites to be audited should consider the results of past oversight activities and the volume of activity at each site, as well as the main risk areas identified.

AMC1 21.B.432(d) and (e) Oversight programme

ED Decision 2023/014/R

EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS

(a) When at the time before applicability of Commission Delegated Regulation (EU) 2022/201 the oversight planning cycle was determined to be 36 months, the oversight planning cycle can continue to be 36 months unless the criteria of point (b) would apply.

(b) If the results of the oversight activities indicate an overall decrease in the safety performance or regulatory compliance of the organisation, the competent authority should consider reverting back to a 24-month oversight planning cycle or adapt the oversight planning accordingly.

(c) In order to be able to apply an oversight planning cycle beyond 36 months, the competent authority should agree on the format and contents of regular reporting to be made by the organisation on its safety performance and regulatory compliance.

21.B.433 Findings and corrective actions; observations

Regulation (EU) 2022/201

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when a non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the design organisation's certificate including the terms of approval, which may lead to uncontrolled non-compliances and to a potential unsafe condition.

The level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;
2. obtaining the design organisation approval or maintaining its validity by falsification of the submitted documentary evidence;
3. any evidence of malpractice or fraudulent use of the design organisation approval;
4. failure to appoint a head of the design organisation pursuant to point 21.A.245(a).

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval, which is not classified as a level 1 finding.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non- compliance(s) identified. Where a level 1 finding directly relates to a product, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall:
   (i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding and that in any case shall not be more than 21 working days. That period shall commence from the date of the written communication of the finding to the organisation requesting corrective action to address the non-compliance(s) identified;
   (ii) assess the corrective action plan and implementation plan proposed by the organisation, and if it concludes that they are sufficient to address the non-compliance(s), accept them;
   (iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted by the competent authority, take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, take action to revoke the design organisation approval or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. That period shall commence from the date of the written communication of the finding requesting corrective action. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed by the competent authority;

(ii) assess the corrective action and the implementation plan proposed by the organisation, and if it concludes that they are sufficient to address the non-compliance(s), accept them;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (d)(1).

(e) The competent authority may issue observations for any of the following cases not requiring level 1 or level 2 findings:

1. for any item whose performance has been assessed to be ineffective;

2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c);

3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.

GM1 21.B.433(b) Findings and corrective actions; observations

ED Decision 2023/014/R

EVIDENCE

A finding can only be raised on the basis of evidence.

Evidence is a fact that is, or can be, documented based on observations, measurements, or tests that can be verified. Evidence generally comes from the following:

(a) documents or manuals;

(b) examination of equipment/products; and

(c) information from interview questions and from observations of an organisation’s activities, as applicable.

AMC1 21.B.433(d) Findings and corrective actions ; observations

ED Decision 2023/014/R

NOTIFICATION OF FINDINGS

(a) Findings should be notified to the design organisation through:

(1) the debrief at the end of an audit (only when no further internal review is necessary); or

(2) the audit report; or

(3) a separate communication.

(b) The finding notification should be supplemented by a record in which all relevant data to the finding are specified, such as notification date, identification of evidence, the corrective action implementation period, and the relevant Part 21 requirement(s).

(c) Level 1 findings should only be notified to the design organisation after an internal review by the competent authority, to make sure that the prerequisites for such a finding are fulfilled. Confirmation should be obtained in a timely manner that the head of the design organisation has taken note of the level 1 finding and its details.

(d) A finding requires effective oversight by the competent authority to monitor the timely completion of the corrective action.

GM1 21.B.433(e) Findings and corrective actions; observations

ED Decision 2023/014/R

DIFFERENTIATION BETWEEN A 'LEVEL 2 FINDING' AND AN 'OBSERVATION'

'Findings' are issued for non-compliance with the Regulation, with the organisation's procedures and manuals, or with the certificate including the terms of approval, whereas 'observations' may be issued to an organisation that remains compliant with the Regulation while additional input to the organisation could be considered for continuous improvement (see points (1), (2) and (3) of point 21.B.433(e)).

The competent authority may decide to issue a level 2 finding when the observations process is not managed correctly or overlooked (see point 21.A.258(c)).

21.B.435 Changes in the design management system

Regulation (EU) 2022/201

(a) Upon receiving an application for a significant change to the design management system, the competent authority shall verify the organisation's compliance with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, before issuing the approval.

(b) The competent authority shall establish the conditions under which the organisation may operate during the change unless the competent authority determines that the design organisation approval needs to be suspended.

(c) When it is satisfied that the organisation complies with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, the competent authority shall approve the change.

(d) Without prejudice to any additional enforcement measures, if the organisation implements a significant change to the design management system without having received the approval of the competent authority pursuant to point (c), the competent authority shall consider the need to suspend, limit or revoke the organisation's certificate.

(e) For non-significant changes to the design management system, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles set forth in point 21.B.431. If any non-compliance is found, the competent authority shall notify the organisation, request further changes and act in accordance with point 21.B.433.

AMC1 21.B.435 Changes in the design management system

ED Decision 2023/014/R

APPLICATION FOR SIGNIFICANT CHANGES OR CHANGE OF TERMS OF APPROVAL OF THE DOA

(a) The competent authority should review any changes in the personnel specified in points 21.A.245 (a) and (b).

(b) When an organisation submits the application for a significant change for any of the personnel positions specified in points 21.A.245 (a) and (b), the competent authority should require the organisation to produce a résumé of the proposed person. The competent authority may interview the nominee or request additional evidence of their suitability before deciding upon the nominee being acceptable.

(c) For changes requiring prior approval, in order to verify the organisation's compliance with the applicable requirements, the competent authority should determine the necessary activities to verify continued compliance of the organisation, limited to the extent of the changes, and determine whether the organisation needs to provide a safety risk assessment.

(d) If required for verification, the activities may include interviews and inspections carried out at the organisation's facilities.

AMC2 21.B.435 Changes in the design management system

ED Decision 2023/014/R

ALTERNATIVE MEANS OF COMPLIANCE

The competent authority should have a procedure for formally recording the proposal, discussion and disposition of alternative means of compliance (deviations from existing AMC). This procedure is necessary to record satisfaction by the competent authority that the use of alternative means provides for compliance with the applicable requirements. The alternative means of compliance should only be allowed to be used by the organisation once agreement has been found with the competent authority. For those alternative means of compliance where previously no formal satisfaction was recorded, a pragmatic approach should be followed on both organisation and competent authority side as to the need to formally record acceptance of such an alternative means of compliance.

Note: EASA Management Board Decisions 03-2004 (Section 2, Article 2, Paragraph 2) and 12-2007 (Section 2, Article 3, Paragraph 2) already required a formal process on the handling of deviations from AMC.

21.B.435A Changes to the information security management system

Regulation (EU) 2023/203

(a) For changes managed and notified to the competent authority in accordance with the procedure set out in point IS.D.OR.255(a) of the Annex (Part-IS.D.OR) to Delegated Regulation (EU) 2022/1645, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles laid down in point 21.B.431. If any non-compliance is found, the competent authority shall notify the organisation thereof, request further changes and act in accordance with point 21.B.433.

(b) For other changes requiring an application for approval in accordance with point IS.D.OR.255(b) of the Annex (Part-IS.D.OR) to Delegated Regulation (EU) 2022/1645:

(1) upon receiving the application for the change, the competent authority shall check the organisation's compliance with the applicable requirements before issuing the approval;

(2) the competent authority shall establish the conditions under which the organisation may operate during the implementation of the change;

(3) if it is satisfied that the organisation complies with the applicable requirements, the competent authority shall approve the change.

[applicable from 22 February 2026 – Regulation (EU) 2023/203]

SUBPART K — PARTS AND APPLIANCES

Administrative procedures established by the Agency shall apply

(SUBPART L — NOT APPLICABLE)

SUBPART M — REPAIRS

21.B.450 Type-certification basis and environmental protection requirements for a repair design approval

Regulation (EU) 2019/897

The Agency shall designate any amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation, which the Agency considers necessary for maintaining a level of safety equal to that previously established and notify them to the applicant for a repair design.

21.B.453 Issuance of a repair design approval

Regulation (EU) 2022/201

(a) The Agency shall issue an approval of a major repair design, provided that:

1. the applicant has demonstrated its capability in accordance with point 21.A.432B;
2. the applicant has complied with point 21.A.433;
3. the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement established pursuant to point 21.B.100(a), has not found any non-compliance with the type-certification basis and environmental protection requirements; and
4. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(b) The Agency shall issue an approval of a minor repair design, provided that the applicant has complied with points (2) and (4) of point (a) and provided that the Agency, through its verifications of the demonstration of compliance in accordance with the level of involvement pursuant to point 21.B.100(b), has not found any non-compliance with the type-certification basis and environmental protection requirements.

(SUBPART N — NOT APPLICABLE)

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.B.480 Issuance of an ETSO authorisation

Regulation (EU) 2022/201

The Agency shall issue an ETSO authorisation, provided that:

(a) the applicant has complied with point 21.A.606;

(b) the Agency, through its verifications of the demonstration of compliance in accordance with the level of involvement pursuant to point 21.B.100(b), has not found any non-compliance with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any; and

(c) no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.

SUBPART P — PERMIT TO FLY

21.B.520 Investigation

Regulation (EU) No 748/2012

(a) The competent authority shall perform sufficient investigation activities to justify the issuance, or revocation of the permit to fly.

(b) The competent authority shall prepare evaluation procedures covering at least the following elements:

1. evaluation of the eligibility of the applicant;
2. evaluation of the eligibility of the application;
3. evaluation of the documentation received with the application;
4. inspection of the aircraft;
5. approval of the flight conditions in accordance with point 21.A.710(b).

AMC 21.B.520(b) Application for a permit to fly

ED Decision 2012/020/R

The competent authority must receive an application for permit to fly in a form and manner established by that authority, e.g. on EASA Form 21 (see below) completed by the applicant.

Application for Part 21 Permit to Fly	
1. Applicant:	*[Name of applicant]*
2. Aircraft nationality and identification marks:	
3. Aircraft owner:	
4. Aircraft manufacturer/type	**5. Serial number**
6. Purpose of flight *[Use terminology of* 21.A.701(a) *and add any additional information for accurate description of the purpose, e.g. place, itinerary, duration…]* [For an application due to a change of purpose (ref. 21.A.713): reference to initial request and description of new purpose]	
7. Expected target date(s) for the flight(s) and duration	
8. Aircraft configuration as relevant for the permit to fly 8.1 The above aircraft for which a permit to fly is requested is defined in [add reference to the document(s) identifying the configuration of the aircraft. Same as required in AMC 21.A.263(c)(6) or AMC 21.A.709(b) application approval form 18A or 18B, box 6] 8.2 The aircraft is in the following situation related to its maintenance schedule: *[Describe status]*	
9. Approval of flight conditions *[if not available at the time of application, indicate reference of request for approval]* *[Reference to:* *1. EASA approval, if flight conditions are approved by EASA; or* *2.* DOA approval form (see AMC 21.A.263(c)(6)), if approved under DOA privilege; or *3. Competent authority approval.*	
10. Date:	**11. Name and signature:** *[Authorised signatory]*

EASA Form 21

21.B.525 Issuance of a permit to fly

Regulation (EU) 2022/203

The competent authority shall issue a permit to fly (EASA Form 20a, see Appendix III) without undue delay:

(a) upon presentation of the data required by point 21.A.707; and

(b) when the flight conditions referred to in point 21.A.708 have been approved in accordance with point 21.A.710; and

(c) when the competent authority, through its own investigations, which may include inspections, or through procedures agreed with the applicant, is satisfied that the aircraft conforms to the design defined under point 21.A.708 before flight.

SUBPART Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

Administrative procedures established by the Agency shall apply

APPENDICES

EASA FORMS

Regulation (EU) 2020/570

When the Forms of this Annex are issued in a language other than English they shall include an English translation.

The EASA ('European Aviation Safety Agency') Forms referred to in the appendices to this Part shall have the following obligatory features. Member States shall ensure that the EASA Forms they issue are recognisable and shall be responsible for having those Forms printed.

Appendix I — EASA Form 1 Authorised release Certificate

Appendix II — EASA Form 15a and 15c — Airworthiness Review Certificate

Appendix III — EASA Form 20a Permit to Fly

Appendix IV — EASA Form 20b Permit to Fly (issued by approved organisations)

Appendix V — EASA Form 24 Restricted Certificate of Airworthiness

Appendix VI — EASA Form 25 Certificate of Airworthiness

Appendix VII — EASA Form 45 Noise Certificate

Appendix VIII — EASA Form 52 Aircraft Statement of Conformity

Appendix IX — EASA Form 53 Certificate of Release to Service

Appendix X — EASA Form 55 Production Organisation Approval Certificate

Appendix XI — EASA Form 65 Letter of Agreement for production without production organisation approval

Appendix I — EASA Form 1 — Authorised Release Certificate

Regulation (EU) No 69/2014

Appendix I

Authorised Release Certificate — EASA Form 1 referred to in Annex I (Part 21)

<table>
<tr><td colspan="3">1. Approving Competent Authority / Country</td><td colspan="2">2. AUTHORISED RELEASE CERTIFICATE
EASA FORM 1</td><td>3. Form Tracking Number</td></tr>
<tr><td colspan="5">4. Organisation Name and Address:</td><td>5. Work Order/Contract/Invoice</td></tr>
<tr><td>6. Item</td><td>7. Description</td><td>8. Part No.</td><td>9. Qty.</td><td>10. Serial No.</td><td>11. Status/Work</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="6">12. Remarks</td></tr>
<tr><td colspan="3">13a. Certifies that the items identified above were manufactured in conformity to:
□ approved design data and are in a condition for safe operation
□ non-approved design data specified in block 12</td><td colspan="3">14a □ Part-145.A.50 Release to Service □ Other regulation specified in block 12
Certifies that unless otherwise specified in block 12, the work identified in block 11 and described in block 12, was accomplished in accordance with Part-145 and in respect to that work the items are considered ready for release to service.</td></tr>
<tr><td colspan="2">13b. Authorised Signature</td><td>13c. Approval/Authorisation Number</td><td colspan="2">14b. Authorised Signature</td><td>14c. Certificate/Approval Ref. No.</td></tr>
<tr><td colspan="2">13d. Name</td><td>13e. Date (dd mmm yyyy)</td><td colspan="2">14d. Name</td><td>14e. Date (dd mmm yyyy)</td></tr>
<tr><td colspan="6">USER/INSTALLER RESPONSIBILITIES</td></tr>
</table>

This certificate does not automatically constitute authority to install the item(s).
Where the user/installer performs work in accordance with regulations of an airworthiness authority different than the airworthiness authority specified in block 1, it is essential that the user/installer ensures that his/her airworthiness authority accepts items from the airworthiness authority specified in block 1.
Statements in blocks 13a and 14a do not constitute installation certification. In all cases aircraft maintenance records must contain an installation certification issued in accordance with the national regulations by the user/installer before the aircraft may be flown.

EASA Form 1-21 Issue 2.

Instructions for the use of EASA Form 1

These instructions relate only to the use of EASA Form 1 for production purposes. Attention is drawn to Appendix II to Annex I (Part-M) of Regulation (EU) No 1321/2014 which covers the use of EASA Form 1 for maintenance purposes.

1. PURPOSE AND USE

1.1. A primary purpose of the certificate is to declare the airworthiness of new aviation products, parts and appliances ('the item(s)').

1.2. Correlation must be established between the certificate and the item(s). The originator must retain a certificate in a form that allows verification of the original data.

1.3. The certificate is acceptable to many airworthiness authorities, but this may be dependent on bilateral agreements and/or the policy of the airworthiness authority.

1.4. The certificate is not a delivery or shipping note.

1.5. Aircraft are not to be released using the certificate.

1.6. The certificate does not constitute approval to install the item on a particular aircraft, engine, or propeller but helps the end user determine its airworthiness approval status.

1.7. A mixture of production released and maintenance released items is not permitted on the same certificate.

1.8. A mixture of items certified in conformity with 'approved data' and to 'non-approved data' is not permitted on the same certificate.

2. GENERAL FORMAT

2.1. The certificate must comply with the format attached including block numbers and the location of each block. The size of each block may however be varied to suit the individual application, but not to the extent that would make the certificate unrecognisable.

2.2. The certificate must be in 'landscape' format, but the overall size may be significantly increased or decreased so long as the certificate remains recognisable and legible. If in doubt, consult the competent authority.

2.3. The user/installer responsibility statement can be placed on either side of the form.

2.4. All printing must be clear and legible to permit easy reading.

2.5. The certificate may either be pre-printed or computer generated but in either case the printing of lines and characters must be clear and legible and in accordance with the defined format.

2.6. The certificate should be in English, and if appropriate, in one or more other languages.

2.7. The details to be entered on the certificate may be either machine/computer printed or hand-written using block letters and must permit easy reading.

2.8. Limit the use of abbreviations to a minimum, to aid clarity.

2.9. The space remaining on the reverse side of the certificate may be used by the originator for any additional information but must not include any certification statement. Any use of the reverse side of the certificate must be referenced in the appropriate block on the front side of the certificate.

3. COPIES

3.1. There is no restriction in the number of copies of the certificate sent to the customer or retained by the originator.

4. ERROR(S) ON A CERTIFICATE

4.1. If an end user finds an error(s) on a certificate, they must identify it (them) in writing to the originator. The originator may issue a new certificate if they can verify and correct the error(s).

4.2. The new certificate must have a new tracking number, signature and date.

4.3. The request for a new certificate may be honoured without re-verification of the item(s) condition. The new certificate is not a statement of current condition and should refer to the previous certificate in block 12 by the following statement: 'This certificate corrects the error(s) in block(s) [enter block(s) corrected] of the certificate [enter original tracking number] dated [enter original issuance date] and does not cover conformity/condition/release to service'. Both certificates should be retained according to the retention period associated with the first.

5. COMPLETION OF THE CERTIFICATE BY THE ORIGINATOR

Block 1 Approving competent authority/Country

State the name and country of the competent authority under whose jurisdiction this certificate is issued. When the competent authority is the Agency, only 'EASA' must be stated.

Block 2 EASA Form 1 header

'AUTHORISED RELEASE CERTIFICATE EASA FORM 1'

Block 3 Form Tracking Number

Enter the unique number established by the numbering system/procedure of the organisation identified in block 4; this may include alpha/numeric characters.

Block 4 Organisation Name and Address

Enter the full name and address of the production organisation (refer to EASA Form 55 Sheet A) or natural or legal persons releasing the item(s) covered by this certificate. Logos, etc. of the organisation are permitted if they can be contained within the block.

Block 5 Work Order/Contract/Invoice

To facilitate customer traceability of the item(s), enter the work order number, contract number, invoice number, or similar reference number.

Block 6 Item

Enter line item numbers when there is more than one line item. This block permits easy cross-referencing to the Remarks in block 12.

Block 7 Description

Enter the name or description of the item. Preference should be given to the term used in the instructions for continued airworthiness or maintenance data (e.g. Illustrated Parts Catalogue, Aircraft Maintenance Manual, Service Bulletin, Component Maintenance Manual).

Block 8 Part Number

Enter the part number as it appears on the item or tag/packaging. In the case of an engine or propeller, the type designation may be used.

Block 9 Quantity

State the quantity of items.

Block 10 Serial Number

If the item is required by regulation to be identified with a serial number, enter it here. Additionally, any other serial number not required by regulation may also be entered. If there is no serial number identified on the item, enter 'N/A'.

Block 11 Status/Work

Enter either 'PROTOTYPE' or 'NEW'.

Enter 'PROTOTYPE' for:

(i) the production of a new item in conformity with non-approved design data;

(ii) the production of a new item in conformity with design data that has not yet been declared by a declarant in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light);

(iii) re-certification by the organisation identified in block 4 of the previous certificate after alteration or rectification work on an item, prior to entry into service, (e.g. after incorporation of a design change, correction of a defect, inspection or test, or renewal of shelf life). Details of the original release and the alteration or rectification work are to be entered in block 12;

Enter 'NEW' for:

(i) the production of a new item in conformity with the approved design data;

(ii) the production of a new item in conformity with design data declared by the declarant in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light);

(iii) re-certification by the organisation identified in block 4 of the previous certificate after alteration or rectification work on an item, prior to entry into service, (e.g. after incorporation of a design change, correction of a defect, inspection or test, or renewal of shelf-life). Details of the original release and the alteration or rectification work are to be entered in block 12;

(iv) re-certification by the product manufacturer or the organisation identified in block 4 of the previous certificate of items from 'prototype' (conformity only to non-approved data) to 'new' (conformity to approved data and in a condition for safe operation), subsequent to approval of the applicable design data, provided that the design data has not changed.

For certified products, the following statement must be entered in block 12:

'RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW': THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA [INSERT TC/STC NUMBER, REVISION LEVEL], DATED [INSERT DATE IF NECESSARY FOR IDENTIFICATION OF REVISION STATUS], TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.'

The box 'approved design data and are in a condition for safe operation' should be marked in block 13a;

For aircraft subject to a declaration of design compliance in accordance with Subpart C of Section A of Annex Ib (Part 21 Light), the following statement must be entered in block 12:

'RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW': THIS DOCUMENT CERTIFIES THE DECLARATION OF THE DESIGN DATA [INSERT DECLARATION REFERENCE, REVISION LEVEL], DATED [INSERT DATE IF NECESSARY FOR IDENTIFICATION OF REVISION STATUS], TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.'

(v) the examination of a previously released new item prior to entry into service in accordance with a customer-specified standard or specification (details of which and of the original release are to be entered in block 12) or to establish airworthiness (an explanation of the basis of release and details of the original release are to be entered in block 12).

Block 12 Remarks

Describe the work identified in block 11, either directly or by reference to supporting documentation, necessary for the user or installer to determine the airworthiness of item(s) in relation to the work being certified. If necessary, a separate sheet may be used and referenced from EASA Form 1. Each statement must clearly identify which item(s) in block 6 it relates to. If there is no statement, state 'None'.

Enter the justification for release to non-approved design data in block 12 (e.g. pending type certificate, for test only, pending approved data).

If the item has been produced in accordance with design data that has not yet been declared by the declarant in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light), then the following statement shall be included in Block 12:

'PENDING DECLARATION OF DESIGN COMPLIANCE IN ACCORDANCE WITH SUBPART C, F or N of Section A of Annex Ib (Part 21 Light)'

If the item has been produced in accordance with design data that has been declared by the declarant in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light), then the following statement shall be included in Block 12:

'PRODUCED IN CONFORMITY WITH THE DESIGN DATA OF A DECLARATION OF DESIGN COMPLIANCE IN ACCORDANCE WITH SUBPART C, F or N of Section A of Annex Ib (Part 21 Light)'

If printing the data from an electronic EASA Form 1, any data not appropriate in other blocks should be entered in this block.

Block 13a Mark only one of the two boxes:

1. Mark the 'approved design data and are in a condition for safe operation' box if the item(s) was (were) manufactured using approved design data and found to be in a condition for safe operation.

2. Mark the 'non-approved design data specified in block 12' box if the item(s) was (were) manufactured using applicable non-approved design data.

This box shall also be marked when the item has been produced in conformity with design data that has been declared in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light).

Identify the data in block 12 (e.g. pending type certificate, for test only, pending approved data, conformity to design data from a declaration of design compliance in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light).

Mixtures of items released against approved and non-approved design data are not permitted on the same certificate.

Block 13b Authorised Signature

This space shall be completed with the signature of the authorised person. Only persons specifically authorised under the rules and policies of the competent authority are permitted to sign this block. To aid recognition, a unique number identifying the authorised person may be added.

Block 13c Approval/Authorisation Number

Enter the approval/authorisation number/reference. This number or reference is issued by the competent authority for approved or declared production organisations (for parts produced under Annex Ib (Part 21 Light). If the organisation has produced a part that conforms to design data declared by a declarant in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light) and the organisation is not an approved or a declared production organisation, then they should enter the following statement:

'PRODUCED UNDER SUBPART R of Section A of Annex Ib (Part 21 Light)'

Block 13d Name

Enter the name of the person signing block 13b in a legible form.

Block 13e Date

Enter the date on which block 13b is signed, the date must be in the format dd = 2 digit day, mmm = first 3 letters of the month, yyyy = 4 digit year.

Block 14a-14e General Requirements for blocks 14a-14e:

Not used for production release. Shade, darken, or otherwise mark to preclude inadvertent or unauthorised use.

User/Installer Responsibilities

Place the following statement on the certificate to notify end users that they are not relieved of their responsibilities concerning installation and use of any item accompanied by the form:

'THIS CERTIFICATE DOES NOT AUTOMATICALLY CONSTITUTE AUTHORITY TO INSTALL.

WHERE THE USER/INSTALLER PERFORMS WORK IN ACCORDANCE WITH REGULATIONS OF AN AIRWORTHINESS AUTHORITY DIFFERENT THAN THE AIRWORTHINESS AUTHORITY SPECIFIED IN BLOCK 1, IT IS ESSENTIAL THAT THE USER/INSTALLER ENSURES THAT HIS/HER AIRWORTHINESS AUTHORITY ACCEPTS ITEMS FROM THE AIRWORTHINESS AUTHORITY SPECIFIED IN BLOCK 1.

STATEMENTS IN BLOCKS 13A AND 14A DO NOT CONSTITUTE INSTALLATION CERTIFICATION. IN ALL CASES AIRCRAFT MAINTENANCE RECORDS MUST CONTAIN AN INSTALLATION CERTIFICATION ISSUED IN ACCORDANCE WITH THE NATIONAL REGULATIONS BY THE USER/INSTALLER BEFORE THE AIRCRAFT MAY BE FLOWN.'

Appendix II — EASA Form 15a and 15c — Airworthiness Review Certificate

Regulation (EU) 2021/699

Appendix II

Airworthiness Review Certificate – EASA Form 15a

[MEMBER STATE]

A Member of the European Union[1]

AIRWORTHINESS REVIEW CERTIFICATE

ARC reference: …….

Pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council the [COMPETENT AUTHORITY OF THE MEMBER STATE] hereby certifies that the following aircraft:

Aircraft manufacturer: ……

Manufacturer's designation: ……

Aircraft registration: ……

Aircraft serial number: ……

is considered airworthy at the time of the review.

Date of issue: …… Date of expiry: ……

Airframe flight hours (FH) at date of issue[2]: ……

Signed: …… Authorisation No: ……

1st extension: The aircraft has remained in a controlled environment in accordance with point M.A.901 of Annex I (Part-M) to Commission Regulation (EU) No 1321/2014 for the last year. The aircraft is considered to be airworthy at the time of the issuance of this certificate.

Date of issue: …… Date of expiry: ……

Airframe flight hours (FH) at date of issue[1]: ……

Signed: …… Authorisation No: ……

Company Name: …… Approval reference: ……

2nd extension: The aircraft has remained in a controlled environment in accordance with point M.A.901 of Annex I (Part-M) to Commission Regulation (EU) No 1321/2014 for the last year. The aircraft is considered to be airworthy at the time of the issuance of the certificate.

Date of issue: …… Date of expiry: ……

Airframe flight hours (FH) at date of issue[1]: ……

Signed: …… Authorisation No: ……

[1] Delete for non-EU Member States.

[2] Except for airships.

Company Name: …… Approval reference: ……

EASA Form 15a – Issue 5

Airworthiness Review Certificate – EASA Form 15c

NOTE: persons and organisations performing the airworthiness review in combination with the 100-h/annual inspection may use the reverse side of this form in order to issue the CRS referred to in point ML.A.801 corresponding to the 100-h/annual inspection.

AIRWORTHINESS REVIEW CERTIFICATE (ARC) (for aircraft complying with Part-ML)

ARC reference: ……

Pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council:

[NAME OF THE COMPETENT AUTHORITY] (**)

hereby certifies that:

☐…..it has performed an airworthiness review in accordance with Regulation (EU) No 1321/2014 on the following aircraft:

[or]

☐…..the following new aircraft:

Aircraft manufacturer:……Manufacturer's designation:……

Aircraft registration:……Aircraft serial number:……

(and that this aircraft) is considered airworthy at the time of the review.

Date of issue: ……Date of expiry: ……

Airframe flight hours (FH) at date of review (*): ……

Signed: ……Authorisation No (if applicable): ……

[OR]

[NAME OF APPROVED ORGANISATION, ADDRESS and APPROVAL REFERENCE] (**)

[or]

[FULL NAME OF THE CERTIFYING STAFF AND PART-66 LICENCE NUMBER (OR NATIONAL EQUIVALENT)] (**)

hereby certifies that it has performed an airworthiness review in accordance with Regulation (EU) No 1321/2014 on the following aircraft:

Aircraft manufacturer:……Manufacturer's designation:……

Aircraft registration:……Aircraft serial number:……

and that this aircraft is considered airworthy at the time of the review.

Date of issue: ……Date of expiry: ……

Airframe flight hours (FH) at date of review (*): ……

Signed: ……Authorisation No (if applicable): ……

==========

1st extension: The aircraft complies with the conditions of ML.A.901(c) of Annex Vb (Part-ML)

Date of issue: ……Date of expiry: ……

Airframe flight hours (FH) at date of issue (*): ……

Signed: .....Authorisation No: ……

Company name: .....Approval reference: ……

==========

2nd extension: The aircraft complies with the conditions of ML.A.901(c) of Annex Vb (Part-ML)

Date of issue: .....Date of expiry: ……

Airframe flight hours (FH) at date of issue (*): ……

Signed: .....Authorisation No: ……

Company name: .....Approval reference: ……

(*) Except for balloons and airships

(**) The issuer of the Form can tailor it to his need by deleting the name, the certifying statement, the reference to the subject aircraft and the issuance details that are not relevant for his use.

EASA Form 15c, Issue 4

Appendix III — EASA Form 20a — Permit to Fly

Regulation (EU) No 748/2012

Appendix III

Competent authority logo	**PERMIT TO FLY**

[1]	
This permit to fly is issued pursuant to Regulation (EC) No 216/2008, Article 5(4)(a) and certifies that the aircraft is capable of safe flight for the purpose and within the conditions listed below and is valid in all Member States This permit is also valid for flight to and within non-Member States provided separate approval is obtained from the competent authorities of such States:	1. Nationality and registration marks:
2. Aircraft manufacturer/type:	3. Serial No:
4. The permit covers: [purpose in accordance with 21.A.701(a)]	
5. Holder: [in case of a permit to fly issued for the purpose of 21.A.701(a)(15) this should state: 'the registered owner']	
6. Conditions/remarks:	
7. Validity period:	
8. Place and date of issue:	9. Signature of the competent authority representative:

EASA Form 20a

[1] For use by State of Registry.

Appendix IV — EASA Form 20b — Permit to Fly (issued by approval organisations)

Regulation (EU) No 748/2012

Appendix IV

Member State of the Competent Authority having issued the organisation approval under which the permit to fly is issued; or 'EASA' when approval issued by EASA

PERMIT TO FLY

Name and Address of the organisation issuing the permit to fly	[1]
This permit to fly is issued pursuant to Regulation (EC) No 216/2008, Article 5(4)(a) and certifies that the aircraft is capable of safe flight for the purpose and within the conditions listed below and is valid in all Member States This permit is also valid for flight to and within non-Member States provided separate approval is obtained from the competent authorities of such States.	1. Nationality and registration marks:
2. Aircraft manufacturer/type:	3. Serial No:
4. The permit covers: [purpose in accordance with 21.A.701(a)	
5. Holder: *[Organisation issuing the permit to fly]*	
6. Conditions/remarks:	
7. Validity period:	
8. Place and date of issue:	9. Authorised signature: Name: Approval Reference No:

EASA Form 20b

[1] For use by Organisation Approval holder.

Appendix V — EASA Form 24 — Restricted Certificate of Airworthiness

Regulation (EU) No 748/2012

Appendix V

Restricted Certificate of Airworthiness — EASA Form 24

Competent authority LOGO

RESTRICTED CERTIFICATE OF AIRWORTHINESS

[1]	[Member State of registry] [COMPETENT AUTHORITY OF THE MEMBER STATE]	[1]
1. Nationality and registration marks	2. Manufacturer and manufacturer's designation of aircraft	3. Aircraft serial number
4. Categories		
5. This Certificate of Airworthiness is issued pursuant to [2] [the Convention on International Civil Aviation dated 7 December 1944] and Regulation (EC) No 216/2008, Article 5(4)(b) in respect of the abovementioned aircraft which is considered to be airworthy when maintained and operated in accordance with the foregoing and the pertinent operating limitations. In addition to above the following restrictions apply: [1] [1] [The aircraft may be used in international navigation notwithstanding above restrictions].		
Date of issue:	Signature:	
6. This Restricted Certificate of Airworthiness is valid unless revoked by the competent authority of the Member State of registry. A current Airworthiness Review Certificate shall be attached to this certificate.		

EASA Form 24 Issue 2.

This certificate shall be carried on board during all flights

[1] For use by the State of Registry.

[2] Delete as applicable.

Appendix VI — EASA Form 25 — Certificate of Airworthiness

Regulation (EU) No 748/2012

Appendix VI

Certificate of Airworthiness — EASA Form 25

Competent authority LOGO

CERTIFICATE OF AIRWORTHINESS

[1]	[Member State of registry] [COMPETENT AUTHORITY OF THE MEMBER STATE]	[1]
1. Nationality and registration marks	2. Manufacturer and manufacturer's designation of aircraft	3. Aircraft serial number
4. Categories		
5. This Certificate of Airworthiness is issued pursuant to the Convention on International Civil Aviation dated 7 December 1944 and Regulation (EC) No 216/2008, Article 5(2)(c) in respect of the abovementioned aircraft which is considered to be airworthy when maintained and operated in accordance with the foregoing and the pertinent operating limitations. Limitations/Remark: [1] Date of issue: Signature:		
6. This Certificate of Airworthiness is valid unless revoked by the competent authority of the Member State of registry. A current Airworthiness Review Certificate shall be attached to this certificate.		

EASA Form 25 Issue 2.

This certificate shall be carried on board during all flights

[1] For use by the State of Registry.

Appendix VII — EASA Form 45 — Noise Certificate

Regulation (EU) No 748/2012

Appendix VII

For use by State of registry	1. **State of registry**	3. Document No:
	2. NOISE CERTIFICATE	
4. Registration marks: …….	5. Manufacturer and manufacturer's designation of aircraft: ……	6. Aircraft serial No: ……
7. Engine: ……	8. Propeller:[1] ……	
9. Maximum take-off mass (kg) ……	10. Maximum landing mass (kg)[1] ……	11. Noise certification standard: ……
12. Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards: ……		
13. Lateral/full-power noise level:[1] ……	14. Approach noise level[1] ……	15. Flyover noise level[1] ……
16. Overflight noise level[1] ……	17. Take-off noise level[1] ……	
Remarks		
18. This Noise Certificate is issued pursuant to Annex 16, Volume I to the Convention on International Civil Aviation dated 7 December 1944 and Regulation (EC) No 216/2008, Article 6 in respect of the abovementioned aircraft, which is considered to comply with the indicated noise standard when maintained and operated in accordance with the relevant requirements and operating limitations.		
19. Date of issue ……20. Signature ……		

EASA Form 45

[1] These boxes may be omitted depending on noise certification standard.

Appendix VIII — EASA Form 52— Aircraft statement of conformity

Regulation (EU) 2022/201

Appendix VIII

Aircraft statement of conformity — EASA Form 52

AIRCRAFT STATEMENT OF CONFORMITY		
1. State of manufacture	2. [MEMBER STATE][1] A Member of the European Union[2]	3. Statement ref. no:
4. Organisation		
5. Aircraft type	6. Type-certificate ref. nos:	
7. Aircraft registration or mark	8. Production organisation identification no:	
9. Engine/propeller details[3]		
10. Modifications and/or service bulletins[4]		
11. Airworthiness directives		
12. Concessions		
13. Exemptions, waivers or derogations[5]		
14. Remarks		
15. Certificate of airworthiness		
16. Additional requirements		
17. Statement of conformity It is hereby certified that the aircraft conforms fully to the type-certificated design and to the items in blocks 9, 10, 11, 12 and 13. The aircraft is in a condition for safe operation. The aircraft has been satisfactorily tested in flight.		
18. Signed	19. Name	20. Date (d/m/y)
21. Production organisation approval reference		

EASA Form 52 - Issue 3

Instructions for the use of the "Aircraft statement of conformity – EASA Form 52"

1. PURPOSE AND SCOPE

1.1. The use of the aircraft statement of conformity issued by a production organisation that produces under Part 21 Section A Subpart F is described in point 21.A.130 and in the related acceptable means of compliance (AMC).

1.2. The purpose of the aircraft statement of conformity (EASA Form 52) issued under Part 21 Section A Subpart G is to enable the holder of an appropriate production organisation approval certificate to exercise the privilege to obtain an individual aircraft certificate of airworthiness and, if requested, a certificate of noise from the competent authority of the Member State of registry.

[1] Or "EASA", if EASA is the competent authority.

[2] Delete for non-EU Member States or EASA.

[3] Delete as applicable.

[4] Delete as applicable.

[5] Delete as applicable.

2. GENERAL

2.1. The statement of conformity must comply with the model, including the block numbers and the location of each block. The size of each block may, however, be varied to suit the individual application, but not to the extent that would render the statement of conformity unrecognisable. If in doubt, consult the competent authority.

2.2. The statement of conformity must be either preprinted or computer generated, but in either case, the printing of lines and characters must be clear and legible. Preprinted wording is permitted in accordance with the attached model, but no other certification statements are permitted.

2.3. The completion of the statement may be either machine/computer printed or handwritten, using block letters to allow for easy reading. English, and where relevant, one or more of the official language(s) of the issuing Member State, are acceptable.

2.4. A copy of the statement and all the referenced attachments are to be retained by the approved production organisation.

3. COMPLETION OF THE STATEMENT OF CONFORMITY BY THE ORIGINATOR

3.1. There must be an entry in all blocks to render the document a valid statement.

3.2. A statement of conformity may not be issued to the competent authority of the Member State of registry unless the design of the aircraft and its installed products are approved.

3.3. The information required in blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the production organisation, unless the competent authority agrees otherwise.

3.4. This statement of conformity is not intended to include those items of equipment that may be required to be fitted in order to satisfy the applicable operational rules. However, some of those individual items may be included in block 10 or in the approved type design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operations.

Block 1 Enter the name of the State of manufacture.

Block 2 The competent authority that issues the statement of conformity under its authority.

Block 3 A unique serial number must be preprinted in this block for statement control and traceability purposes. An exception is in the case of a computer-generated document: the number need not be preprinted where the computer is programmed to produce and print a unique number.

Block 4 The full name and the address of the location of the organisation that issues the statement. This block may be preprinted. Logos, etc., are permitted if the logo, etc., can be contained within the block.

Block 5 The aircraft type in full as specified in the type-certificate and its associated data sheet.

Block 6 The type-certificate reference numbers and issue for the subject aircraft.

Block 7 If the aircraft is registered, then this mark will be the registration mark. If the aircraft is not registered, then this will be the mark that is accepted by the competent authority of the Member State and, if applicable, by the competent authority of a third country.

Block 8 The identification number assigned by the production organisation for control and traceability and product support purposes. This is sometimes referred to as a “production organisation serial number” or “constructor’s number”.

Block 9 The engine type and the propeller type(s) in full as specified in the relevant type-certificate and its associated data sheet. Their production organisation identification number and the associated location must also be stated.

Block 10 Approved design changes to the aircraft definition.

Block 11 A listing of all the applicable airworthiness directives (or equivalent) and a declaration of compliance, together with a description of the method of compliance of the subject individual aircraft, including products and installed parts, appliances and equipment. Any future compliance requirement time must be stated.

Block 12 Approved unintentional deviations from the approved type design, sometimes referred to as “concessions”, “divergences” or “non-conformances”.

Block 13 Only agreed exemptions, waivers or derogations may be included here.

Block 14 Remarks. Any statement, information, particular data or limitation which may affect the airworthiness of the subject aircraft. If there is no such information or data, state “NONE”.

Block 15 Enter “certificate of airworthiness”, or “restricted certificate of airworthiness”, as requested.

Block 16 Additional requirements such as those notified by an importing country must be noted in this block.

Block 17 The validity of the statement of conformity is subject to the full completion of all the blocks on the form. A copy of the flight test report, together with any recorded defects and rectification details, must be kept on file by the production organisation approval certificate holder. The report must be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g. the test pilot or the flight test engineer. The flight tests performed are those defined under the control of the quality management element of the production system, as established by point 21.A.139, in particular point 21.A.139(d)(1)(vi), to ensure that the aircraft conforms to the applicable design data, and is in condition for safe operation.

The listing of items provided (or made available) to satisfy the aspects of this statement that relate to the safe operation of the aircraft must be kept on file by the production organisation approval certificate holder.

Block 18 The statement of conformity may be signed by the person that is authorised to do so by the production approval holder in accordance with point 21.A.145(d). A rubber stamp signature must not be used.

Block 19 The name of the person that signs the statement must be typed or printed in a legible form.

Block 20 The date on which the statement of conformity is signed must be given.

Block 21 The competent authority approval reference must be quoted.

Appendix IX — EASA Form 53 — Certificate of Release to Service

Regulation (EU) No 748/2012

Appendix IX

CERTIFICATE OF RELEASE TO SERVICE

[APPROVED PRODUCTION ORGANISATION NAME]

Production organisation approval Reference:

Certificate of release to service in accordance with 21.A.163(d)**.**

Aircraft: …….. Type: …….. Constructor No/Registration: ……..

has been maintained as specified in Work Order: ……..

Brief description of work performed:

Certifies that the work specified was carried out in accordance with 21.A.163(d) and in respect to that work the aircraft is considered ready for release to service and therefore is in a condition for safe operation.

Certifying Staff (name):

(signature):

Location:

Date: . . - . . - . . . . (day, month, year)

EASA Form 53

COMPLETION INSTRUCTIONS

The Block BRIEF DESCRIPTION OF WORK PERFORMED appearing in EASA FORM 53 should include reference to the approved data used to perform the work.

The Block LOCATION appearing in EASA FORM 53 refers to the location where the maintenance has been performed, not to the location of the facilities of the organisation (if different).

Appendix X — EASA Form 55 — Production organisation approval certificate

Regulation (EU) 2022/201

Appendix X

Production organisation approval certificate — EASA Form 55

Production organisation approval certificates referred to in Subpart G of Annex I (Part 21)

[MEMBER STATE][1]

A Member of the European Union[2]

PRODUCTION ORGANISATION APPROVAL CERTIFICATE

Reference: [MEMBER STATE CODE[3]].21G.XXXX

Pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council and to Commission Regulation (EU) No 748/2012, for the time being in force and subject to the conditions specified below, the [COMPETENT AUTHORITY OF THE MEMBER STATE] hereby certifies:

[COMPANY NAME AND ADDRESS]

as a production organisation in compliance with Annex I (Part 21) Section A of Regulation (EU) No 748/2012, is approved to produce products, parts and appliances listed in the attached approval schedule and issue the related certificates using the above references.

CONDITIONS:

1. This approval is limited to that specified in the enclosed terms of approval.
2. This approval is subject to compliance with the procedures specified in the approved production organisation exposition.
3. This approval is valid while the approved production organisation remains in compliance with Annex I (Part 21) to Regulation (EU) No 748/2012].
4. Subject to compliance with the foregoing conditions, this approval shall remain valid for an unlimited period of time unless it has previously been surrendered, superseded, suspended or revoked.

Date of original issue: ……

Date of this revision: ……..

Revision No: ……

Signed: ……

[1] Or “EASA”, if EASA is the competent authority.

[2] Delete for non-EU Member States.

[3] Or “EASA”, if EASA is the competent authority.

For the competent authority: [COMPETENT AUTHORITY IDENTIFICATION[1]]

EASA Form 55a - Issue 3

[1] Or "EASA", if EASA is the competent authority.

[MEMBER STATE][1] A Member of the European Union[2]	**Terms of Approval**	TA: [MEMBER STATE CODE[3]].21G.XXXX

This document is part of production organisation approval number [MEMBER STATE CODE[4]].21G.XXXX issued to:
Company name:

Section 1. **SCOPE OF WORK**:

PRODUCTION OF	PRODUCTS/CATEGORIES

For details and limitations, refer to the Production Organisation Exposition, Section xxx

Section 2. **LOCATIONS**:

Section 3. **PRIVILEGES**:

The production organisation is entitled to exercise, within its terms of approval and in accordance with the procedures of its Production Organisation Exposition, the privileges laid down in point 21.A.163, subject to the following:

[keep only applicable text]

Prior to the approval of the design of the product, the EASA Form 1 may be issued only for conformity purposes.

A statement of conformity may not be issued for a non-approved aircraft.

Maintenance may be performed, until compliance with the maintenance regulations is required, in accordance with the Production Organisation Exposition Section xxx

Permits to fly may be issued in accordance with the Production Organisation Exposition Section yyy

Date of original issue:	Signed:
Date of this revision:	
Revision No.:	For [COMPETENT AUTHORITY IDENTIFICATION[5]]

EASA Form 55b - Issue 3

1 Or “EASA”, if EASA is the competent authority.

2 Delete for non-EU Member States.

3 Or “EASA”, if EASA is the competent authority.

4 Or “EASA”, if EASA is the competent authority.

5 Or “EASA”, if EASA is the competent authority.

Appendix XI – EASA Form 65 – Letter of Agreement for production without a production organisation approval

Regulation (EU) 2022/201

Appendix XI

Letter of agreement for production without a production organisation approval — EASA Form 65

Letter of agreement referred to in Subpart F of Annex I (Part 21)

[MEMBER STATE][1]

A Member of the European Union[2]

LETTER OF AGREEMENT FOR PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

[NAME OF THE APPLICANT]

[TRADE NAME (if different from the name of the applicant)]

[FULL POSTAL ADDRESS OF THE APPLICANT]

Date (Day, Month, Year)

Reference: [MEMBER STATE CODE[3]].21F.XXXX

Dear Mr/Ms [Name of the Applicant],

Your production inspection system has been evaluated and found to be in compliance with Section A, Subpart A and Subpart F of Annex I (Part 21) to Commission Regulation (EU) No 748/2012.

Therefore, subject to the conditions specified below, we agree that the showing of conformity of the products, parts and appliances mentioned below may be done under Section A, Subpart F of Annex I (Part 21) to Regulation (EU) No 748/2012.

No of Units	P/N	S/N
AIRCRAFT		
PARTS		

The following conditions are applicable to this letter of agreement:

(1) It is valid while [Company Name] remains in compliance with Section A, Subpart A and Subpart F of Annex I (Part 21) to Regulation (EU) No 748/2012.

(2) It requires compliance with the procedures specified in [Company Name] manual ref./issue date.....

(3) It terminates on .....

(4) The statement of conformity issued by [Company Name] under point 21.A.130 of Regulation (EU) No 748/2012 shall be validated by the issuing authority of this letter of agreement in accordance with the procedure..... of the referenced manual.

1 Or "EASA", if EASA is the competent authority.

2 Delete for non-EU Member States.

3 Delete for non-EU Member States.

(5) [Company Name] shall notify the issuing authority of this letter of agreement immediately of any changes to the production inspection system that may affect the inspection, conformity or airworthiness of the products and parts listed in this letter.

For the competent authority: [COMPETENT AUTHORITY IDENTIFICATION[1] [2]]

Date and Signature

EASA Form 65 – Issue 3

[1] Or "EASA", if EASA is the competent authority.

[2] Delete for non-EU Member States.

Appendix XII — Categories of flight tests and associated flight test crew qualifications

Regulation (EU) 2015/1039

Appendix XII

Categories of flight test and associated flight test crew qualifications

A. General

This Appendix establishes the qualifications necessary for flight crew involved in the conduct of flight tests for aircraft certified or to be certified in accordance with CS-23 for aircraft with a maximum take-off mass (MTOM) of or above 2 000 kg, CS-25, CS-27, CS-29 or equivalent airworthiness codes.

B. Definitions

1. "Flight test engineer" means any engineer involved in flight test operations either on the ground or in flight.

2. "Lead flight test engineer" means a flight test engineer assigned for duties in an aircraft for the purpose of conducting flight tests or assisting the pilot in the operation of the aircraft and its systems during flight test activities.

3. "Flight tests" mean:

3.1. flights for the development phase of a new design (aircraft, propulsion systems, parts and appliances);

3.2. flights to demonstrate compliance to certification basis or conformity to type design;

3.3. flights intended to experiment new design concepts, requiring unconventional manoeuvres or profiles for which it could be possible to exit the already approved envelope of the aircraft;

3.4. flight test training flights.

C. Categories of flight tests

1. General

The descriptions below address the flights performed by design and production organisations under Annex I (Part 21).

2. Scope

If more than one aircraft is involved in a test, each individual aircraft flight shall be assessed under this Appendix to determine if it is a flight test and when appropriate, its category.

The flights referred to in point (6)(B)(3) are the only flights that belong to the scope of this Appendix.

3. Categories of flight tests

Flights tests include the following four categories:

3.1. Category One (1)

(a) Initial flight(s) of a new type of aircraft or of an aircraft of which flight or handling characteristics may have been significantly modified;

(b) Flights during which it can be envisaged to potentially encounter flight characteristics significantly different from those already known;

(c) Flights to investigate novel or unusual aircraft design features or techniques;

(d) Flights to determine or expand the flight envelope;

(e) Flights to determine the regulatory performances, flight characteristics and handling qualities when flight envelope limits are approached;

(f) Flight test training for Category 1 flight tests.

3.2. Category Two (2)

(a) Flights not classified as Category 1 on an aircraft whose type is not yet certified;

(b) Flights not classified Category 1 on an aircraft of an already certified type, after embodiment of a not yet approved modification and which:

(i) require an assessment of the general behaviour of the aircraft; or

(ii) require an assessment of basic crew procedures, when a new or modified system is operating or is needed; or

(iii) are required to intentionally fly outside of the limitations of the currently approved operational envelope, but within the investigated flight envelope.

(c) Flight test training for Category 2 flight tests.

3.3. Category Three (3)

Flights performed for the issuance of statement of conformity for a new-built aircraft which do not require flying outside of the limitations of the type certificate or the aircraft flight manual.

3.4. Category Four (4)

Flights not classified as Category 1 or 2 on an aircraft of an already certified type, in case of an embodiment of a not yet approved design change.

D. Competence and experience of pilots and lead flight test engineers

1. General

Pilots and lead flight test engineers shall have the competences and experience specified in the following table.

	Categories of flight tests			
Aircraft	**1**	**2**	**3**	**4**
CS-23 commuter or aircraft having a design diving speed (Md) above 0.6 or a maximum ceiling above 7 260 m (25 000 ft), CS-25, CS-27, CS-29 or equivalent airworthiness codes	Competence level 1	Competence level 2	Competence level 3	Competence level 4
Other CS-23 with an MTOM of or above 2 000 kg	Competence level 2	Competence level 2	Competence level 3	Competence level 4

1.1 Competence level 1:

1.1.1 Pilots shall comply with the requirements of Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011 of 3 November 2011[1].

1.1.2 Lead flight test engineer shall have:

(a) satisfactorily completed a Competence level 1 training course; and

(b) a minimum of 100 hours of flight experience, including flight test training.

1.2 Competence level 2:

1.2.1 Pilots shall comply with the requirements of Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011 of 3 November 2011.

1.2.2 The lead flight test engineer shall have:

(a) satisfactorily completed a Competence level 1 or level 2 training course; and

(b) a minimum of 50 hours of flight experience, including flight test training.

The competence level 1 or level 2 training courses for Lead flight test engineer shall cover at least the following subjects:

(i) Performance;

(ii) Stability and control/handling qualities;

(iii) Systems;

(iv) Test management; and

(v) Risk/safety management.

[1] Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p.1).

1.3 Competence level 3:

1.3.1 Pilot(s) shall hold a valid licence appropriate to the category of aircraft under test, issued in accordance with Part-FCL and hold a Commercial Pilot Licence (CPL) as a minimum. In addition, the pilot-in-command shall:

(a) hold a flight test rating, or;

(b) have at least 1 000 hours of flight experience as pilot-in-command on aircraft having similar complexity and characteristics, and

(c) have participated, for each class or type of aircraft, in all flights that are part of the programme leading to the issuance of the individual certificate of airworthiness of at least five aircraft;

1.3.2 Lead flight test engineer shall:

(a) satisfy Competence level 1 or level 2, or;

(b) have gained a significant amount of flight experience relevant to the task; and

(c) have participated in all flights that are part of the programme leading to the issuance of the individual certificate of airworthiness of at least five aircraft.

1.4 Competence level 4:

1.4.1 Pilot(s) shall hold a valid licence appropriate to the category of aircraft under test, issued in accordance with Part-FCL and hold a CPL as a minimum. The pilot-in-command shall hold a flight test rating or have at least 1 000 hours as pilot-in-command on aircraft having similar complexity and characteristics.

1.4.2 Competence and experience for lead flight test engineers is defined in the flight test operations manual.

2. Lead flight test engineers

Lead flight test engineers shall receive an authorisation from the organisation that employs them detailing the scope of their functions within the organisation. The authorisation shall contain the following information:

(a) name;

(b) date of birth;

(c) experience and training;

(d) position in organisation;

(e) scope of the authorisation;

(f) date of first issue of the authorisation;

(g) date of expiry of the authorisation, if appropriate; and

(h) identification number of the authorisation.

Lead flight test engineers shall only be appointed for a specific flight if they are physically and mentally fit to safely discharge assigned duties and responsibilities.

The organisation shall make all relevant records related to authorisations available to their holders.

E. Competence and experience of other flight test engineers.

Other flight test engineers on board the aircraft shall have an amount of experience and training commensurate with the tasks assigned to them as crew members, and in accordance with the flight test operations manual, when applicable.

The organisation shall make all relevant records related to their flight activities available to the relevant flight test engineer.

AMC No 1 to Appendix XII – Training courses for Lead Flight Test Engineers (LFTEs)

ED Decision 2015/026/R

GENERAL

1. Competency-based training

1.1. LFTE training courses should be competency-based. The training programme should, as much as possible, follow the syllabus outlined below, but may be adapted taking into account the previous experience, skills and theoretical knowledge level of the students.

1.2. It should also be recognised that the syllabus below assume that suitable flight test experience will be gained subsequent to course attendance. Should the student be significantly experienced already, then consideration should be made of that experience and it is possible that the course content might be reduced in areas where that experience has been gained.

1.3. Furthermore, it should be noted that LFTE courses are specific both to a certain category of aircraft (aeroplanes or helicopters) and to a certain category of flight test (Category 1 or 2). Therefore, an LFTE wishing to extend their privileges to further categories of aircraft or to further categories of flight test (this is only relevant for someone having already undertaken a Category 2 course) should not be requested to undertake the same course as an 'ab initio applicant'. In these cases, the organisation providing the training should develop specific 'bridge courses' taking into account the same principles mentioned above.

1.4. To allow proper consideration of the student's previous experience, a pre-entry assessment of the student's skills should be undertaken on the basis of which the organisation providing the training may evaluate the level of the applicant in order to better tailor the course. Consequently, the syllabi listed below should be regarded as a list of individual demonstrable competencies and qualifications rather than a list of mandatory training objectives.

2. Continuous evaluation

2.1. Training courses should be built on a continuous evaluation model in order to ensure that successful completion of the course ensures that the student has reached the level of competence (both theoretical and practical) necessary to carry on their functions.

COURSE CONTENT

3. In addition, the content of the course should vary taking into account whether the student wants to undertake a Category 1 or Category 2 flight test, as well as the relevant category of aircraft, and their level of complexity. In order to better take these factors into account, LFTE training courses have been divided into levels similar to those for the pilot flight test rating.

3.1 Competence Level 1 courses apply to Category 1 flight tests on:

a. helicopters certified in accordance with the standards of CS-27 or CS-29 or equivalent airworthiness codes;

b. aeroplanes certified in accordance with:

(i) the standards of CS-25 or equivalent airworthiness codes; or

(ii) the standards of CS-23 or equivalent airworthiness codes within the commuter category or having a design diving speed (MD) above 0,6 or a maximum ceiling above 25 000 ft.

3.2 Competence Level 2 courses apply to:

a. Category 2 flight tests for:

(i) helicopters certified in accordance with the standards of CS-27 or CS-29 or equivalent airworthiness codes;

(ii) aeroplanes certified in accordance with:

— the standards of CS-25 or equivalent airworthiness codes; or

— the standards of CS-23 or equivalent airworthiness codes (including those mentioned in 3.1.b.(ii)), except for aeroplanes with a maximum take-off mass of less than 2 000 kg.

b. Category 1 flight tests for aeroplanes certified in accordance with the standards of CS-23, with a maximum take-off mass of 2 000 kg or above, with the exclusion of those mentioned in 3.1.b.(ii) (which are subject to competence Level 1 courses).

AEROPLANES

4. Competence Level 1 courses for aeroplanes

4.1. These courses should include approximately:

a. 350 hours of ground training; and

b. 60 hours of flight training, during which at least 10 flights should be made without an FTE tutor on board (i.e. unsupervised).

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable to the certification activity and safety assessments should be taught. A review of the principles of Crew Resource Management (CRM) tailored to the flight test environment should be included.

4.2. These courses should include instruction on at least six different aircraft types, of which at least one should be certified in accordance with CS-25 standards or equivalent airworthiness codes.

4.3. During the course, the student should be required to develop at least five substantial flight test reports.

4.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

4.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 1 — AEROPLANES		
Theoretical knowledge	— Aerodynamics — Stability and control/handling qualities — Engines and performance — Measurements and flight test instrumentation (including telemetry) — Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Climb multi-engine — Take-off and landing, including turboprop/turbofan one-engine-inoperative (OEI) — Level flight performance
	Engines	— Turboprop/turbofan limitations and relight envelope
	Handling qualities (at least two flight test reports should be developed)	— Flight controls characteristics — Longitudinal handling qualities — Longitudinal manoeuvre stability — Take-off and landing multi-turboprop/ turbofan, including Vmcg and Vmu — Lateral-directional handling qualities — Handling qualities evaluation — Variable stability demo flights including High-Order Flight Control Systems (HOFCS) — Stalls — Spins — Vmca
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Autopilot/Automatic Flight Control System (AFCS) — Glass cockpit evaluation — Radio navigation, instruments qualification and integrated avionics — Enhanced Ground Proximity Warning System (EGPWS) — ACAS
	High-speed certification test	
	Final evaluation exercise (a flight test report should be developed)	

5. Competence Level 2 courses for aeroplanes

5.1. These courses should include approximately:

a. 150 hours of ground training; and

b. 30 hours of flight training, during which at least 6 flights should be made without an FTE tutor on board (i.e. unsupervised).

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable

to the certification activity and safety assessments should be taught. A review of the principles of CRM tailored to the flight test environment should be included.

5.2. These courses should include instruction on at least five different aircraft types, of which at least one should be certified in accordance with CS-25 standards or equivalent airworthiness codes.

5.3. During the course, the student should be required to develop at least three substantial flight test reports.

5.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

5.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 2 — AEROPLANES		
Theoretical knowledge	— Aerodynamics — Stability and control/handling qualities — Engines and performance — Measurements and flight test instrumentation (including telemetry) — Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Climb multi-engine — Take-off and landing multi-turboprop/ turbofan — Level flight performance
	Handling qualities	— Flight control characteristics — Longitudinal static/dynamic stability and control/handling qualities — Lateral-directional stability and control/ handling qualities — Stalls — Spins
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Autopilot/AFCS — Glass cockpit evaluation — Radio navigation, instruments qualification and integrated avionics — EGPWS — ACAS
	Final evaluation exercise (a flight test report should be developed)	

HELICOPTERS

6. Competence Level 1 courses for helicopters

6.1. These courses should include approximately:

a. 350 hours of ground training; and

b. 60 hours of flight training, during which at least 15 flights should be made without an FTE tutor on board (i.e. unsupervised).

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable to the certification activity and safety assessments should be taught. A review of the principles of CRM tailored to the flight test environment should be included.

6.2. These courses should include instruction on at least six different aircraft types, of which at least one should be certified in accordance with CS-29 standards or equivalent airworthiness codes.

6.3. During the course, the student should be required to develop at least five substantial flight test reports.

6.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

6.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 1 — HELICOPTERS		
Theoretical knowledge	— Aerodynamics — Stability and control/handling qualities — Engines and performance — Measurements and flight test instrumentation (including telemetry) — Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Level flight, climb and descent, vertical and hover performance
	Engines	— Digital engine governing — Turbine/piston engine evaluation
	Handling qualities (at least one flight test report should be developed)	— Flight control characteristics — Longitudinal static/dynamic stability and control/handling qualities — Lateral-directional stability and control/ handling qualities — ADS 33 — Rotor assessment with different control powers — Variable stability demo flights including High-Order Flight Control Systems (HOFCS)
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Navigation management systems — Auto-pilot/AFCS — Night-vision goggles/electro-optics — Glass cockpit evaluation
	Height/velocity envelope and Engine-Off Landings (EOL), including relights	
	Category A procedure	
	Vibrations and rotor adjustments	
	Autorotations	
	Final evaluation exercise (a flight test report should be developed)	

7. Competence Level 2 courses for helicopters.

7.1. These courses should include approximately:

a. 150 hours of ground training; and

b. 30 hours of flight training, during which at least 6 flights should be made without an FTE tutor on board (i.e. unsupervised);

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable to the certification activity and safety assessments should be taught. A review of the principles of CRM tailored to the flight test environment should be included.

7.2. These courses should include instruction on at least four different aircraft types, of which at least one should be certified in accordance with CS-29 standards or equivalent airworthiness codes.

7.3. During the course, the student should be required to develop at least three substantial flight test reports.

7.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

7.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 2 — HELICOPTERS		
Theoretical knowledge	Aerodynamics Stability and control/handling qualities Engines and performance Measurements and flight test instrumentation (including telemetry) Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Level flight, climb and descent, vertical and hover performance
	Engines	— Digital engines governing — Turbine/piston engine evaluation
	Handling qualities	— Flight control characteristics — Longitudinal static/dynamic stability and control/handling qualities — Lateral-directional stability and control/ handling qualities
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Navigation management systems — Auto-pilot/AFCS — Night-vision goggles/electro-optics — Glass cockpit evaluation
	Vibration and rotor adjustments	
	Final evaluation exercise (a flight test report should be developed)	

AMC No 2 to Appendix XII – Conditions for appointment of Lead Flight Test Engineers (LFTEs) – Medical fitness

ED Decision 2015/026/R

1. Before the organisation issues an authorisation for an LFTE, the LFTE should undergo an initial medical examination and assessment. Afterwards, the LFTE should be regularly (typically every 2 years) reassessed to ensure that they will remain physically and mentally fit to safely discharge their duties. These examinations and assessments should take due account of the actual flight environment of the intended flight test activity.
2. Any medical examination or assessment should be carried out according to best aero-medical practice by an aero-medical practitioner who has sufficient, detailed knowledge of the applicant's medical history.
3. The organisation should maintain a record of medical fitness for each LFTE.
4. These assessments should attest that the LFTE:
   a. is in good health;
   b. is free from any physical or mental illness which might lead to incapacitation or inability to perform crew duties;
   c. has normal cardiorespiratory function;
   d. has normal central nervous system;
   e. has adequate visual acuity 6/9 with or without glasses;
   f. has adequate hearing; and
   g. has normal function of ear, nose and throat.
5. If the LFTE holds a Class 1 or Class 2 medical certificate issued in accordance with Part-MED, the assessment or examination is not necessary.

AMC No 3 to Appendix XII – Demonstration of compliance with competence level 1 or level 2 requirements

ED Decision 2017/024/R

The design organisation could demonstrate compliance with the LFTE competence level 1 or level 2 training course Part 21 requirements using one of the following:

1. training carried out internally, established in accordance with AMC No 1 to Appendix XII under a procedure agreed with EASA;
2. a certificate of course completion for the training established in accordance with AMC No 1 to Appendix XII, issued by an approved training organisation under its privilege in accordance with ORA.ATO.355; or
3. a national document (i.e. licence) issued by an EASA Member State after 1 January 2018, under its national regulations, ensuring compliance with the competence requirements of Part 21.

GM No 1 to Appendix XII – Lead Flight Test Engineer (LFTE)

ED Decision 2015/026/R

LFTEs are Flight Test Engineers (FTEs) that have specific duties and privileges as a flight test crew member, to operate the test aircraft's systems either directly or through dedicated flight test instrumentation, that could significantly interfere with the aircraft basic systems (such as flight controls and engine controls), or that could significantly impact aircraft stability and control (e.g. through weight and balancing flight management or flight control configuration changes). As an example, an LFTE could be permitted to shut down the engines or change the engine parameters through controls which are not accessible to the pilots.

The word 'assisting' (the pilots) should be understood in the sense of the critical actions (e.g. actions described above) which could be performed by the LFTE, if requested by the flight test order and agreed by the pilot-in-command.

Flight test categories

The purpose of this GM is to help operators to:

— determine whether an operation is a flight test; and

— to classify the flight test.

Flight test categories are defined in Appendix XII to Part-21, and are described in this GM in such a manner that an operator who wishes to classify a flight, should first determine whether the flight is defined as a flight test according to the 'General' paragraph. The operator should then determine if the flight test falls within the definition of Category 1 before moving to Category 2 and so on throughout the list until the correct category is determined.

Other types of flights, such as maintenance check flights, are not included in the flights described in this GM and are, therefore, not subject to it.

a) General

The testing of aircraft performance, handling qualities and systems, including checking compliance with Certification Specifications (CSs), requires specialist techniques, skills and theoretical knowledge. Therefore, flight test training and specific experience is required to enable a test crew to:

— safely perform systematic and comprehensive flight envelope exploration;

— acquire specific skills and abilities for some particularly difficult tests;

— mitigate risks by anticipating potentially hazardous situations, and by applying methods that permit the safest flight possible in these situations;

— understand the relevant CSs; and

— learn methods to assess whether the aircraft or its systems comply with these regulations.

It should be noted that the content of the flight test determines its category, and the flight test category determines the required competence of the crew.

Nevertheless,

— flight tests of an aircraft which does not have a Type Certificate (TC) should be considered either as Category 1 or Category 2 flight test until the type has been certified; and

— flight tests for a modification of an already certified type may be Category 1, 2 or 4, depending on the purpose of the test.

The rationale for this difference is the fact that a new aircraft type is considered under continuous assessment until the TC is issued.

Cases where more than one aircraft is involved in a flight test point:

Chase flights are a typical example of flights in which more than one aircraft is involved. Every aircraft participating in the test point(s) should be evaluated through this classification. The guiding principle should be the role of the crew of the chase aircraft in the safety of the aircraft under test or of the formation.

b) Category 1 flight test

Below are examples of flight tests to be considered as Category 1:

— Fixed-wing aircraft: V_{MCG}, V_{MU}, spinning, initial stalling, or for rotary-wing aircraft: H/V diagrams and Category A engine failures.

— Where encounter of surprising or even hazardous flight characteristics can be expected.

— Upon determination, aircraft handling and performance in conditions where at least one of the following parameters is approaching the actual limits of the aircraft envelope: altitude, attitudes, weights, CG, speed/Mach, stalls, temperature, engine and aerofoil performance.

— Where the embodiment of new systems is anticipated to significantly affect the aircraft's handling or performance characteristics.

— When the crew of the chase aircraft has the duty to assist the test aircraft crew in recovering from a critical flight situation (i.e. assist the spinning aircraft crew in assessing the spin or triggering recovery actions).

c) Category 2 flight test

Below are examples of flight tests to be considered as Category 2:

— The flight test envelope has already been opened and it has been demonstrated that the general behaviour of the aircraft is adequately safe and there are no unsafe flight characteristics.

— All-engines-operating climb performance.

— Cruise performance.

— Static stability demonstration.

— Function and reliability flights.

— Systems tests of autopilot or guidance/warning systems such as Terrain Awareness and Warning System (TAWS) or Airborne Collision Avoidance System (ACAS), when the modes themselves are tested, requiring operating the aircraft by deviating from the standard operational procedures. Additionally, in the case of embodiment of such systems on an already certified aircraft, when the system integration in an existing

cockpit requires a more global crew procedure assessment — for example, when the system has been integrated in cockpit screens and a centralised warning system which requires a new cockpit procedure assessment (note that some system tests may fall under Category 4; see below).

d) Category 3 flight test

These flights are commonly referred to as production flight tests. They are performed on each new aircraft of a type that is already certified. The aim is to check that the aircraft and its systems are working properly and conform to the certified type. As the type is already certified, the behaviour of the aircraft is known.

However, experience has shown that during production flight tests of a new aircraft, unexpected failures can occur which could not be described in the Aircraft Flight Manual (AFM). For this reason, it is considered that special experience should be required.

It should be noted that a TC or a Supplemental Type Certificate (STC) should have been issued in order for a production flight test to be considered as Category 3. Until a TC or STC is issued, any flight, including production flight tests, will be Category 1, 2 or 4 according to classification criteria.

It should be noted also that if the flight of an aircraft with a TC or STC requires flying outside the AFM limitations, then this flight should be considered as Category 1 or Category 2 flight.

e) Category 4 flight test

Typical Category 4 flights are those required by a DOA to demonstrate compliance with the airworthiness requirements of 'not yet approved data':

- cabin conversion;
- zonal drying system installation;
- Emergency Locator Transmission (ELT) installation;
- new cabin installation;
- cabin aircraft location pictorial system installation;
- new entertainment system installation;
- SATCOM and telephone installation; and
- new radio equipment installation.

Category 4 includes also flights after embodiment of guidance/warning systems which are not Category 2 and for which:

- good functioning test only is required; and
- there is no need to fly the aircraft outside the AFM limitations.

The modification should not affect the behaviour of the aircraft in any way.

However, there may be modifications whose tests, despite the fact that they have no influence on the behaviour of the aircraft, require flying in conditions which deviate significantly from the standard operational use of the aircraft. These unusual flight test conditions may require classifying the flight as Category 2, as mentioned above. The typical example to consider here is the approval of the modification of an already certified TAWS system. In this situation, it is required to fly at very low altitude and/or towards high terrain. Such a flight can be classified as

Category 4 flight on a light aircraft (or helicopter) because that flight test is performed in a domain corresponding to the normal operation of the aircraft, whereas the same flight performed with a heavy CS-25 aircraft, especially if it needs to be flown in clean configuration significantly below gear and flaps warning heights, should be classified as Category 2 because such a flight does not correspond to the normal use of the aircraft and needs to adopt specific testing procedures as demonstrated in the Category 2 training.

GM No 2 to Appendix XII – Competence and experience of pilots for Category 3 and Category 4 flight tests and of Lead Flight Test Engineers (LFTEs)

ED Decision 2015/026/R

Definition of similar 'complexity and characteristics':

Similar 'complexity and characteristics' for aircraft can normally be assumed for aircraft of the same category and in the same class, and certified under the same CSs, e.g. CS-23/CS-25. However, it could be considered that aircraft certified under different CSs but having small difference in weight and operating procedure (e.g. Citation 525/Citation 550, 560) have similar complexity and characteristics.

Flight experience of LFTEs:

The flight experience includes experience as a crew member in flight tests or other flights (e.g. flights as a student pilot or with a pilot licence).

GM No 3 to Appendix XII. Demonstration of compliance with competence level 1 or level 2 requirements

ED Decision 2017/024/R

It is the organisation's responsibility to show proof of compliance with the competence requirements of Part 21 defined in AMC No 3 to Appendix XII.

ANNEX IB

21L.1 Scope

Regulation (EU) 2022/1361

(a) Section A of this Annex (Part 21 Light) establishes the provisions governing the rights and obligations of the following persons having their principal place of business located in a Member State:

1. the applicant for, and holder of, any certificate issued or to be issued in accordance with this Annex;
2. natural and legal persons declaring, in accordance with this Annex, design compliance, design capabilities or production capabilities, or intending to make such declarations;
3. the signatory of a statement of conformity for an aircraft, or an authorised release certificate (EASA Form 1) for an engine, propeller or part produced in accordance with this Annex.

(b) Section B of this Annex establishes the provisions governing the certification, oversight and enforcement by the Agency and national competent authorities in accordance with this Annex and establishes requirements for their administration and management systems relating to the exercise of these tasks.

21L.2 Competent authority

Regulation (EU) 2022/1361

For the purpose of this Annex, 'competent authority' shall be:

(a) for Section A, Subpart A,

1. for design organisations, the Agency;
2. for a production organisation, the authority designated by the Member State where the organisation has its principal place of business; or the Agency, if that responsibility has been reallocated to the Agency in accordance with Article 64 or 65 of Regulation (EU) 2018/1139;

(b) for Section A, Subparts B, C, D, E, F, J, K, M, N, and Q, the Agency;

(c) for Section A, Subparts G, H, I and R, the authority designated by the Member State where the organisation has its principal place of business; or the Agency, if that responsibility has been reallocated to the Agency in accordance with Article 64 or 65 of Regulation (EU) 2018/1139;

(d) for Section A, Subpart P:

1. for aircraft registered in a Member State, the authority designated by the Member State of registry;
2. for unregistered aircraft, the authority designated by the Member State which prescribed the identification marks;
3. for the approval of flight conditions related to the safety of the design, the Agency.

GM1 21L.2 Competent authority

ED Decision 2023/013/R

RESPONSIBILITY FOR IMPLEMENTATION

Each certificate or registration of a declaration of capability in accordance with Part 21 Light Section A Subparts G, H, I, P and R is normally issued and overseen by the competent authority of the Member State in which the natural or legal person is located. Therefore, to ensure consistency between the competent authorities of the Member States in issuing certificates and registering declarations of capability, the implementation of Part 21 Light should be based on the following three principles:

(a) The establishment and maintenance of an effective organisation and the corresponding processes by all competent authorities.

(b) The operation of all the competent authorities in accordance with Part 21 Light and the acceptable means of compliance (AMC) and guidance material (GM) thereto; and

(c) A standardisation process that is established and applied by EASA to assess the standard(s) achieved, and to provide timely advice and guidance to the competent authorities.

As a result, the responsibility for implementation consists of two main objectives:

(d) to ensure that certificates and registration of declarations of capability are only granted to natural or legal persons that comply with the requirements of Part 21 Light; and

(e) to ensure that there is sufficient visibility of the processes to give the Agency and the Member States the necessary confidence in the certificates granted or the capability of natural or legal persons that have a registered declaration of design or production capability or use Subpart R for production.

GM2 21L.2 Competent authority

ED Decision 2023/013/R

PERMIT TO FLY

An aircraft registered in a Member State is under the responsibility of that Member State regarding continuing airworthiness aspects. Consequently, permits to fly under Part 21 Light may be issued by that Member State, including any cases in which the aircraft flies in another State. The permit to fly contains all the conditions and restrictions to ensure safe flight, but other airspace and operational rules remain within the competence of the authority of the State where the flight takes place, and may apply. Therefore, the applicant is also required to ensure compliance with the relevant applicable regulations of that State.

SECTION A - TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

21L.A.1 Scope

Regulation (EU) 2022/1358

This Section establishes general rights and obligations that are applicable to:

(a) the applicant for, and holder of, any certificate issued or to be issued in accordance with this Annex;

(b) any declarant of design or production capability or of design compliance; and

(c) any natural or legal person issuing a statement of conformity for an aircraft, or an authorised release certificate (EASA Form 1) for an engine, propeller or part produced.

21L.A.2 Obligations and actions performed by a person other than the applicant for, or holder of, a certificate or the declarant of a declaration of design compliance

Regulation (EU) 2022/1358

The actions and obligations required to be undertaken by the applicant for, or holder of, a certificate for a product or part or by the declarant of a declaration of design compliance under this Section may be undertaken on its behalf by any other natural or legal person, provided that the applicant's, holder's or declarant's obligations are and will be properly discharged.

21L.A.3 Reporting system

Regulation (EU) 2022/1358

(a) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council[1] and its delegated and implementing acts, any natural or legal person who holds or has applied for a type certificate, supplemental type certificate, major repair design approval, or any other relevant certificate deemed to have been issued under this Annex, or who has declared the compliance of an aircraft design, or a design change or repair design to it under this Annex shall:

1. establish and maintain a system for collecting, investigatingand analysing occurrence reports in order to identify adverse trends or to address deficiencies, and to extract occurrences, whose reporting is mandatory in accordance with point (3) and those which are reported voluntarily. The reporting system shall include:

(i) reports of and information related to failures, malfunctions, defects or other events which cause or might cause adverse effects on the continuing airworthiness of the product or part covered by the type certificate, supplemental type

[1] Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

certificate, major repair design approval, or any other relevant certificate deemed to have been issued under this Annex, or by the declaration of design compliance issued under this Annex;

(ii) reports of errors, near misses, and hazards that do not fall under point (i);

2. make available to known operators of the product or part, and, on request, to any person authorised under other associated implementing acts or delegated acts, the information about the system established in accordance with point (a)(1), and on how to provide such reports of and information related to failures, malfunctions, defects or other events referred to in point (a)(1)(i);

3. report to the Agency any failure, malfunction, defect or other event of which they are aware related to a product or part, covered by the type certificate, supplemental type certificate, major repair design approval, or any other relevant certificate deemed to have been issued under this Annex, or by a declaration of design compliance issued under this Annex, and which has resulted in or may result in an unsafe condition.

(b) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, any natural or legal person who has declared their production capability under SUBPART G of this Annex, or who produces a product or part under SUBPART R of this Annex, shall:

1. establish and maintain a system for collecting and assessing internal occurrence reports, including reports on internal errors, near misses, and hazards, in order to identify adverse trends or to address deficiencies, and extract occurrences, whose reporting is mandatory in accordance with points (2) and (3) and those which are reported voluntarily;

2. report, to the responsible design approval holder or declarant of a declaration of design compliance, all cases in which products or parts have been released by them and subsequently identified to have possible deviations from the applicable design data, and investigate with the design approval holder or the declarant of a declaration of design compliance, to identify those deviations which could lead to an unsafe condition;

3. report to the Agency and the competent authority of the Member State responsible in accordance with point 21L.2, if any, the deviations which could lead to an unsafe condition that were identified according to point (2) of point 21L.A.3(b);

4. if acting as a supplier to another production organisation, report to that other organisation all the cases in which it has released products or parts to that organisation and subsequently identified them to have possible deviations from the applicable design data.

The reporting obligations of point 21.A.3A(b) of Annex I of natural and legal persons who hold or have applied for a production organisation approval shall include occurrences related to products and parts produced in conformity with design data approved or declared in accordance with this Annex, and, where the design compliance was declared, reports shall be made to the declarant of design compliance.

(c) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, any natural or legal person referred to in points (a) and (b) when reporting in accordance with points (a)(3), (b)(2), (b)(3) and (b)(4), shall appropriately safeguard the confidentiality of the reporter and of the persons mentioned in the report.

(d) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, any natural or legal person referred to in points (a) and (b) shall make the reports defined in points (a)(3) and (b)(3) in a form and manner established by the competent authority as soon as practicable, and in any case, dispatch the reports not later than 72 hours after the natural or legal person referred to in points (a) and (b) has identified the possible unsafe condition, unless exceptional circumstances prevent this.

(e) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, if an occurrence reported under point (a)(3) or under point (b)(3) results from a deficiency in the design, or a production deficiency, the holder of the type certificate, supplemental type certificate, major repair design approval, or any other relevant certificate deemed to have been issued under this Annex, the declarant of a declaration of design compliance or the production organisation referred to in point (b) as appropriate, shall investigate the reason for the deficiency and report to the Agency and to the competent authority of the Member State responsible in accordance with point 21L.2, if any, the results of its investigation and any action it is taking or proposes to take to correct that deficiency.

(f) If the competent authority finds that an action is required to correct the deficiency, the holder of the type certificate, supplemental type certificate, major repair design approval, or any other relevant certificate deemed to have been issued under this Annex, the declarant of a declaration of design compliance, or the production organisation referred to in point (b) as appropriate, shall submit the relevant data to the competent authority upon its request.

GM1 21L.A.3 Reporting system

ED Decision 2023/013/R

LINK BETWEEN POINT 21L.A.3 AND REGULATION (EU) No 376/2014

Regulation (EU) No 376/2014[1] of the European Parliament and of the Council lays down requirements on the reporting, analysis and follow-up of occurrences in civil aviation. Compliance with point 21L.A.3 of Part 21 Light does not exempt organisations from compliance with Regulation (EU) No 376/2014. For each category of reporter, Regulation (EU) 2015/1018[2] defines the nature of items to be mandatorily reported. Regulation (EU) No 376/2014 also considers voluntary reporting of other items that are perceived by the reporter as a threat to aviation safety.

Point 21L.A.3 lays down requirements for the mandatory reporting of events to the competent authority in view of performing the necessary activities linked to the continued airworthiness of products or parts.

For Part 21 Light design and production organisations and natural or legal persons that use Subpart R for production, the reportability criteria (i.e. potential unsafe condition) are the same as for Regulation (EU) No 376/2014.

[1] Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0376&qid=1678272619346).

[2] Commission Implementing Regulation (EU) 2015/1018 of 29 June 2015 laying down a list classifying occurrences in civil aviation to be mandatorily reported according to Regulation (EU) No 376/2014 of the European Parliament and of the Council (OJ L 163, 30.6.2015, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1018&qid=1669631925416).

Furthermore, compliance with Regulation (EU) No 376/2014 does not exempt organisations from compliance with point 21L.A.3. However, this should not give rise to two parallel reporting systems, and point 21L.A.3 and Regulation (EU) No 376/2014 should be seen as complementary in that respect.

In practice, this means that reporting obligations under point 21L.A.3 on one hand and reporting obligations under Regulation (EU) No 376/2014 on the other hand are compatible. These reporting obligations may be discharged using one reporting channel.

In addition, any natural or legal person that has more than one role subject to the obligation to report may discharge all those obligations through a single report. Natural or legal persons (organisations) are encouraged to properly describe this in their procedures, to address cases in which the responsibilities are discharged on behalf of the organisation.

AMC1 21L.A.3(a) Reporting system

ED Decision 2023/013/R

COLLECTION, INVESTIGATION AND ANALYSIS OF EVENTS

In the context of the following AMC and GM, the term 'event' refers to any failure, malfunction, defect, error, near miss, hazard identification, incident, accident or other occurrence that is subject to a reporting system.

The 'collection', 'investigation' and 'analysis' functions of the reporting system should include means to:

— analyse events and related available information;

— identify adverse trends;

— investigate the associated root cause(s); and

— determine any necessary corrective action(s).

It should also allow the determination of reportable occurrences as required under points 21L.A.3(a)(3) or 21L.A.3(b)(3), as applicable.

In addition, for parts whose failure could lead to an unsafe condition, the 'analysis' function of the reporting system should ensure that reports and information sent, or available, to the design approval holder or declarant of a declaration of design compliance are fully investigated so that the exact nature of any event and its effect on continuing airworthiness is understood. This may then result in changes to the design and/or to the instructions for continued airworthiness (ICAs), and/or in establishing a mitigation plan to prevent or minimise the possibility of such occurrences in the future, as necessary. The 'analysis' is not limited to those occurrences that require the involvement of the Agency under point 21L.A.3(e).

GM1 21L.A.3(a);(b) Reporting system

ED Decision 2023/013/R

GENERAL — SYSTEM FOR COLLECTING OCCURRENCE REPORTS

The term 'collecting' means the setting up of systems and procedures which should enable relevant failures, malfunctions and defects, or other occurrences, to be properly collected when they occur.

As the collection system needs to accept reports that originate outside the organisation (from operators, maintenance organisation, suppliers, etc.), it is necessary to inform possible reporters of the existence of the system and the appropriate means to introduce reports into it. This does not presume that direct access to the system is to be granted if other mechanisms are more appropriate.

The collection system should also ensure the collection, through an internal reporting scheme, of internal errors, near misses and hazards that are perceived by the reporter as an actual or potential aviation safety risk.

Considerations for the collection of information related to events should include the following:

— grouping of events;

— analysis of failure rates;

— the early rejection of parts from service; and

— comparison with the certification assumptions.

GM1 21L.A.3(a);(e);(f) Reporting system

ED Decision 2023/013/R

GENERAL

Approval holders of minor changes and minor repairs or declarants of a design compliance for a minor change or minor repair other than the natural or legal person that submitted the declaration under Part 21 Light Subpart C do not have to comply with the requirements in point 21L.A.3(a), since according to the classification criteria for design changes and repairs (see points 21L.A.63 and 21L.A.203), minor changes and minor repairs have no appreciable effect on the characteristics affecting the airworthiness of a product. However, it should be noted that the obligations under Regulation (EU) No 376/2014 and its implementing acts still apply.

GM2 21L.A.3(a);(e);(f) Reporting system

ED Decision 2023/013/R

GENERAL

A certificate is 'deemed to have been issued under this Annex' if a certificate holder has elected to use Article 2a of Regulation (EU) No 748/2012 and that certificate is now governed by the provisions of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012 as detailed in the type-certificate data sheet or supplemental type-certificate data sheet.

GM1 21L.A.3(a)(1);(b)(1) Reporting system

ED Decision 2023/013/R

EVENTS REPORTED VOLUNTARILY TO THE ORGANISATION

Any natural person or legal person may voluntarily report to an organisation any event that is perceived by that person as posing an actual or potential hazard to aviation safety.

Voluntary reports may be originated by:

(a) persons that are not listed in Article 4(6) of Regulation (EU) No 376/2014; or

(b) persons that are listed in Article 4(6) of Regulation (EU) No 376/2014, even though such events are not included in Regulation (EU) 2015/2018;

(c) an organisation, if such organisation cannot determine whether the event should be mandatorily reported.

Example:

A maintenance staff member in a maintenance organisation reports to their maintenance organisation a perceived aircraft design issue that is not covered by Regulation (EU) 2015/2018. The maintenance organisation should make a final assessment on the voluntary report and if it assesses that the reported event 'may involve an actual or potential aviation safety risk', then it should mandatorily report it to the type-certificate holder or declarant, the competent authority, etc., as per point 145.A.60 'Occurrence reporting' of Annex II (Part-145) to Regulation (EU) No 1321/2014[1]. If the maintenance organisation cannot determine whether a safety risk exists (due to a lack of competence, lack of data, etc.), it could voluntarily report it to the type-certificate holder or declarant for further assessment.

GM2 21L.A.3(a)(1);(b)(1) Reporting system

ED Decision 2023/013/R

INTERNAL SAFETY REPORTING SCHEME

The internal safety reporting scheme is part of the overall collection system. The objective of this GM is to provide specific guidance on the internal safety reporting scheme only.

(a) The overall objectives of the internal safety reporting scheme are to:

— collect information that is reported by the organisation's staff; and

— use that reported information to improve the safety of operations.

Each internal safety reporting scheme should include provisions for confidentiality and enable and encourage free and frank reporting of events as those listed in point 21L.A.3(a)(1)(i) and (ii). This is facilitated by the establishment of a just culture.

(b) The specific objectives of the internal safety reporting scheme are to:

(1) enable an assessment of the safety implications of each relevant event that is reported, including previous similar events, so that any necessary action can be initiated; and

(2) ensure that lessons from relevant events are shared so that other persons and other entities within the organisation may learn from them.

(c) The internal safety reporting scheme is an essential part of the overall management system or the production control system and should be complementary to the routine procedures and control systems; it is not intended to duplicate or supersede any of them. The internal safety reporting scheme is a tool to identify those instances in which routine procedures have failed or may fail.

(d) All safety-related reports should be retained, as the significance of such reports may only become obvious later.

(e) The collection and analysis of timely, appropriate and accurate data will allow the organisation to react to the information that it receives, and to take the necessary action.

[1] Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R1321&qid=1669641196734).

AMC1 21L.A.3(a)(3);(b)(3);(d) Reporting system

ED Decision 2023/013/R

REPORTING TO THE COMPETENT AUTHORITY

Within the overall limit of 72 hours, the degree of urgency for the submission of a report should be determined by the level of risk that is judged to have resulted from the occurrence.

If an occurrence is judged by the person identifying the possible unsafe condition to have resulted in an immediate and particularly significant hazard, the Agency (or the competent authority of the Member State as required) should be advised immediately and by the fastest possible means (telephone, fax, email, telex, etc.) of whatever details are available at the time. The initial report must be followed up by a full written report within 72 hours. An example would be an uncontained engine failure resulting in damage to the aircraft's primary structure.

In all other cases, the submission of the report may be delayed up to a maximum of 72 hours after determination of the possible unsafe condition, in order to provide more details.

GM1 21L.A.3(a)(3);(b)(3) Reporting system

ED Decision 2023/013/R

REPORTING TO THE COMPETENT AUTHORITY — GENERAL

(a) The reference to 'aware of' an occurrence implies that the organisation identifies the event as one that falls into the category of occurrences to be reported — usually when the organisation determines that the event is reportable. The 72-hour period starts when the possible unsafe condition is identified.

(b) Regulation (EU) 2015/1018 lays down a generic 'list classifying occurrence in civil aviation to be mandatorily reported'. This list should not be understood as being an exhaustive collection of all issues that may pose a significant risk to aviation safety and, therefore, reporting should not be limited to the items listed in that Regulation.

(c) AMC-20 'General Acceptable Means of Compliance for Airworthiness of Products, Parts and Appliances' provides further details on occurrence reporting (AMC 20-8).

(d) Point 21L.A.3(a)(3) requires the reporting of occurrences that may result in an unsafe condition. AMC1 21L.B.23(b) may be used to assist in the determination of an unsafe condition.

AMC1 21L.A.3(e) Reporting system

ED Decision 2023/013/R

FOLLOW-UP AND CLOSURE OF REPORTED OCCURRENCES

(a) The organisation should transmit the following information to the competent authority within 30 days from the date of notification of the occurrence to the competent authority:

(1) the latest position of the organisation responsible for design as to whether an unsafe condition is confirmed;

(2) the results of the analysis and of the first investigation — including the cause(s) of the occurrence, if known; and

(3) the measures it has taken, intends to take or proposes to be taken, including:

(i) containment measures that have already been defined by the reporting organisation and put in place (if any); and

(ii) in the case of reports made by the organisation responsible for design, for unsafe conditions, a risk assessment supporting that the product can be operated safely until the corrective action is defined and implemented, or that immediate mitigation measures need to be implemented until a more refined risk assessment can be provided.

Organisations are encouraged to provide a complete analysis and follow-up as soon as available and, in principle, no later than 3 months after the occurrence notification. It is recognised that analysing an occurrence may take longer than 3 months, especially if the investigation is complex or where the services of a specialist investigator are required.

The requirements for follow-up are not intended to jeopardise the quality and thoroughness of an occurrence analysis. It may be detrimental to safety if the analysis is completed in a rush within the encouraged 3-month period without properly establishing the root cause(s), making a risk assessment and determining whether remedial action is required.

The designer (any natural or legal person that holds a type certificate, supplemental type certificate, major repair design approval, or that has declared the compliance of an aircraft design, or a design change or repair design to it under this Annex) and the production organisation (any natural or legal person that has declared their production capability under Subpart G of this Annex, or that produces a product or part under Subpart R) should cooperate, as necessary, to ensure that any corrective action can be implemented. In addition, affected organisations are expected to cooperate under their respective regulatory framework from the reporting of an occurrence until its closure, to ensure complete results.

The final (close-out) report should include:

— the final designer position as to whether an unsafe condition exists;

— the results of the occurrence analysis and of the final investigation, including the cause(s) of the occurrence;

— any corrective and preventive action by the reporting organisation; and

— in the case of reports made by the organisation responsible for the design, a risk assessment supporting that those corrective and preventive measures allow the product to be operated safely.

(b) Notwithstanding point (a), when the organisation identifies that no unsafe condition exists as a result of its analysis of a voluntarily reported occurrence, it can delay further communication to the competent authority up to the issue of the final report and report the occurrence as closed upon issue (data exchange). In such cases, no follow-up report should be submitted. The final report to EASA should include confirmation and justification that no unsafe condition exists. The organisation is requested to provide information on the cause(s) of the occurrence and on the corrective or preventive action that was taken by the organisation.

This way of reporting should not be understood as an accepted deviation from the requirements of Part 21 Light. If at any stage during the investigation, the organisation identifies that a possible unsafe condition exists, it should communicate it to EASA by means of a mandatory report within 72 hours.

21L.A.4 Airworthiness directives

Regulation (EU) 2022/1358

When an airworthiness directive has to be issued by the Agency in accordance with point 21L.B.23 to correct an unsafe condition, or to require the performance of an inspection, the holder of the type certificate, supplemental type certificate, major repair design approval, or any other relevant certificate deemed to have been issued under this Annex, as well as the declarant of a declaration of design compliance, as applicable, shall:

(a) propose the appropriate corrective action or required inspections, or both, and submit details of these proposals to the Agency for approval;

(b) following the approval by the Agency of the proposals referred to under point (a), make available to all known operators or owners of the product or part, and, on request, to any person required to comply with the airworthiness directive, appropriate descriptive data and accomplishment instructions.

21L.A.5 Collaboration between design and production

Regulation (EU) 2022/1358

The holder of a type certificate, supplemental type certificate, approval of a change to type certificate or approval of a repair design, the declarant of a declaration of design compliance, and the organisation or the natural or legal person producing products or parts of that specific design shall collaborate so as to ensure that the product or part are in conformity to that design and to ensure the continued airworthiness of the product or part.

AMC1 21L.A.5 Collaboration between design and production

ED Decision 2023/013/R

TRANSFER OF INFORMATION ON ELIGIBILITY AND STATUS FROM THE DESIGNER TO A PRODUCTION ORGANISATION

Where there is a need to provide (normally outside the organisation or entity responsible for design) a visible statement of approved or declared design data or airworthiness, or environmental protection data associated with the approved or declared design data, the following minimum information should be provided. The need for a visible statement may be in relation to an organisation that holds a production organisation approval (POA) in relation to point 21.A.163(c) or a registered declaration of production capability (declared production organisation) or a natural or legal person using Subpart R.

Information to be provided:

Company name: the name of the responsible organisation (or natural or legal person) for design (type certificate, supplemental type certificate, approval of repair or minor change design, declarant of a declaration of design compliance) that issues the information.

Date: the date at which the information is released.

Eligibility: indicate the specific products for which data has been approved or declared.

Identification: the part number of the part. Preference should be given to the use of the Illustrated Parts Catalogue (IPC) designation. Alternatively, the reference to the instructions for continued airworthiness (e.g. service bulletins (SBs), aircraft maintenance manual (AMM), etc.) could be stated. Marking requirements of Part 21 Light Section A Subpart Q should be taken into account.

Description: the name or description of the part or document should be given. In the case of a part, preference should be given to the use of the IPC designation. The description should include reference to any applicable European Parts Approval (EPA) marking, or previous national approvals still valid.

Purpose of data: the reason for the provision of the information should be stated by the organisation responsible for design.

Examples:

(a) Provision of approved or declared design data to a production organisation to permit manufacture (AMC1 21L.A.122(c), AMC1 21L.A.272 or AMC No 1 to 21.A.133(b) and (c)).

(b) Information regarding eligibility for installation (replacement parts, repair, modification, etc.).

(c) Direct Delivery Authorisation (AMC1 21L.A.122(c), AMC1 21L.A.272 or AMC No 1 to 21.A.133(b) and (c)).

If the data is in support of a change or repair, then reference to the aircraft level approval or declarations should be given (make reference to the approved supplemental type certificate, declaration, change or repair).

Limitations/remarks: state any information, either directly or by reference to supporting documentation, which identifies any particular data or limitations (including specific importing requirements) needed by a production organisation to complete Block 12 of the EASA Form 1.

Approval/declaration: provide reference information related to the approval or declaration of the data (EASA document / DOA privilege / registered declaration).

Authorised signature: name and handwritten or electronic signature of the person who has written authority from the organisation responsible for design, as indicated in the procedures overseen by EASA.

21L.A.6 Marking

Regulation (EU) 2022/1358

(a) The holder of a type certificate, supplemental type certificate, approval of a change to type certificate or approval of a repair design, or the declarant of a declaration of design compliance shall specify the marking for products or parts in accordance with Subpart Q of this Annex.

(b) The organisation or the natural or legal person producing products or parts shall mark these products and parts in accordance with Subpart Q of this Annex.

21L.A.7 Record-keeping

Regulation (EU) 2022/1358

All natural or legal persons who hold or who have applied for a type certificate, supplemental type certificate, repair design approval, or permit to fly, who have declared design compliance, who have issued a declaration of design or production capability, or who produce products or parts under this Regulation shall:

(a) when designing a product or part or changes or repairs thereto, establish a record-keeping system that incorporates the requirements imposed on its partners and subcontractors and maintain the relevant design information/data and hold it at the disposal of the Agency in order to provide the information necessary to ensure their continued airworthiness and compliance with the applicable environmental protection requirements;

(b) when producing a product or part, establish a record-keeping system and record the details of the work relevant to the conformity of the products or parts, and the requirements imposed on its partners and suppliers, and hold them at the disposal of the competent authority in order to provide the information necessary to ensure the continuing airworthiness of the product and part;

(c) with regard to permits to fly, in addition to the record-keeping requirements established in point 21.A.5(c) of Annex I, record any documents produced to demonstrate compliance with the additional requirements established in point 21L.A.241(b), and hold them at the disposal of the Agency and the competent authority;

(d) retain records of competence and the qualifications of personnel who are involved in design or production and in the independent function to monitor the compliance, if required by points 21L.A.125(c), 21L.A.175(b) or 21L.A.175(e).

AMC1 21L.A.7 Record-keeping

ED Decision 2023/013/R

(a) The record-keeping system should ensure that all the records required by point 21L.A.7 are accessible within a reasonable time. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.

(b) The records should remain legible throughout the required retention period and be protected against damage, alteration and tampering.

(c) The format of the records should be specified in the organisation's procedures.

(d) The organisation should ensure that copies of all the documents and supporting information that are developed:

(1) under the privileges that are defined under points 21.A.163 and 21.A.263 of Annex I (Part 21); or

(2) under the design and production activities conducted under points 21L.A.126, 21L.A.176 or 21L.A.274;

(3) for type certificates, supplemental type certificates, major changes and major repair design approvals that are not issued under the privileges defined under point 21.A.263 of Annex I (Part 21),

or

(4) for declarations of design compliance in accordance with Subpart C, F or N,

are retained throughout the operational life of the product or part.

(e) The retention period starts when the record is created or when it was last amended.

If the organisation transfers a certificate to another natural or legal person, the records related to the certificate should be transferred to the new holder.

GM1 21L.A.7 Record-keeping

ED Decision 2023/013/R

For organisations that hold or have applied for a type certificate, supplemental type certificate, change to the type-certificate approval, repair design approval, permit to fly or have submitted a declaration of design compliance or a declaration of design or production capability under Part 21 Light or produces (or intends to) using Subpart R, the relevant design information/data should include at least, as applicable:

— design data such as type design data as defined in points 21L.A.26 and 21L.A.46 and changes to that data, and repair design data;

— drawings and test reports, including inspection records for the product tested;

— the certification demonstration plan, including related certification basis data (certification review items (CRIs), special conditions (SCs), equivalent safety findings (ESFs)); and

— compliance-demonstration data.

For production organisations, the relevant records should include at least:

— conformity justification data; and

— conformity attestation data (e.g. EASA Form 1, EASA Form 52B).

AMC1 21L.A.7(a) Record-keeping

ED Decision 2023/013/R

REPAIR DESIGN AND RECORD-KEEPING

(a) The relevant substantiation data associated with a new major repair design and record-keeping should include:

(1) identification of the damage and the source of the report;

(2) the major repair design approval/declaration sheet, identifying the applicable specifications and the references of the justifications;

(3) the repair drawing and/or instructions, and the scheme identifier;

(4) any correspondence with the type-certificate holder, supplemental type-certificate holder or declarant, if their advice on the design was sought;

(5) the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to that data;

(6) the effect on the aircraft, engines and/or systems (performance, flight handling, etc., as appropriate);

(7) the effect on the maintenance programme;

(8) the effect on the airworthiness limitations, the flight manual and the operating manual;

(9) any change in the weight and moment;

(10) any special test requirements; and

(11) the justification that the certified or declared noise or emissions level remain unchanged after the repair.

(b) The relevant minor repair documentation includes points (a)(1) and (a)(3). Other elements of point (a) may be included where necessary. If the repair is outside the approved or declared data, a justification for the classification is required.

(c) Special consideration should be given to repairs that impose subsequent limitations on the part or product (e.g. oversizing of fastener holes, etc.).

(d) Special consideration should also be given to life-limited parts and critical parts, notably with the involvement of the type-certificate or supplemental type-certificate holder, when deemed necessary under point 21.A.208(c).

(e) Repairs to engines and/or propeller critical parts would normally only be accepted with the involvement of the type-certificate holder or the declarant if compliance of the engine has been included within the aircraft declaration of compliance.

GM1 21L.A.7(a);(b) Record-keeping

ED Decision 2023/013/R

RECORD-KEEPING AND ARCHIVING SYSTEM

The main purpose of record-keeping for organisations responsible for design and production is to ensure the retrievability of data required for the continued airworthiness of in-service products.

In addition, the records within a design environment are essential to ensure a proper control of the configuration of type design and its compliance with the certification basis or applicable technical specifications.

In the production environment, the records are required to ensure that products or parts are in conformity with the applicable data throughout the manufacturing cycle. In addition, certain records of milestones are needed to subsequently provide objective evidence that all the prescribed stages of the production process have been satisfactorily completed.

Therefore, organisations responsible for design or production are required to implement a system for the compilation and retention of records during all stages of design or production, which covers short-term and long-term records as appropriate to the nature of the product and its processes.

The management of such information is subject to the appropriately documented procedures in the management system required by points 21L.A.124, 21L.A.174 or in the manual/procedures required by point 21L.A.273 as appropriate.

All forms of recording media (paper, film, magnetic, etc.) are acceptable, including the use of electronic records*, provided they can meet the required duration for archiving under the conditions provided and that the continued readability of the records is ensured.

The related procedures are required to:

— identify the records to be kept;

— describe the organisation of, and responsibility for, the archiving system (its location, compilation, format) and the conditions for access to the information (e.g. by product, subject, etc.);

— control access to the data and provide effective protection against deterioration or accidental damage;

— ensure the continued readability of the records;

— demonstrate to the competent authority the proper functioning of the records system;

— define an archiving period for each type of data subject as follows:

— production data that supports the conformity of a product or part, is kept for not less than 3 years from the issue date of the related statement of conformity or authorised release certificate; and

— design data, including data which supports the compliance of a product or part with the certification basis or applicable technical specifications, as well as data that is considered essential for continuing airworthiness is kept throughout the operational life of the product or part; such continued airworthiness data may include but are not limited to in-service occurrence reports and mandatory continuing airworthiness information;

— organisations responsible for design or production should ensure that the recording and record-keeping system used by the partners, suppliers and subcontractors meet the record-keeping objectives with the same level of confidence as for their own system; in each case, it should be defined who should retain the data record (organisation, partner, supplier or subcontractor) as well as the method of surveillance of the recording / record-keeping system of the partners, suppliers or subcontractors.

* In relation to electronic records, the following definitions apply:

— 'electronic record': electronic or digital data that is created, generated, sent, communicated, received, or stored by electronic means;

— 'electronic data': it is typically in the form of documentation that is statically stored in a computer file that is not modifiable (e.g. pdf of a scanned document with wet ink signatures);

— 'digital data': it is typically in the form of computer-generated bytes of information that is stored in a computer-workable file (e.g. MS Word file, MS Excel file, 3D CAD file).

AMC1 21L.A.7(d) Record-keeping

ED Decision 2023/013/R

RECORDS OF PERSONNEL INVOLVED IN DESIGN OR PRODUCTION

(a) The following should be the minimum information to be recorded for personnel that are involved in design or production and in the independent function to monitor the compliance, if required by points 21L.A.125(c), 21L.A.125(d), 21L.A.175(b) or 21L.A.175(e):

(b)

(1) first name and surname;

(2) date of birth;

(3) basic training received and qualifications attained;

(4) specific training received and qualifications attained;

(5) continuation training (if appropriate);

(6) experience gained;

(7) scope of the authorisation;

(8) date of first issue of the authorisation;

(9) expiry date of the authorisation (if appropriate);

(10) identification number of the authorisation (or equivalent means to identify the link between the authorisation and the individual that holds the authorisation);

(11) changes to the data.

(c) The record may be kept in any format and should be controlled by an internal procedure of the organisation. That procedure is part of the management system of the organisation.

(d) Staff members should be given reasonable access, on request, to their own records as per Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Regulation) (OJ L 119, 4.5.2016, p. 1).

(e) A design or production organisation should keep the record of a particular staff member for at least 3 years after the staff member is no longer employed by the organisation or has changed their position in the organisation, or after the withdrawal of the authorisation, whichever occurs first.

21L.A.8 Manuals

Regulation (EU) 2022/1358

The holder of a type certificate or supplemental type certificate or the declarant of a declaration of design compliance shall produce, maintain and update master copies of all the manuals or variations in the manuals required by the applicable type-certification basis, the applicable detailed technical specifications and the applicable environmental protection requirements for the product or part, and provide copies, on request, to the Agency.

21L.A.9 Instructions for continued airworthiness

Regulation (EU) 2022/1358

(a) The holder of a type certificate, supplemental type certificate, design change or repair design approval or the declarant of a declaration of design compliance shall establish the information which is necessary for ensuring that the airworthiness of the aircraft type and any associated part, conforming to that design, is maintained throughout the operational life.

(b) The holder of a type certificate, supplemental type certificate, design change or repair design approval or the declarant of a declaration of design compliance shall provide the information established in (a) before that design is released to service.

(c) The instructions for continued airworthiness shall be provided by:

1. the holder of a type certificate or by the declarant of a declaration of design compliance to each known owner of one or more products upon its delivery or upon the issuance of the first certificate of airworthiness or restricted certificate of airworthiness, as applicable, for the affected aircraft, whichever occurs later;

2. the holder of a type certificate, supplemental type certificate or minor change approval or by the declarant of a declaration of design compliance for a design change to all known operators of the product affected by the change upon the release to service of the modified product;

3. the holder of a repair design approval or by the declarant of a declaration of design compliance for a repair design to all known operators of the product affected by the repair upon the release to service of the product in which the repair design is embodied. The repaired product or part may be released into service before the related instructions for continued airworthiness have been completed, but this shall be for a limited service period, and in agreement with the Agency.

Thereafter, these certificate holders or declarants shall make this information available on request to any other person required to comply with those instructions for continued airworthiness.

(d) By way of derogation from point (b), the type-certificate holder or declarant of a declaration of design compliance may delay the availability of a part of the instructions for continued airworthiness, dealing with long lead accomplishment instructions of a scheduled nature, until after the product or modified product has entered into service, but shall make those instructions available before the use of this data is required for the product or modified product.

(e) The design approval holder or declarant of a declaration of design compliance who is required to provide instructions for continued airworthiness in accordance with point (b) shall also make available all the changes to those instructions to all the known operators of the product affected by the change, and, on request, to any other person required to comply with those changes.

AMC1 21L.A.9(a) Instructions for continued airworthiness

ED Decision 2023/013/R

INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs) — CONTENTS

(a) The ICAs should identify the following, in accordance with the applicable certification specifications or applicable technical specifications:

(1) any limitations that are necessary for the continued airworthiness of the product or article;

(2) the means to determine when the product or article has deteriorated to the extent that it is no longer airworthy;

(3) the minimum actions required to restore the airworthiness of the product or article before the limitations (as per point (1)) have been exceeded or before their deterioration (as per point (2)), as an alternative to the withdrawal of the product or part from service.

(b) The ICAs should, therefore, include, in accordance with the applicable certification specifications or applicable technical specifications:

(1) any limitations determined through the certification or demonstration of compliance resulting in a declaration of compliance of the product or article, and instructions on how to determine that the limitations have been exceeded;

(2) any inspection, servicing or maintenance actions determined to be necessary by the certification process or demonstration of compliance resulting in a declaration of compliance;

(3) any inspection or troubleshooting actions determined to be necessary to establish the nature of faults and the necessary remedial actions;

(4) sufficient general information on the operation of the product or article to enable the understanding of the instructions in points (a)(1) to (a)(3) above.

AMC2 21L.A.9(a) Instructions for continued airworthiness

ED Decision 2023/013/R

IDENTIFICATION OF THE INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs)

The ICAs may be provided together with other, additional or optional, maintenance information, or in another acceptable format as per GM1 21L.A.9(a), with the following conditions:

(a) The information that is necessary for the continued airworthiness is clearly identified (refer to AMC1 21L.A.9(b)).

(b) The ICAs may reference additional instructions for continued airworthiness in separate publications, where necessary (for example, those produced by suppliers).

If the product's ICAs reference the use of supplier data (e.g. component maintenance manual (CMM) or section of it) as the appropriate location for the ICAs, those applicable instructions are incorporated by reference and become part of the complete set of the ICAs for the particular product.

(c) Additional or optional maintenance information that is not considered ICAs but referenced by the design approval holder (DAH) or declarant together with the ICAs should be evaluated appropriately by the DAH or declarant in order to ensure that its use will not compromise the continued airworthiness of the product or article.

(d) If the maintenance data made available by a DAH or declarant includes data from an operator (i.e. in order to customise the data for the operator, and created under the authority of the operator), the operator data should be identified as such, and the DAH or declarant is not required to additionally evaluate it.

AMC3 21L.A.9(a) Instructions for continued airworthiness

ED Decision 2023/013/R

DESIGN APPROVAL HOLDER (DAH) OR DECLARANT RESPONSIBILITY TO CHECK THE SUPPLIER DATA WHICH IS PART OF THE ICAs OR REFERENCED TOGETHER WITH THE ICAs

The DAH or declarant may carry out a complete check of the supplier data, or may choose to rely, in whole or in part, on the supplier's process for ensuring the accuracy and completeness of the data. In the latter case, the DAH or declarant will propose a means to validate the supplier's process. Supplier data may also be issued by the supplier to the DAH or declarant under a contract or an arrangement, addressing the following:

(a) the accuracy and the adequacy of the technical documentation, which should be checked through a verification process (e.g. component workshop verification);

(b) evidence showing that workshop verification has been performed should be kept by the supplier and a clear statement should be given in the introduction to the supplier data as a confirmation that component verification is complete;

(c) evidence that the supplier has taken into account all justified feedback and changes to data requested by any person required to use the ICAs; typical examples would be the correction of reported errors, or mistakes.

In addition, some validation activities may be decided by the DAH or declarant, depending on the articles and the capability level of the supplier.

For articles subject to an ETSO authorisation, the validation of the supplier's process for ensuring the accuracy and completeness of the data is not needed. This is also valid for other national TSO authorisations (e.g. FAA TSOs) accepted by EASA as stipulated in related bilateral agreements.

GM1 21L.A.9(a) Instructions for continued airworthiness

ED Decision 2023/013/R

SCOPE OF THE INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs), THEIR PUBLICATION FORMAT AND TYPICAL ICA DATA

(a) The ICAs may be published in documents or in a manner other than the traditional understanding of a document — for example, as a series of web pages, or Information Technology (IT) tools, or in a publishing format linked to tasks or data modules rather than pages.

(b) The design approval holder (DAH) or declarant may decide, within the framework provided by point 21L.A.9 and its acceptable means of compliance and guidance material, to publish the ICAs in the most suitable location as part of all the information published to support the airworthiness of a given aircraft.

(c) The requirement for ICAs is not intended to ensure that all products or articles may be restored to an airworthy condition. A certain level of deterioration may require a product or an article to be permanently withdrawn from service, and restoration may not be reasonably achievable.

Certain deteriorations or levels of deterioration may require specific instructions (e.g. inspection or restoration) that will only be developed and provided on a case-by-case basis, as needed, for a given product or article, and as such, will not be included in the ICAs.

In some exceptional cases, ICAs for products may ultimately instruct the user to contact the DAH or declarant in order to define the specific instructions on a case-by-case basis. This typically happens when the definition of generic instructions covering all possible cases is not possible. For example, following an aircraft hard landing, a detailed analysis may have to be carried out by the DAH or declarant to determine the specific instructions to be followed, which depend on the touchdown loads.

GM2 21L.A.9(a) Instructions for continued airworthiness

ED Decision 2023/013/R

DETERMINATION OF WHICH SUPPLIER DATA IS PART OF THE INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs)

Note 1: For the purposes of this GM, the term 'supplier data' also applies to similar types of data when issued directly by the DAH or declarant (e.g. component maintenance manuals (CMMs) issued by the DAH or declarant).

Note 2: For the purposes of this GM, the term 'supplier data' should be understood as data coming from the supplier and related to either a full CMM or to part of a CMM.

Note 3: The link between the aircraft ICAs and the engine/propeller CMM, as detailed below, is similar to the link between engine/propeller ICAs and the CMM of equipment fitted to the engine/propeller.

Note 4: If the supplier is also the DAH (for instance, an engine or propeller manufacturer), then the ICAs for these items will be made available by virtue of the DAH obligations as type-certificate holder (TCH) and need not be included in the aircraft ICAs.

Note 5: If the supplier is an engine or propeller manufacturer, then the ICAs for these items will be made available by virtue of the DAH obligations as type-certificate holder (TCH) and need not be included in the aircraft ICAs. If the supplier is an engine or propeller manufacturer that is not the TCH due to the aircraft TC or declaration of design compliance also including the compliance of the engine or propeller, then the supply of ICAs from the engine or propeller manufacturer will need to be subject to a suitable arrangement.

(a) When determining whether a supplier data is part of the ICAs, the following should be considered:

(1) Supplier data related to the Airworthiness Limitations Section (ALS) of the ICAs is part of the ICAs.

(2) Supplier data related to instructions on how to accomplish the scheduled maintenance part of the aircraft ICAs are part of the aircraft ICAs. A typical case is the periodical removal of a component to perform a workshop task.

(3) Supplier data related to scheduled maintenance on the component should be endorsed by the DAH or declarant before becoming part of the aircraft ICAs, to define and confirm that the supplier data is applicable and effective.

(4) If the ICAs are defined at aircraft level, the following principles apply to the other supplier data that is not related to the ALS nor to scheduled maintenance:

(i) If the supplier data includes a maintenance instruction for an action identified in the aircraft-level ICAs, including an engine or propeller, this supplier data should be referenced in the aircraft-level ICAs and should be made available like any other ICAs.

As an alternative to linking such supplier data to the aircraft-level ICAs (e.g. with cross references), it is possible to include the relevant data directly into the aircraft ICAs. In such a case, the supplier data is not part of the aircraft ICAs since the aircraft ICAs already contain all the required information.

(ii) If an aircraft ICAs' task only requires a replacement task for an engine, propeller or part (i.e. 'remove and replace' or 'discard') and does not refer to the supplier data for further maintenance of the removed engine, propeller or part, this means that the aircraft airworthiness may only be maintained by replacement action, and that the supplier data is not part of the ICAs for the particular aircraft. In such cases, the supplier data does not need to be referenced in the aircraft ICAs.

Example: If supplier data provides off-aircraft maintenance instructions for an engine, propeller, or other article (i.e. workshop maintenance), then this data may not be considered as part of the complete set of the ICAs for the aircraft, but may be considered as part of the complete set of the ICAs for the engine or propeller. However, the procedure for removal from / installation on the aircraft is necessarily part of the aircraft ICAs.

(b) However, for the above cases, aircraft-level ICAs can provide, as additional or optional maintenance information, the references to the supplier data even if it is not considered part of the ICAs. In such cases, it should be made clear that the supplier data references are provided as additional or optional maintenance information and is not part of the product ICAs. Besides,

it should be ensured that the use of additional or optional maintenance information not considered as ICAs but referenced together with the ICAs will not compromise the continued airworthiness of the product or article.

(c) For the supplier data identified as part of the ICAs, the DAH or declarant should:

(1) identify the supplier data that is part of the ICAs; this can be achieved either by creating a listing or by any other acceptable means that allow to identify which data is part of the ICAs and which data is not part of the ICAs (refer to AMC1 21L.A.9(b));

(2) just as for any other ICAs, ensure the publication of the supplier data;

(3) ensure the accuracy and the adequacy of the technical content of the supplier data.

GM3 21L.A.9(a) Instructions for continued airworthiness

ED Decision 2023/013/R

NON-ICAs SUPPLIER DATA (e.g. COMPONENT MAINTENANCE MANUALS (CMMs))

(a) Non-ICAs supplier data referenced together with the ICAs

Supplier data, or parts of the supplier data, which is not considered part of the ICAs but is additional or optional maintenance information referenced together with the product-level ICAs may be issued by the supplier to the DAH or declarant under a contract or an arrangement, using the methodology proposed in AMC3 21L.A.9(a).

(b) Other non-ICAs supplier data

Non-ICAs supplier data, which is not referenced together with the ICAs, but which can be used for the maintenance of components approved for installation by the DAH or declarant, should be acceptable to the DAH or declarant. This non-ICAs supplier data may be documented in a list.

AMC1 21L.A.9(b) Instructions for continued airworthiness

ED Decision 2023/013/R

IDENTIFICATION OF A COMPLETE SET OF INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs)

The design approval holder (DAH) or declarant should identify the complete set of ICAs according to point 21L.A.9(b) in such a way that the complete set can be:

(a) directly listed in the product's type certificate data sheet (TCDS) or airworthiness data sheet; or

(b) indirectly referenced in the TCDS or airworthiness data sheet through other means, which allow the complete list of the ICAs to be obtained (e.g. a complete listing of ICAs contained in a 'principal manual' or a reference to the DAH's or declarant's website); or

(c) directly listed in the product's supplemental type certificate (STC); or

(d) indirectly referenced in the STC through other means, which allow the obtainment of the complete list of the ICAs; or

(e) if direct reference is made to the ICAs in the product's TCDS or the STC or airworthiness data sheet, no reference to the revision level of the ICAs should be made; in this case, the revision level should be available elsewhere (e.g. on the DAH's or declarant's website).

For design changes and repairs to type certified or declared aircraft, the identification of 'a complete set of the changes to the instructions for continued airworthiness' should be performed by the DAH or declarant by a statement to provide this information, or by confirmation that there are no changes

to the ICAs. This statement may also be made in the accomplishment document (e.g. embodiment instructions).

For products and articles for which the DAH or declarant holds a design organisation approval (DOA), the ICAs are considered to have been issued under the authority of the DOA and, therefore, the approval of the ICAs should be made explicit to the reader in accordance with point 21.A.265(h) of Annex I (Part 21) to this Regulation, unless otherwise agreed with EASA.

GM1 21L.A.9(b) Instructions for continued airworthiness

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ANY OTHER PERSONS REQUIRED TO COMPLY

For the purposes of this GM, 'any other person required to comply' means:

(a) any independent certifying staff that performs maintenance on a product or article, in accordance with Regulation (EU) No 1321/2014, in the framework of a contract (or work order) with the person or organisation responsible for the aircraft continuing airworthiness;

(b) any maintenance organisation approved to maintain a product or article, in accordance with Regulation (EU) No 1321/2014, in the framework of a contract (or work order) with the owner of the engine or article, or the person or organisation responsible for the aircraft continuing airworthiness;

(c) any organisation approved to manage the aircraft continuing airworthiness in accordance with Regulation (EU) No 1321/2014, in the framework of a contract with the aircraft owner or aircraft operator.

GM2 21L.A.9(b) Instructions for continued airworthiness

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INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs) — FORMAT

The ICAs may be furnished or made available by various means (including paper copies, electronic documents, or web-based access). Regardless of the format, the design approval holder (DAH) or declarant is expected to furnish or make the ICAs available in a means that is readily accessible for and useable by the owner and any other person required to comply with the ICAs. Service documents, such as service information letters, may be used for transmitting ICAs information and updates.

(a) Formatting standards

DAHs or declarants may use the latest ATA, AECMA/ASD or GAMA formatting standards such as:

(1) AeroSpace and Defence Industries Association of Europe (ASD), ASD-S1000D, *International Specification for Technical Publications Utilizing a Common Source Data Base*, version 4 or higher;

(2) the Air Transport Association's (ATA) iSpec 2200, *Information Standards for Aviation Maintenance*, latest edition (ATA is now known as Airlines for America (A4A) but the standard is still listed as ATA); or

(3) General Aviation Manufacturers Association (GAMA) Specification No. 2, *Specification for Manufacturers Maintenance Data*, latest edition.

With regard to scheduled maintenance, DAHs or declarants may also refer to the glossary of the ATA MSG-3 standard, latest revision, for standardised task definitions and designations.

(b) General considerations

The ICAs should be easy to read and to follow. All ICAs should include a means to identify their applicability (model, type, etc.), and the associated revision status. Refer to sample formats in the Air Transport Association's iSpec 2200, *Information Standards for Aviation Maintenance*, latest edition, or AECMA/ASD standards. There is no requirement for any specific format or arrangement of the ICAs in a document or documents. However, the specific format selected by the DAH or declarant should be used and applied in a uniform manner. Empty pages in a document should contain the statement 'Intentionally left blank' or similar.

At the beginning of each procedure, the ICAs should contain cautions and warnings regarding possible mistakes that can be made when following the instructions.

Abbreviations, acronyms and symbolisation should be either avoided or explained as part of the ICAs documentation.

The ICAs contain units of measurement. Measurements could be, for instance, instrument readings, temperatures, pressures, torque values with tolerances, limits, and ranges when applicable. If the ICAs contain units of measurement of a system other than the metric, the ICAs should include a conversion to the metric system for each measurement, tolerance, or torque value. A general conversion table alone should not be provided, as it may introduce an additional source of error.

The DAH or declarant should use a means to indicate changes to the ICAs directly in relation to each item of the information/data of the ICAs, e.g. using a vertical change bar in the margin next to the line.

(c) Publication of the ICAs in multiple documents

DAHs or declarants may prepare ICAs as a document, or several documents, depending on how much data is necessary to provide a complete set of ICAs.

If there are multiple documents, there should be a principal document that describes the general scope of all other documents, in order to provide an overview of the multiple document structure.

According to different standards, the Airworthiness Limitations Section (ALS) needs to be included in the principal document as a dedicated section. However, EASA may also accept a separate Airworthiness Limitations document when it is at least referenced as such in the principal document.

DAHs or declarants that decide to segregate information dedicated to a specific subject from a principal document into a separate document, e.g. 'Fuel Pipe Repair Manual', 'Cable Fabrication Manual', 'Duct Repair Manual' or 'Instrument Display Manual', should declare these documents to be ICAs.

DAHs or declarants may decide to integrate certain information in a principal document (as, for example, troubleshooting information as part of the aircraft maintenance manual (AMM) instead of a separate troubleshooting manual (TSM)).

(d) Language

The ICAs should be provided in any of the official language(s) of the European Union which is (are) acceptable to the competent authority.

Note: In certain countries, such as the USA, English is required for ICAs. EASA, therefore, recommends that DAHs or declarants include a version of the ICAs in simplified technical English (e.g. in accordance with ASD Specification STE100).

(e) Electronic media

The ICAs may be provided in an electronic format (e.g. CDs, via the internet, etc.) instead of paper copies or microfilms (refer to AMC1 21L.A.9(b)).

When electronic format is used, the DAH or declarant should consider aspects such as the traceability of updates, keeping previous versions (record-keeping), data security and the obligations of the person(s) or organisation(s) responsible for the aircraft continuing airworthiness, considering that the ICAs form the basis of the data used for continuing airworthiness activities.

GM3 21L.A.9(b) Instructions for continued airworthiness

ED Decision 2023/013/R

APPROVAL STATUS OF THE MANUAL FOR A COMPONENT OR ARTICLE

When the ICAs refer to a document for a specific component or article, it is possible that this document is used for products from more than one DAH. In such cases, instead of placing approval statements from each DAH in the same manual, it may be more practical to identify the approved status of the relevant document through its inclusion in lists managed by the DAH in accordance with AMC1 21L.A.9(b).

GM4 21L.A.9(b) Instructions for continued airworthiness

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INTEGRATION OF THE INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs) BETWEEN PRODUCTS (AIRCRAFT, ENGINES, PROPELLERS)

The aircraft/engine/propeller type-certificate holder (TCH) and, if applicable, the declarant, should ensure the availability of ICAs to allow maintenance of the aircraft, including engines/propellers when installed on the aircraft.

When referring to engine/propeller ICAs directly in the aircraft ICAs, the aircraft TCH or declarant should not perform additional verification and validation. However, the integration and interface aspects between the aircraft and the engine/propeller are still under the responsibility of the aircraft TCH or declarant.

If the ICAs published by the aircraft TCH or declarant include some engine/propeller ICAs developed by the engine/propeller TCH, the engine/propeller TCH should make an arrangement with the aircraft TCH setting out engine/propeller TCH and aircraft TCH or declarant shared responsibilities with respect to the ICAs under point 21L.A.9.

This arrangement should:

— define the part of the engine/propeller ICAs which is published in the aircraft ICAs; and

— address the development, publication and update processes of these ICAs, including completeness and timely availability aspects.

— The incorporated engine/propeller data content remains under the responsibility of the engine/propeller TCH, and the publication is under the responsibility of the aircraft TCH or declarant. Therefore, the aircraft TCH or declarant should coordinate with the engine/propeller TCH regarding any modification or alteration of the incorporated data.

AMC1 21L.A.9(d) Completeness and timely availability of the Instructions for Continued Airworthiness

ED Decision 2023/013/R

COMPLETENESS AND TIMELY AVAILABILITY OF THE INSTRUCTIONS FOR CONTINUED AIRWORTHINESS (ICAs) FOR TYPE-CERTIFICATE (TC) APPLICANTS OR DECLARATION OF DESIGN COMPLIANCE

(a) An applicant or declarant may wish to choose among the three options described below. Once the certification programme or demonstration of compliance for a declaration starts, it may be necessary to modify the initially selected option to accommodate programme changes. All such changes should be coordinated with EASA.

(1) *Option 1*: Complete ICAs are available at the time of the design approval (type certificate (TC)) or submission of a declaration of design compliance

(i) The ICAs will be made available at the time of the design approval or submission of the declaration of design compliance. This option minimises the risk of incomplete ICAs, especially for changes.

(ii) With all ICAs available at the time of the design approval or submission of the declaration of design compliance, they should also be furnished / made available to the aircraft operator / aircraft owner and made available to any other person required to comply with any of those instructions in accordance with point 21L.A.9, without using the provision to delay certain parts of the ICAs after the entry into service of the product.

(iii) Frequently, there is only a short period of time between the design approval or submission of the declaration of design compliance and the entry into service. Nevertheless, applicants/DAHs or declarants may still wish to apply Option 2 or 3 for a part of their ICAs as stated below.

(2) *Option 2*: Complete ICAs are available at entry into service (TC or submission of the declaration of design compliance)

If an applicant or declarant plans to make part of the ICAs available to EASA upon entry into service, the following approach is acceptable:

(i) For the Airworthiness Limitations Section (ALS), as part of the type design, notwithstanding the selection of Option 2: the applicant or declarant submits the ALS prior to the design approval or submission of the declaration of design compliance. Any ALS content that is incomplete, not yet demonstrated for compliance, or delayed beyond the design approval or submission of the declaration of design compliance, requires to be compensated through an interim limitation to establish compliance within this limitation. The interim limitation is notified to the aircraft operator(s) concerned as a temporary operational limitation in a manner agreed with EASA.

In this context, ALS content is understood as the task method (e.g. a detailed inspection), including its reference, title and applicability, and the associated threshold / interval / life-limit. The accomplishment procedure itself, i.e. how to carry out the task, is usually described in other parts of the ICAs (e.g. in the aircraft maintenance manual (AMM) or the non-destructive testing (NDT) manual). However, a feasibility study of the accomplishment procedure is required for compliance with specific requirements.

(A) This may typically apply when the aircraft's structural full-scale fatigue testing required for compliance with the fatigue- and damage-tolerance requirements, considering the expected operational life, will not be completed prior to the type certificate being issued. In this case, a temporary operational limitation is assigned and stated in the ALS, dependent on the aircraft's full-scale fatigue testing progress. The ALS is effectively incomplete beyond this temporary operational limitation, as the required justification and the resulting ICAs are not yet available to support the safe operation of the aircraft beyond this limitation.

(B) A type certificate data sheet (TCDS) or airworthiness data sheet notation is not necessary since the product is provided with complete ALS content up to the established temporary operational limitation.

(ii) A compliance plan identifying those parts of the ICAs that are only to be made available upon entry into service is produced, submitted to EASA and agreed between the applicant/declarant and EASA prior to the design approval or registration of the declaration of design compliance (refer also to point (iv) for the ICAs considered necessary at the time of the design approval/registration of a declaration of design compliance).

(iii) A commitment is made to produce, verify and, when requested, submit to EASA the relevant ICAs prior to entry into service. This commitment should be provided in a compliance document (e.g. the compliance plan). If the respective organisation responsible for design has not previously exercised the practice of delaying the ICAs beyond the design approval or submission of a declaration of design compliance, the required procedure should be agreed with EASA.

(iv) The ICAs considered necessary at the time of design approval or submission of the declaration of design compliance are provided or made available in a format that adequately defines the data. Furthermore, the way the data is presented at the time of the design approval or submission of the declaration of design compliance offers the same understanding of the data as the final published format does.

The applicant or declarant should agree with EASA, in a compliance plan, on all ICAs necessary at the time of the design approval or registration of the declaration of design compliance. The Agency investigation may vary from no involvement or evaluating a limited sample of the ICAs to performing a thorough review of specific parts of the ICAs.

(v) In cases where EASA has doubts as to whether the applicant/holder or declarant can fulfil the applicable requirements of point 21L.A.9 to control and support delaying the ICAs beyond the design approval, or type certificate (TC), or submission of the declaration of design compliance and until entry into service, EASA may decide to assign a condition for entry into service for non-ALS ICAs or withhold the registration of the declaration of design compliance.

As a condition for the entry into service, a note should be included in the type certificate data sheet (TCDS) or airworthiness data sheet as a result of these pending issues under the ICAs paragraph as follows:

'*Note*: The ICAs are not complete. As per point 21L.A.9 of Annex Ib (Part 21 Light) to Commission Regulation (EU) No 748/2012, they must be completed before the entry into service of the aircraft. Contact EASA for information on the status.'

The decision to assign a condition may be based on the applicant's or declarant's performance, e.g. if the applicant or declarant has already demonstrated in previous projects that it has provided the complete set of ICAs before the entry into service, if the applicant or declarant has already experienced difficulties in providing the ICAs considered necessary at the time of the design approval or submission of the declaration of design compliance, or has previously failed on a different project to meet its commitment to complete the ICAs prior to entry into service, or if the applicant/holder or declarant has no previous experience with the practice of delaying the ICAs beyond the design approval or submission of the declaration of design compliance.

(vi) Post-TC action or the submission of the declaration of design compliance is established together with EASA (if EASA requests such a review) to review the ICAs' status upon entry into service.

(vii) If all ICAs are made available to EASA at the time of entry into service, they should also be furnished at that time to the aircraft operator / aircraft owner and made available to any other person(s) required to comply with any of those instructions in accordance with point 21.A.7, without using the provision to delay certain parts of the ICAs beyond the entry into service.

(3) *Option 3*: Complete ICAs are available after the entry into service (TC or registration of declaration of design compliance)

As per point 21L.A.9(d), certain ICAs dealing with the 'overhaul or other forms of heavy maintenance' may be delayed until after the aircraft entry into service. Although there is no definition of what is meant by 'overhaul or other forms of heavy maintenance', the intention of the requirement is to provide flexibility to applicants/holders or declarants for long-lead ICAs of a scheduled nature.

If an applicant or declarant plans to make part of the ICAs available only after the entry into service, the following is acceptable for the complete set of ICAs:

(i) For the ALS, as it cannot be delayed until after the entry into service, point (i) of Option 2 applies.

(ii) For ICAs considered necessary at the time of the design approval or submission of the declaration of design compliance, point (iv) of Option 2 applies.

(iii) A detailed compliance plan identifying those parts of the ICAs that are to be provided prior to and after the entry into service. For ICAs made available after the entry into service, the plan should account for when the ICAs are needed so that they can be complied with. This approach may only be used for scheduled maintenance accomplishment procedures, where threshold / interval / life-limit requirements of the related scheduled tasks are established. In that respect, the following aspects should be considered:

(A) The majority of the ICAs are of an unscheduled nature; therefore, these items should be available at entry into service at the latest.

(B) Consideration should be given to the fact that a number of tasks are used for both scheduled and unscheduled maintenance (e.g. an operational check of a system is planned as a scheduled task at a certain point in time, but is also required as part of the installation procedure to determine the operational status of the system).

(C) For ICAs to be made available after entry into service, the detailed plan should contain threshold(s) controlled by the applicant/holder, stating the maximum value in flight hours (FHs) / flight cycles (FCs) or calendar time (CT), or a combination of them as applicable, by which point in time the delayed ICAs should be made available.

(D) This detailed plan should be available prior to the time of the design approval or submission of the declaration of design compliance and should be either directly integrated or cross-referenced in a compliance plan.

(E) Information on the format in which the ICAs delayed until after entry into service will be made available in time (e.g. regular revisions or temporary revisions (TRs) or service information (SBs, SIL, etc.).

(iv) A procedure/programme that ensures a detailed plan is produced and implemented in the applicant's or declarant's organisation in order to ensure the timely availability (to the aircraft operator / aircraft owner and to any other person(s) required to comply with any of those instructions and to EASA, if involved and when requested).

(v) A commitment is made to produce, verify and provide the relevant ICAs in accordance with the established detailed plan. This commitment should be provided in an appropriate document (e.g. a compliance plan). If the respective organisation responsible for design has not previously exercised the practice of delaying the ICAs beyond the design approval or submission of the declaration of design compliance, the required procedure should be agreed with EASA.

(vi) In order to ensure that the applicant/holder or declarant can meet their obligations as set out in point 21L.A.9 to control and support delaying the ICAs, EASA may decide:

(A) for ICAs delayed until entry into service, to assign a condition/notation for the entry into service to be included in the TCDS or airworthiness data sheet as a result of these pending issues under the ICAs paragraph, as per point (v) of Option 2;

(B) for ICAs delayed until after entry into service, to assign an interim limitation to be published and included in the ALS as a temporary operational limitation, also for non-ALS ICAs, to compensate for the delayed ICAs; this approach may only be used for scheduled maintenance accomplishment procedures, where task and interval requirements are available.

The decision to assign a condition/limitation may be based on the applicant's or declarant's performance, e.g. if the applicant or declarant has already demonstrated in previous projects that it has provided the complete set of ICAs before the entry into service, if the applicant or declarant had already difficulties in providing the ICAs considered necessary at the time of the design approval or submission of the declaration of design compliance, or has failed before in a different project to control and support delaying the ICAs, or if the applicant/holder or declarant has not previously exercised the practice of delaying the ICAs beyond the design approval or submission of the declaration of design compliance.

(vii) Post-TC action or the submission of the declaration of design compliance should be established with EASA to regularly review the ICAs' status, if EASA requests such a review, taking into account other oversight activities.

(viii) An applicant/holder or declarant should provide visibility, regarding the ICAs that are delayed beyond entry into service, to the aircraft operator / aircraft owner and to any other person(s) required to comply with any of those instructions. This can be achieved by providing this information, for example, on a website or in a document, such as a maintenance planning document (MPD) or an aircraft maintenance manual (AMM), preferably in the principal ICAs manual. This visibility information is then itself considered ICAs information.

(ix) It is assumed that for those ICAs that are made available to EASA at the time of entry into service, they are also at the same time furnished to the aircraft operator / aircraft owner and made available to any other person(s) required to comply with any of those instructions in accordance with point 21L.A.9.

This is to satisfy EASA that such a delayed publication will not have an adverse effect on the continuing airworthiness of any given aircraft.

To allow the timely review and incorporation of a delayed part of the ICAs into continuing airworthiness activities and processes (e.g. amendment of the aircraft maintenance programme) by the person or organisation responsible for the aircraft continuing airworthiness or for performing maintenance, EASA considers that the delayed ICAs should typically be made available 2 years before the actual ICAs have to be used, when using normal revisions as a format. However, shorter time margins may be acceptable, provided that the format used ensures the prompt notification of the availability of the delayed ICAs or the ICAs itself, but they should not be shorter than 1 year before the ICAs have to be used.

(b) Completeness and timely availability of changes to the ICAs (TC or declaration of design compliance)

Point 21L.A.9(e) regulates the distribution of changes to the ICAs required from the TC holder or declarant. Those changes to the ICAs could result from the design change process (minor and major changes), in-service experience, corrections, and others.

A programme showing how changes to the ICAs are distributed is part of the respective procedures (e.g. design organisation procedures, or other procedures used to demonstrate design capabilities). For changes to the ICAs triggered by design changes, typically these procedures follow the same principles as those available for TCs or the initial declaration of design compliance (Options 1 to 3), while taking into account the relevant privileges, e.g. that a DOA may approve minor changes in accordance with point 21.A.263(c)(2) of Annex I (Part 21).

21L.A.10 Access and investigation

Regulation (EU) 2022/1358

All natural or legal persons who hold or who have applied for a type certificate, supplemental type certificate, major repair design approval, permit to fly, certificate of airworthiness, restricted certificate of airworthiness, noise certificate or restricted noise certificate, who have declared design compliance, who have declared their design or production capability or who produce aircraft, engines, propellers or parts under Subpart R of this Annex, shall:

(a) grant the competent authority access to any facility, product, part, document, record, data, processes, procedures or any other material, and permit the review of any report and make any inspection and perform or witness any test that is necessary to verify the compliance and the continued compliance with the applicable requirements of this Section;

(b) if the natural or legal person uses partners, suppliers or subcontractors, make arrangements with them to ensure that the competent authority has access and can investigate as described in point (a).

GM1 21L.A.10 Access and investigation

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ARRANGEMENTS

Natural or legal persons that hold or that have applied for a type certificate (TC), a supplemental type certificate (STC), a major repair design approval, a permit to fly, a certificate of airworthiness, a restricted certificate of airworthiness, a noise certificate or a restricted noise certificate, that have declared design compliance, that have declared their design or production capability or that produce aircraft, engines, propellers or parts under Subpart R are required to allow the competent authority to make investigations that include the complete organisation including its partners, subcontractors and suppliers, whether they are in the State of the natural or legal person or not.

The investigations may include audits, enquiries, questions, discussions and explanations, monitoring, witnessing, inspections, checks, flight and ground tests, and inspections of completed products or parts that are either designed or produced.

In order to maintain its confidence in the standards achieved by the natural or legal person, the competent authority may conduct an investigation of a sample product or part and of its associated records, reports and certifications/declarations.

The arrangements are required to enable the natural or legal person to assist the competent authority and cooperate with it in conducting the investigation during the initial assessment and for the subsequent surveillance.

'Cooperation in performing investigations' means the competent authority has been granted full and free access to the facilities and to any information relevant to demonstrating compliance with the Part 21 Light requirements, and has provided assistance as necessary.

'Assistance to the competent authority' includes all the appropriate means regarding the facilities of the natural or legal person to allow the competent authority to conduct the investigation, such as meeting rooms, offices, support personnel, records, documentation, computer data, and communication facilities, all properly and promptly made available as necessary.

The competent authority seeks to have a good working relationship with the natural or legal person, and suitable liaison staff are required to be nominated to facilitate this, including one or more suitable representative(s) to accompany competent authority staff during visits, not only at the natural or legal person's own facilities, but also with subcontractors, partners or suppliers.

21L.A.11 Findings and observations

Regulation (EU) 2022/1358

(a) After the receipt of the notification of findings, the natural or legal person who holds or who has applied for a type certificate, supplemental type certificate, major repair design approval, permit to fly, certificate of airworthiness, restricted certificate of airworthiness, noise certificate or restricted noise certificate, who has declared design compliance, who has declared their design or production capability or who produces aircraft, engines, propellers or parts under Subpart R of this Annex, shall take the following steps within the time period determined by the competent authority in accordance with point (d) or (e) of point 21L.B.21:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;
2. define a corrective action plan and propose it to the competent authority;
3. demonstrate the implementation of the corrective action(s) to the satisfaction of the competent authority.

(b) An observation notified by the competent authority in accordance with point (f) of point 21L.B.21 shall be given due consideration. The natural or legal person shall record the decision taken in respect of those observations.

GM1 21L.A.11(a) Findings and observations

ED Decision 2023/013/R

ROOT-CAUSE ANALYSIS

(a) It is important that the analysis does not primarily focus on establishing who or what caused the non-compliance, but on why it was caused. Establishing the root cause(s) of non-compliance often requires an overarching view of the events and circumstances that led to it, to identify all the possible systemic and contributing factors (human factors (HFs), regulatory, organisational, technical factors, etc.) in addition to the direct factors.

(b) A narrow focus on single events or failures, or the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the non-compliance, may not properly reflect the complexity of the issue and, therefore, there is a risk that important factors that must be considered to prevent reoccurrence will be ignored.

Such an inappropriate or partial root-cause analysis often leads to applying ‘quick fixes’ that only address the symptoms of the non-compliance. A peer review of the results of the root-cause analysis may increase its reliability and objectivity.

AMC1 21L.A.11(a) Findings and observations

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FINDINGS — CORRECTIVE ACTION PLAN AND IMPLEMENTATION

After receipt of notification of findings, the natural or legal person (‘organisation’) should identify and define the action for all findings, to address the effects of the non-compliance, as well as the root cause(s) and contributing factor(s).

Depending on the issues identified, the organisation may need to take immediate corrective action.

The respective corrective action plan should:

— include the rectification of the issue, corrective and preventive action, as well as the planning to implement them; and

— be timely submitted to the competent authority for acceptance before it is effectively implemented.

After receiving the competent authority's acceptance of the corrective action plan, the organisation should implement the associated action.

Within the agreed period, the organisation should inform the competent authority that the corrective action plan has been implemented and should send the associated pieces of evidence, on request from the competent authority.

AMC1 21L.A.11(b) Findings and observations

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DUE CONSIDERATION TO OBSERVATIONS

For each observation that is notified by the competent authority, the natural or legal person ('organisation') should analyse the related issues and determine when action is needed.

The handling of observations may follow a process similar to the handling of findings by the organisation.

The organisation should record the analysis and the related outputs, such as action taken, or the reasons why no action was taken.

21L.A.12 Means of compliance

Regulation (EU) 2022/1358

(a) A legal or natural person may use any alternative means of compliance to the acceptable means of compliance (AMC) to establish compliance with this Regulation.

(b) If a natural or legal person wishes to use an alternative means of compliance, they shall, prior to using it, provide the competent authority with a full description. The description shall include any revisions to manuals or procedures that may be relevant, as well as an explanation indicating how compliance with this Regulation is achieved.

(c) The natural or legal person may use those alternative means of compliance subject to prior approval from the competent authority.

AMC1 21L.A.12(b) Means of compliance

ED Decision 2023/013/R

DESCRIPTION SUPPORTING THE ALTERNATIVE MEANS OF COMPLIANCE (AltMoC)

(a) The description of the AltMoC should include:

(1) a summary of the AltMoC;

(2) the content of the AltMoC;

(3) a statement that compliance with the applicable regulation is achieved; and

(4) in support of that statement, an assessment which demonstrates that the AltMoC reach(es) an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding Agency's AMC.

(b) All these elements that describe the AltMoC are an integral part of the management system records, in accordance with point 21L.A.7.

GM1 21L.A.12 Means of compliance

ED Decision 2023/013/R

GENERAL

(a) Acceptable means of compliance (AMC), as referred to in Article 76(3) of Regulation (EU) 2018/1139[1], are a tool to standardise the demonstration of compliance with, and facilitate the verification activities of the competent authorities in relation to, that Regulation and its delegated and implementing acts. AMC are published by EASA to achieve those objectives. While competent authorities and regulated entities are not legally bound to use the AMC, applying them is recommended.

(b) If an organisation wishes to use other means to comply with Regulation (EU) 2018/1139 and its delegated and implementing acts, which are different from the AMC that are published by EASA, that organisation may need to demonstrate compliance by using AltMoC that are established:

(1) by its competent authority (see GM1 21L.B.24); or

by that organisation and approved by its competent authority (see point (c)).

An AltMoC does not allow deviation from Regulation (EU) 2018/1139 and its delegated or implementing acts.

(c) AltMoC that are established by an organisation and approved by its competent authority

An organisation that wishes to use a different means of compliance than the one published by EASA may propose an AltMoC to the competent authority and use it only once the competent authority has approved it. In that case, the organisation is responsible for demonstrating how that AltMoC establishes compliance with the relevant regulation.

The approval of an AltMoC is granted to the organisation by its competent authority on an individual basis and is restricted to that specific organisation. Other organisations that wish to use the same AltMoC should go through the AltMoC process (i.e. demonstrate how that AltMoC establishes compliance with the relevant regulation) and obtain an individual approval from their competent authority.

GM2 21L.A.12 Means of compliance

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WHEN AN ALTERNATIVE MEANS OF COMPLIANCE (AltMoC) IS REQUIRED

When there is no Agency AMC to a certain point of a given regulation, the means of compliance that are proposed by an organisation to that point do not need to go through the AltMoC process. It is the responsibility of the competent authority to verify that compliance with a given regulation is achieved. However, in certain cases, the organisation may propose, and the competent authority may agree, to have such means of compliance go through the AltMoC process.

[1] Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139).

When there is an Agency AMC, the AltMoC process is required in the following cases (non-exhaustive list):

— an AltMoC to a given regulation is technically different from the AMC that is published by EASA; and

— a form is significantly different from the one that is included in the EASA AMC.

Note: *A form that is required by a delegated or implementing act cannot be modified.*

Examples of issues that are not considered to require the AltMoC process include but are not limited to:

— editorial changes to an Agency AMC, as long as they do not change the intent of the AMC; and

— incorporating an Agency AMC into the organisational structure, organisational processes, or standard operating procedures of an organisation with different wording and terminology that are customised to the organisation's environment if it does not change the intent of the AMC and its associated level of safety.

SUBPART B — TYPE CERTIFICATES

21L.A.21 Scope

Regulation (EU) 2022/1358

This Subpart establishes the procedure for applying for type certificates, and establishes the rights and obligations of the applicants for, and holders of, those certificates for products, when the product is one of the following:

(a) an aeroplane with a maximum take-off mass (MTOM) of 2 000 kg or less with a seating configuration of maximum four persons;

(b) a sailplane or powered sailplane with an MTOM of 2 000 kg or less;

(c) a balloon;

(d) a hot air airship;

(e) a passenger gas airship designed for not more than four persons;

(f) a rotorcraft with an MTOM of 1 200 kg or less with a seating configuration of maximum four persons;

(g) a piston engine and fixed pitch propeller that are intended to be installed on an aircraft referred to in points (a) to (f). In such cases, the type certificate data sheet shall be appropriately annotated to only permit installation of the engine or propeller on such aircraft;

(h) gyroplanes.

GM1 21L.A.21 Scope

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A type certificate (TC) that is issued under Subpart B of Annex I (Part 21) has the same validity as a TC that is issued under Subpart B of Annex Ib (Part 21 Light). However, the eligibility for design organisations is different (e.g. declared design organisations using Subpart J of Annex Ib are permitted to apply for a TC), and also the means of verifying compliance is different.

In addition, the production organisation requirements are also different, and organisations are permitted to become declared production organisations using Subpart G of Annex Ib (Part 21 Light) and produce products and parts within the scope of point 21L.A.21.

As per point 21L.A.23(b), an organisation that holds a design organisation approval (DOA) issued under Subpart J of Annex I (Part 21) meets the eligibility criteria of Subpart B of Annex Ib (Part 21 Light). Such organisations may use the privileges that are granted under that approval (as per points (2), (5) and (8) of point 21.A.263(c) of Annex I (Part 21)) and further described in points 21L.A.69(a) and 21L.A.209(a) of Annex Ib (Part 21 Light).

Furthermore, an organisation that holds a production organisation approval (POA) issued under Subpart G of Annex I (Part 21) is permitted to use that approval to release products and parts within the scope of Subpart B of Annex Ib (Part 21 Light), and use the privileges that are granted under that approval (as per point 21.A.163(b) of Annex I (Part 21)) and further described under points 21L.A.143(c)(1)(ii) and 21L.A.163(c)(1)(i)(C) of Annex Ib (Part 21 Light).

21L.A.22 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person who has demonstrated, or is in the process of demonstrating, their design capability in accordance with point 21L.A.23, may apply for a type certificate under the conditions laid down in this Subpart.

21L.A.23 Demonstration of design capability

Regulation (EU) 2022/1358

An applicant for a type certificate shall demonstrate their design capability by:

(a) holding a design organisation approval with terms of approval that cover the respective category of the product, issued by the Agency in accordance with Subpart J of Section A of Annex I (Part 21); or

(b) declaring their design capability for the type of design work and the category of the product in accordance with Subpart J of this Annex.

GM1 21L.A.23(a) Demonstration of design capability

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TERMS OF APPROVAL COVERING THE RESPECTIVE PRODUCT CATEGORY

If an applicant holds a design organisation approval (DOA) issued under Subpart J of Annex I (Part 21) and it wishes to use this approval to meet the eligibility criteria of point 21L.A.23, that applicant will need to apply for a change to the terms of approval to include the new aircraft type within the list of products.

GM1 21L.A.23(b) Demonstration of design capability

ED Decision 2023/013/R

DECLARATION OF DESIGN CAPABILITY

Organisations that have declared their design capability under Subpart J of Annex Ib (Part 21 Light) should update their declaration of design capability to include the new product type when submitting a new application for a type certificate (see point 21L.A.173 'Scope of work').

21L.A.24 Application for a type certificate

Regulation (EU) 2022/1358

(a) An application for a type certificate shall be made in a form and manner established by the Agency.

(b) An application for a type certificate shall include as a minimum:

1. a justification that the application is within the scope as established in point 21L.A.21;
2. preliminary descriptive data of the product, the intended use, and the kind of operation of the product for which certification is requested;
3. a proposal for the type-certification basis and the applicable environmental protection requirements, prepared in accordance with the requirements and options specified in points 21L.B.43 and 21L.B.45;

4. a compliance demonstration plan detailing the means and methods of compliance that shall be updated by the applicant when there are changes to the certification project that affect points (1) to (3) or any changes to the means and methods of compliance.

(c) An application for a type certificate shall remain valid for 3 years. In case a type certificate has not been issued within this period, a new application shall be made in accordance with points (a) and (b).

AMC1 21L.A.24(a) Application for a type certificate

ED Decision 2023/013/R

FORM AND MANNER

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application form for a type certificate, which may be downloaded from the EASA website.

The form should be completed for a type certificate in accordance with the instructions embedded at the bottom of the application form, and sent to the Agency by fax, email or regular mail following the information provided on the EASA website[2].

AMC1 21L.A.24(b)(4) Application for a type certificate

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COMPLIANCE-DEMONSTRATION PLAN

The compliance-demonstration plan is a document that allows the applicant and EASA to manage and control the evolving product type design, as well as the process of compliance demonstration by the applicant and its verification by EASA when required.

In particular, the following information should typically be expected:

— Identification of the relevant personnel that make decisions affecting airworthiness and environmental protection, and that will interface with EASA during the critical design review prior to the issue of the flight conditions and during the first-article inspection, unless otherwise identified to EASA (e.g. within the design organisation procedures).

— A project schedule, including major milestones.

— Subcontracting arrangements for design, environmental protection and/or production.

As requested under Point 21L.A.24(b)(2), 'preliminary descriptive data of the product, the intended use, and the kind of operation of the product for which certification is requested'

Note: An example of an Aeroplane General Description is provided in ABCD-GD-01-00 – Aeroplane General Description – 17.02.16 – v1 (1)[3].

An overview of the following:

— architecture, functions, systems;

— dimensions, design weights, payloads, design speeds;

[1] https://ap.easa.europa.eu (accessed: 20 October 2023)

[2] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (accessed: 20 October 2023)

[3] https://www.easa.europa.eu/download/general-aviation/documents-guidance-and-examples/ABCD-GD-01-00%20-%20Aeroplane%20General%20Description%20-%2017.02.16%20-%20v1.docx

— engines and power/thrust rating;

— materials and technologies;

— cabin configuration aspects;

— options (e.g. weight variants, power/thrust rating variants, optional avionics equipment items, brake options, tyre options, floats, skids);

— operating speed limitations;

— service ceiling, maximum airfield elevation;

— limit load factors;

— number of passengers, payload, range;

— weight and centre-of-gravity (CG) envelope and fuel loading;

— performance;

— environmental envelope;

— runway surface conditions.

As requested under Point 21L.A.24(b)(3), 'a proposal for the type-certification basis and the applicable environmental protection requirements, prepared in accordance with the requirements and options specified in points 21L.B.43 and 21L.B.45'

The proposed certification basis should include applicable certification specifications, proposed special conditions, proposed equivalent safety findings, as well as a proposed 'elect to comply' and proposed deviations, as applicable.

The applicant should provide detailed information about the proposed means of compliance with the applicable airworthiness and environmental protection requirements identified under point 21L.A.24(b)(3). The information provided should be sufficient for EASA to easily determine the means of compliance used.

This should include the following:

— a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC1 21L.A.24(b) below for the relevant codes), and the related compliance document(s);

— identification of industry standards (Society of Automotive Engineers (SAE), American Society for Testing and Materials (ASTM), European Organisation for Civil Aviation Equipment (EUROCAE), AeroSpace and Defence Industries Association of Europe (ASD), etc.), methodology documents, handbooks, technical procedures, technical documents and specifications specified in the type certificate data sheet, certification memoranda, policy statements, guidance material, etc., that are proposed in the demonstration of compliance;

— when the compliance demonstration involves testing (point 21L.A.25(c) and (d)), a description of the ground- and flight-test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and

— when the compliance demonstration involves analyses/calculations, a description/ identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose; furthermore, the validation and verification of such tools and methods should be addressed.

For every aspect mentioned above, the applicant should clearly identify whether the demonstration of compliance involves any method (analysis or test) which is novel or unusual for the applicant. In addition, the applicant should identify any deviations from the published AMC to the relevant CSs.

Appendix A to AMC1 21L.A.24(b) Means-of-compliance codes

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Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analyses
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	*Note*: Equipment qualification is a process that may include all previous means of compliance at equipment level.

AMC2 21L.A.24(b)(4) Application for a type certificate

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UPDATES TO THE COMPLIANCE-DEMONSTRATION PLAN

It is acceptable to provide an initial compliance-demonstration plan that is not fully complete, e.g. due to schedule constraints of the design, analysis and testing activities.

The applicant should provide information in the compliance-demonstration plan that is provided to EASA about the applicable certification specifications and the environmental protection requirements (e.g. for aircraft noise: in terms of the applicable chapter of Volume I of Annex 16 to the Chicago Convention and the related limits).

Furthermore, even if the initial compliance-demonstration plan is complete, it may be necessary to amend it throughout the duration of the project.

The compliance-demonstration plan should be updated and resubmitted to EASA during the certification project. In particular, updates to the following elements should be provided:

— any complementary information that was not included in the initial compliance-demonstration programme;

— any change that may have an impact on the certification basis or means of compliance;

— any change to the intended use or kind of operation of the product;

— a change to the key characteristics of the product such as but not limited to any declared limits that are intended to be recorded in the type certificate data sheet (TCDS);

— any change to the initial type-certification basis or environmental protection requirements, as applicable to the product, regardless whether the change is initiated by EASA or by the applicant;

— any change to the proposed means of compliance, including its/their methodology;

— any relevant change to the design organisation personnel (and design organisation (DO) suppliers) that are involved in the project; and

— any change to the project schedule affecting planned Agency verification activities under point 21L.B.46.

GM1 21L.A.24(c) Application for a type certificate

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PERIOD OF VALIDITY OF AN APPLICATION FOR A TYPE CERTIFICATE

An extension of the 3-year validity period for the initial application for a type-certificate is not possible.

After the 3-year validity period of the application for a type certificate, the new application made in accordance with points (a) and (b) of point 21L.A.24 will be again valid for a period of 3 years.

21L.A.25 Demonstration of compliance

Regulation (EU) 2022/1358

(a) The applicant for a type certificate shall, following the acceptance of the compliance demonstration plan by the Agency and in accordance with its contents, then:

1. demonstrate compliance with the applicable type-certification basis as established and notified to the applicant by the Agency in accordance with point 21L.B.43;

2. demonstrate compliance with the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with point 21L.B.45; and

3. provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant for a type certificate shall provide the Agency with a recorded justification of the means of compliance within compliance documents according to the compliance demonstration plan.

(c) When carrying out testing and inspections to demonstrate compliance in accordance with point (a), the applicant shall have verified and documented this verification prior to carrying out any test:

1. for each test specimen, that:

(i) the materials and processes adequately conform to the specifications for the proposed type design;

(ii) the constituent parts of the products adequately conform to the drawings in the proposed type design;

(iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and

2. that the test and measuring equipment used for the test were adequate for the test and appropriately calibrated.

(d) The flight testing for the purpose of obtaining a type certificate shall be conducted in accordance with the methods for such flight testing specified by the Agency. The applicant for a type certificate shall make all the flight tests necessary to determine compliance with the applicable type-certification basis. The flight tests shall include a period of operation in a final configuration of a sufficient duration to ensure that there will be no safety issues when the aircraft first enters service.

(e) An applicant for a type certificate shall allow the Agency to:

1. review any data and information related to the demonstration of compliance;

2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance;

3. conduct a physical inspection of the first article of that product in the final configuration to verify the compliance of the design with the type-certification basis and the applicable environmental protection requirements and any other investigation determined in accordance with point 21L.B.46.

(f) Upon the completion of the compliance demonstration, the applicant shall declare to the Agency that:

1. they have demonstrated compliance with the type-certification basis and the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with points 21L.B.43 and 21L.B.45, according to the compliance demonstration plan; and

2. no feature or characteristic has been identified that may make the product unsafe or environmentally incompatible for the uses for which certification is requested.

AMC1 21L.A.25(a);(b) Demonstration of compliance

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COMPLIANCE DOCUMENTATION

(a) Compliance documentation comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable type-certification basis and environmental protection requirements is demonstrated.

(b) Each compliance document should normally contain:

— the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;

— substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

— the appropriate authorised signature.

(c) Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7 'Record-keeping'.

AMC1 21L.A.25(c) Demonstration of compliance

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INSPECTIONS AND TESTS

Proposed type design: this term defines the type design (or the portion of the type design) as it is determined at the time when the testing and inspections are performed.

Verification document (also known as 'statement of conformity'): before each testing and inspection the verification document must confirm that the test specimen conforms with the proposed type design and that the test and measuring equipment is adequate for the test and that the sensors and measuring system are appropriately calibrated.

Conformity of the test specimen: the documented verification is intended to ensure that the manufactured test specimen, even in the presence of non-conformities, adequately represents the proposed type design. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the proposed type design at the time of the test. These are typically identified in the early stage of the testing and inspection planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several existing or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity as early as possible, the applicant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed, justified in the verification document or by cross reference to the test plan or other documents. However, testing for the demonstration compliance with the applicable environmental protection requirements should be conducted in the final design of the product.

Type certification is typically an iterative process in which the design is under continuous evolution. If the type design evolves after the time of the testing and inspections, then the final type design should be checked against the proposed type design (as it was at the time of the testing and inspections), and the differences (if any) should be analysed to ensure that the testing and inspection results are representative of the final configuration. However, such changes made to the type design may lead to the invalidation of the testing and inspection results, and the need to repeat the testing and inspections. It is recommended that the design organisation should have a thorough configuration management process to track the evolving type design.

Conformity of test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

  — type/model of sensors, together with their technical characteristics;

  — position and orientation of exciters and sensors; and

  — electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through certification test plans and supporting documentation, according to the design assurance system, if applicable. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The verification document should confirm that the test and measuring equipment conforms to its purpose, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This can be done either in the verification document or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test specimen, as well as the test and measuring equipment, is considered 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up does not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or masking any potential failure mode or behaviour).

Changes that affect the validity of the verification document: if changes need to be introduced to the test specimen or to the test and measuring equipment after the verification is documented (and before the test is undertaken), then the verification document must be updated. The updated verification document must be made available to EASA before the test if EASA has informed the applicant that it will witness or carry out the tests or inspections.

Development versus certification tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for certification (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21L.A.25(c).

Any planned test event should be classified in advance as either a development test or a certification test. Tests that support the compliance demonstration should be classified as certification tests.

It is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a certification test as long as it meets the requirements of point 21L.A.25(c). For this reason, it is important to keep the configuration of such tests under control.

If the test specimen used for a certification test has already undergone a series of previous tests that may affect or ultimately invalidate its acceptance as required by point 21L.A.25(c), this aspect should

be considered when documenting the verification, and specific analyses or inspections may be required.

Because of the above aspects, EASA advises applicants to inform it if they intend to conduct a campaign of development tests that may eventually be used as certification tests to establish whether EASA would wish to witness the test.

GM1 21L.A.25(d) Demonstration of compliance

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FLIGHT TESTING

Detailed material on flight testing for compliance demonstration is included in the applicable CSs and GM. Information on flight testing for compliance demonstration with the environmental protection requirements especially in terms of aircraft noise may be found in Annex 16 to the Chicago Convention and in ICAO Doc 9501 'Environmental Technical Manual'.

The objective of the period of operation in the final configuration is to expose the aircraft to the variety of uses, including training, that are likely to occur when in routine service to provide an assurance that it performs its intended functions to the standard required for certification and should continue to do so in service. The flight tests should include a range of representative ambient operating conditions and airfields.

This period of operation may fully overlap with the compliance-demonstration flight testing if it can be demonstrated that the above criteria are met.

The duration of this period as well as the approach selected (i.e. use of compliance-demonstration flights or extending the period of operation) should be proposed in the compliance-demonstration plan.

The flight testing should cover both routine operations and some simulation of abnormal conditions. The details of the programme should be agreed with EASA prior to commencement of the testing.

It may be possible to combine this testing with any testing required to demonstrate compliance with the applicable CSs. This will be agreed on a case-by-case basis with EASA.

A substantial proportion of the flying should be on a single aircraft (and, if applicable, a combination of engine and propeller). The flying should be carried out to a continuous schedule on an aircraft that is very close to the final type design, operated as though it were in service and should include a range of representative ambient operating conditions and airfields.

AMC1 21L.A.25(e)(1) Demonstration of compliance

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REVIEW OF DATA AND INFORMATION RELATED TO THE DEMONSTRATION OF COMPLIANCE

Availability of compliance data (see point 21L.A.25(e)): data and information required to be provided by the applicant should be made available to EASA in a reliable and efficient way as agreed by EASA.

AMC1 21L.A.25(e)(2) Demonstration of compliance

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TESTS AND INSPECTIONS

The applicant should inform EASA sufficiently in advance about the execution of tests and inspections that:

1. are used for compliance-demonstration purposes; and
2. have been identified as being of particular interest to EASA during the review and approval of the compliance-demonstration plan

in order to permit EASA the opportunity to witness or carry out these inspections or tests.

The applicant may propose to EASA to witness or carry out flight or other tests of particular aspects of the product during its development and before the type design is fully defined.

However, in case of flight tests, the applicant should perform the tests before EASA witnesses or performs them to ensure that no features of the product preclude the safe conduct of the evaluation requested. The Agency may require any such tests to be repeated once the type design is fully defined to ensure that subsequent changes have not adversely affected the conclusions from any earlier evaluation.

A verification document as per point 21L.A.25(c) is required for the above tests.

AMC1 21L.A.25(e)(3) Demonstration of compliance

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PHYSICAL INSPECTION OF THE FIRST ARTICLE

Note: The applicant should be prepared for any additional investigations as notified by EASA according to point 21L.B.46(d).

1. Purpose

The purposes of the first-article inspection (of the article that is in conformance with the proposed type design for certification) prior to the issuance of the type certificate for a particular aircraft, propeller or engine design are the following:

a. for EASA to verify completion of the demonstration-of-compliance activities conducted by the applicant under point 21L.A.25 and in accordance with the approved compliance-demonstration plan;

b. for EASA to verify[1] that the type design complies with the type-certification basis and the applicable environmental protection requirements;

c. In case the applicant is a declared design organisation, for EASA to conduct a further oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the applicant is able to discharge its obligations.

[1] The verification of compliance is limited to the scope of the activities that can be conducted under point 2 and the elements of the design that are selected for review based upon a risk-based approach to compliance.

2. Methodology and evidence

The first-article inspection will be conducted by EASA at an appropriate location(s) selected by the applicant for a type certificate. This (these) location(s) should:

— include the physical location of the aircraft, engine or propeller for which a type certificate has been requested; and

— be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

Note: The principal place of business is defined as follows: 'The head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised.'

The Agency will conduct a physical inspection of the aircraft, engine or propeller for which a type certificate has been requested. This inspection, along with any other activity that EASA deems necessary (see point 21L.A.25(e)), should ensure that the objectives mentioned in point 1 are met.

The applicant for a type certificate should make the following arrangements to support the first-article inspection:

a. prepare the aircraft engine, propeller, systems or components for live testing (including flight testing) upon EASA's request;

b. make available the final version of the compliance-demonstration plan;

c. make available the declaration of compliance for the product (aircraft, engine and/or propeller);

d. provide access to the supporting compliance documentation and test reports;

e. provide access to key design and production personnel;

f. make available any design processes and procedures that were used.

When the applicant has selected to use flight testing to demonstrate compliance (see MC6 in Appendix A to AMC1 21L.A.24(b)), EASA may decide to conduct flight testing to verify compliance. This flight testing will be performed according to a plan proposed by the applicant prior to the first-article inspection and agreed by EASA.

The above list of additional sources of evidence is not exhaustive.

It is possible that during the first-article inspection, EASA may discover evidence that:

a. the design is not in compliance with the type-certification basis or the applicable environmental protection requirements (this could be due to the applicant misinterpreting or misunderstanding the applicable design requirements);

b. the applicant has not fulfilled its design obligations as a declared design organisation;

c. there are shortfalls in the applicant's design management system (in accordance with point 21.A.239 or point 21L.A.174) that result in a non-compliance or loss of control of the design.

If such evidence is discovered, the applicant should support EASA in conducting a more in-depth investigation into the compliance documentation and/or the design practices of the design organisation. The purpose of this in-depth investigation should be to determine whether or not compliance was demonstrated, the root cause and the corrective actions. This investigation should also serve to prevent a reoccurrence of the issue.

3. Aircraft condition and configuration

The aircraft, engine or propeller presented to EASA should be in the final configuration for which a type certificate has been requested and the compliance demonstration has been declared.

The applicant may arrange visits with EASA prior to the declaration of compliance, in accordance with point 21L.A.25(f) (for example, for noise testing).

Any differences between the configuration presented to EASA for the first-article inspection and the final configuration in the declaration of compliance (in accordance with point 21L.A.25(f)) should be justified by the applicant and may, therefore, depending upon their criticality, be subject to more focused scrutiny during the first-article inspection. It is possible that some differences from the final configuration may delay the issuance of the type certificate.

4. Findings and resolution

In the process of the activities mentioned in point 2, EASA will raise an appropriate finding or observation against the aircraft or declared design organisation if a non-compliance is discovered. Findings of non-compliance should be resolved by the applicant before the type certificate is issued.

5. Duration and schedule

The first-article inspection may be a single visit or multiple visits depending on the complexity of the design. For example, EASA may wish to witness or participate to compliance-demonstration testing (for example, noise testing) prior to the first-article inspection.

The applicant should coordinate with the competent authority so that the first-article-inspection activities conducted under point 21L.B.143(b) are conducted as far as practicable at the same time as first-article-inspection activities conducted under point 21L.B.46(c).

GM1 21L.A.25(f) Demonstration of compliance

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DECLARATION OF COMPLIANCE

All compliance-demonstration activities conducted in accordance with the compliance-demonstration plan, including all the testing and inspections conducted in accordance with point 21L.A.25(c) and all flight testing conducted in accordance with point 21L.A.25(d) and those necessary to determine compliance with the applicable environmental protection requirements should be completed before the issuance of the final declaration of compliance.

'No feature or characteristic' that may make the product unsafe in point 21L.A.25(f)(2) means the following: while every effort is made to address in the applicable certification basis all the risks to product safety that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant should declare that it has not identified any such features or characteristics.

'No feature or characteristic' that may make the product environmentally incompatible (point 21L.A.25(f)(2)):

It is assumed that environmental compatibility is demonstrated when the product complies with the applicable environmental protection requirements. Therefore, the applicant, when declaring that the aircraft complies with the applicable environmental protection requirements under point 21L.A.25(f)(1), shall also declare that they have not identified any such feature or characteristic.

21L.A.26 Type design

Regulation (EU) 2022/1358

The applicant for a type certificate shall define the product type design to enable its unique and unambiguous identification, consisting of:

(a) drawings and specifications and a listing of those drawings and specifications that are necessary to define the configuration and the design features of the product;

(b) information on the materials and processes used;

(c) information on the methods of manufacture and assembly;

(d) any airworthiness limitations;

(e) the environmental compatibility requirements; and

(f) any other data allowing by comparison the determination of the airworthiness, and, if relevant, the environmental compatibility of later products of the same type.

21L.A.27 Requirements for the issuance of a type certificate

Regulation (EU) 2022/1358

In order to be issued with a type certificate, the applicant shall:

(a) demonstrate their design capability in accordance with point 21L.A.23;

(b) demonstrate the compliance of the design in accordance with point 21L.A.25;

(c) demonstrate, for aircraft type certificates, that the engine or propeller, or both, if installed on the aircraft, have either:

1. a type certificate issued or determined in accordance with Annex I (Part 21) or issued in accordance with this Annex; or

2. been included within the application for the aircraft type certificate and the applicant has ensured the compliance of the engine and propeller during the compliance demonstration in point 21L.A.25;

(d) demonstrate that there are no unresolved issues from the physical inspection of the first article of that product in the final configuration or any other investigation carried out by the Agency in accordance with points (c) and (d) of point 21L.B.46.

GM1 21L.A.27(c)(1) Requirements for the issuance of a type certificate

ED Decision 2023/013/R

CLARIFICATION OF THE TERM 'DETERMINE'

A type certificate 'determined' in accordance with Part 21 Light means a type certificate or a document that allows the issuance of a certificate of airworthiness issued before 28 September 2003 by a Member State that complies with Article 3(1)(a) of Regulation (EU) No 748/2012.

AMC1 21L.A.27(d) Requirements for the issuance of a type certificate

ED Decision 2023/013/R

DEMONSTRATION OF NO UNRESOLVED ISSUES

After the physical inspection and investigation carried out by EASA in accordance with points 21L.A.46(c) and (d), and upon notification from EASA in accordance with point 21L.B.46(d), the applicant should carry out the necessary actions, such as:

— redesign,

— retesting,

— additional compliance-demonstration activities,

— corrections and updates to compliance-demonstration documents

to ensure that no unresolved issues remain.

When any findings from the first-article inspection are resolved by the applicant to the satisfaction of EASA or no findings are raised by EASA or the competent authority, then point 21L.A.27(d) will be considered met.

21L.A.28 Obligations of a type-certificate holder

Regulation (EU) 2022/1358

The holder of a type certificate shall undertake the obligations of a type-certificate holder set forth in Subpart A of this Annex and shall continue to comply with the eligibility requirement under point 21L.A.22.

21L.A.29 Transferability of a type certificate

Regulation (EU) 2022/1358

A type certificate may be transferred to a new holder, provided that the Agency has verified, in accordance with point 21L.B.49, that the natural or legal person to whom the type certificate is intended to be transferred is eligible in accordance with point 21L.A.22 to hold a type certificate and is able to undertake the obligations of a type-certificate holder under point 21L.A.28. The holder of the type certificate or the natural or legal person who wishes to adopt the certificate shall apply to the Agency to verify whether these conditions are complied with, in a form and manner established by the Agency.

AMC1 21L.A.29 Transferability of a type certificate

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The applicant should file an application using the form for the transfer of a certificate (FO.CERT.00038), which may be downloaded from the EASA website[1].

This form should be completed in accordance with the instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[2].

21L.A.30 Continued validity of a type certificate

Regulation (EU) 2022/1358

(a) A type certificate shall remain valid as long as:

1. the type certificate is not surrendered by the holder;
2. the holder of the type certificate remains in compliance with the relevant requirements of Regulation (EU) 2018/1139 andthe delegated and implementing acts adopted on the basis thereof, taking into account the provisions related to the handling of findings as specified under point 21L.B.21;
3. the type certificate is not revoked by the Agency in accordance with point 21L.B.22.

(b) Upon surrender or revocation, the type certificate shall be returned to the Agency.

[1] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (accessed: 20 October 2023)

[2] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (accessed: 20 October 2023)

SUBPART C — DECLARATIONS OF AIRCRAFT DESIGN COMPLIANCE

21L.A.41 Scope

Regulation (EU) 2022/1358

(a) This Subpart establishes the procedure for declaring the design compliance of aircraft, and establishes the rights and obligations of the persons making such declarations.

(b) This Subpart applies to the following categories of aircraft, provided that the design of the aircraft does not include novel or unusual design features:

1. an aeroplane with a maximum take-off mass (MTOM) of 1 200 kg or less that is not jet-powered, and has a seating configuration of maximum two persons;
2. a sailplane or powered sailplane with an MTOM of 1 200 kg or less;
3. a balloon designed for not more than four persons;
4. a hot air airship designed for not more than four persons.

(c) For the purpose of this Subpart, a design feature shall be considered to be novel or unusual if at the time that the declaration of design compliance is made, that design feature is not covered by the detailed technical specifications established and made available by the Agency in accordance with point 21L.B.61.

21L.A.42 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person may declare the compliance of an aircraft design under the conditions laid down in this Subpart.

21L.A.43 Declaration of design compliance

Regulation (EU) 2022/1358

(a) Prior to producing an aircraft or agreeing with a production organisation to produce an aircraft, a natural or legal person who designs that aircraft shall declare that its design complies with the applicable detailed technical specifications and the applicable environmental protection requirements referred to in point 21L.A.45.

(b) The declaration shall be made in a form and manner established by the Agency and shall contain at least the following information:

1. the name of the person submitting the declaration, and their address/place of business;
2. a unique reference for identifying the aircraft;
3. indication of the applicable detailed technical specifications and the applicable environmental protection requirements according to point 21L.A.45 with which the declarant declares compliance;
4. a signed statement made under the sole responsibility of the person making the declaration that the design of the aircraft, and if applicable the engine or propeller, is in compliance with the applicable detailed technical specifications and the applicable environmental protection requirements referred to in point 3, according to the compliance demonstration plan referred to in point (c) (3);

5. a signed statement made under the sole responsibility of the person making the declaration that no features or characteristics have been identified by that person that may make the aircraft unsafe or environmentally incompatible for the intended use;

6. a signed commitment that the person making the declaration will undertake the obligations referred to in point 21L.A.47;

7. if the aircraft design covered by the declaration includes an engine or propeller:

   (i) a reference to the engine or propeller type certificate issued or determined in accordance with Annex I (Part 21) or issued in accordance with this Annex; or

   (ii) in the case of piston engines and fixed pitch propellers, a statement that the declaration of design compliance of the aircraft covers the compliance of the engine or propeller with the applicable engine or propeller technical specifications;

8. the instructions for continued airworthiness;

9. the operating limitations;

10. the data sheet for airworthiness and, if applicable, emissions;

11. the data sheet for noise, if applicable;

12. any other conditions or limitations prescribed for the aircraft, and if applicable the engine or propeller, in the applicable detailed technical specifications and the applicable environmental protection requirements with which the declarant declares compliance.

(c) The declarant shall submit the declaration of design compliance referred to in point (b) to the Agency. Together with this declaration, the declarant shall provide to the Agency:

1. a drawing of the aircraft;

2. a detailed description of the aircraft design, including all the configurations covered by the declaration, the operating characteristics, design features and any limitations;

3. a compliance demonstration plan detailing the means by which compliance with the applicable detailed technical specifications and the applicable environmental protection requirements has been demonstrated during compliance demonstration;

4. recorded justifications of compliance obtained from the compliance activities that have been conducted according to the compliance demonstration plan;

5. where compliance is demonstrated by carrying out tests, recorded justification of the conformity of the test articles and equipment, demonstrating:

   (i) for the test specimen, that:

      (A) the materials and processes adequately conformed to the specifications for the design;

      (B) the constituent parts of the products adequately conformed to the drawings in the design; and

      (C) the manufacturing processes, construction and assembly adequately conformed to those specified in the design;

   (ii) that the test and measuring equipment used for the test were adequate for the test and appropriately calibrated;

6. reports, results of inspections or tests that the declarant found necessary to determine that the aircraft, and if applicable the engine or propeller, complies with the applicable detailed technical specifications and the applicable environmental protection requirements.

AMC1 21L.A.43(b) Declaration of design compliance

ED Decision 2023/013/R

FORM AND MANNER

The request for registration should be completed as well as the declaration of design compliance which can be found on the EASA Website and sent to EASA by email or regular mail following the information provided on the EASA website[1].

An 'EASA project' will be initiated by EASA in order to provide the declarant with a means to provide the required supporting documentation to EASA.

EASA Form 200

PART 2 – DECLARATION OF DESIGN COMPLIANCE

1. Request for Registration of a Declaration of Design Compliance (Part 21 Light Subpart C)		
1.1 EASA Request No	**6XXXXX**	
1.2 Date of Request for Registration		
1.3 Applicability	Designated Type Name (this must be a unique means to identify the aircraft)	
	Designated Model Name(s)	
Important Note: Points 1.1. and 1.2. should be left blank when the Declaration of Design Compliance (EASA Form 200 – Part 2) is submitted together with the request for registration.		

2. Design Compliance	
2.1 Technical Specifications used for Compliance	Please specify the technical specifications used and the amendment/issue number (e.g. CS-23 Amendment 6)
2.2 Environmental Protection Requirements if applicable	Please specify the environmental protection requirements with which compliance has been determined

[1] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (accessed: 20 October 2023)

2.3 Engine Details if applicable	☐ Engine has been issued with an EASA type certificate	Please provide the EASA type-certificate number and engine details
	☐ Compliance of the engine with the applicable technical specifications (as detailed in 2.1 above) has been declared within this Declaration	
2.4 Propeller Details if applicable	☐ Propeller has been issued with an EASA type certificate	Please provide the EASA type-certificate number and propeller details
	☐ Compliance of the propeller with the applicable technical specifications (as detailed in 2.1 above) has been declared within this Declaration	
2.5 Compliance Demonstration Plan	Please specify the reference, revision number and date of the compliance demonstration plan	
2.6 Documentation in accordance with 21L.A.43 (b)	Documents/information to submit for registration of the Declaration: • Airworthiness Data Sheet • Aircraft Flight Manual including any limitations • Instructions for Continued Airworthiness • Any other conditions/limitations which the declarant wishes to declare • EASA Noise Record Number	

Important Note: The Declaration of Design Compliance for the aircraft described in point 1.3 must be submitted along with the documentation detailed in point 21L.A.43 (b) 8, 9, 10, 11 and 12 and 21L.A.43 (c) of Annex Ib to Regulation (EU) 748/2012.

The supporting documents to the Declaration of Design Compliance can be provided to the Agency using the EASA data repository and do not need to be physically attached to the Declaration of Design Compliance.

3. Declaration of Compliance

I declare that I have the legal capacity to submit this declaration to EASA and that all information provided in this Declaration form is correct and complete.

I hereby declare that the design of the aircraft identified in Section 1.3 is in compliance with the applicable detailed technical specifications detailed in Section 2.1 and the applicable environmental protection requirements detailed in Section 2.2 in accordance with the compliance demonstration plan detailed in Section 2.5.

☐ *(in the case that the engine is not issued with an EASA type certificate)* The engine that is included within the design of the aircraft is compliant with the applicable technical specifications detailed in Section 2.1.

☐ *(in the case that the propeller is not issued with an EASA type certificate)* The propeller that is included within the design of the aircraft is compliant with the applicable technical specifications detailed in Section 2.1. I hereby declare that no features or characteristics have been identified that may make the aircraft unsafe or environmentally incompatible for the intended use. I hereby commit to undertake the obligations of a Declarant of a Declaration of Design Compliance as detailed in point 21L.A.47 of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012. I declare that I have provided the information required in Section 2.6, and that it is accurate and complete and indicated where it is not applicable.

Date/Location	Name	Signature

Important Note: EASA cannot accept Declarations without signature. Please make sure that you sign the Declaration.

This Declaration should be sent by email to:

applicant.services@easa.europa.eu

GM1 21L.A.43(b)(10) Declaration of design compliance

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DATA SHEET FOR AIRWORTHINESS (point 21L.A.43(b)(10))

Templates for the data sheet for airworthiness for aeroplanes, sailplanes and balloons can be requested from the nominated EASA focal point for the project.

AMC1 21L.A.43(b)(11) Declaration of design compliance

ED Decision 2023/013/R

DATA SHEET FOR NOISE

The required noise data for the data sheet for noise (as required by point 21L.A.43(b)(11)) should be provided by the declarant using the EASA's Part 21 Light database of declared noise levels. The declarant should submit a request to EASA for an account to access EASA's Part 21 Light database prior to submitting the declaration of design compliance.

All applicable fields in EASA's Part 21 Light database of declared noise levels should be completed by the declarant before EASA may check the provided noise data. After a reasonability and completeness check, EASA will publish the declared data in the database. This data will be utilised to support the registration of the declaration of design compliance under point 21L.B.63.

The noise data that is provided in EASA's Part 21 Light database of declared noise levels by the declarant is under the sole responsibility of the declarant of the declaration of design compliance.

The individual records in the published version of EASA's Part 21 Light database of declared noise levels are considered 'data sheet for noise'.

It is important that the declarant uses EASA's Part 21 Light database of declared noise levels to ensure that the declared noise levels and supporting data are made available to the competent authority for the issuance of a restricted noise certificate under point 21L.B.172. Otherwise, the competent authority may not be able to issue such a certificate.

GM1 21L.A.43(b)(4);(b)(5) Declaration of design compliance

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SIGNED STATEMENTS

All compliance-demonstration activities conducted in accordance with the compliance-demonstration plan, including all the inspections and tests and all flight tests conducted in accordance with point 21L.A.44, should be completed before signing the statements required in points (4) and (5) of point 21L.A.43(b).

'No feature or characteristic' that may make the aircraft unsafe in point 21L.A.43(b)(5) means the following: while every effort is made to address in the applicable detailed technical specifications all the risks to product safety that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the applicable detailed technical specifications is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the applicable detailed technical specifications. Therefore, the declarant should declare that they have not identified any such features or characteristics.

'No features or characteristics' that may make the aircraft environmentally incompatible (point 21L.A.43(b)(5)):

It is assumed that environmental compatibility is demonstrated when the aircraft complies with the applicable environmental protection requirements. Therefore, the declarant when declaring that the aircraft complies with the applicable environmental protection requirements under point 21L.A.43(b)(4), shall also declare that they have not identified any such features or characteristics.

GM1 21L.A.43(c) Information to be provided to the Agency

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The documents and information that are required to be provided to EASA under point 21L.A.43(c) may be provided to EASA by the declarant in advance of the submission of the declaration of design compliance. This would be advantageous for the declarant to facilitate EASA's investigations prior to the issuance of the flight conditions for a permit to fly under point 21L.B.242(a)(2) and the first-article inspection under AMC 21L.A.47(a).

If so requested, EASA may provide the declarant with an appropriate account for EASA's document management system (for example, SEPIAC) with which the declarant may provide the documents and information listed in point 21L.A.43(c). This would also include the data related to compliance with the environmental protection requirements for noise that is required to be provided under point 21L.A.43(b)(11) which can be facilitated by requesting access to EASA's Part 21 Light database of declared noise levels (see AMC1 21L.A.43(b)). Such data will be required to enable the competent authority to issue a restricted noise certificate under point 21L.B.172(b).

AMC1 21L.A.43(c) Declaration of design compliance

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Data and information required to be provided by the declarant should be made available to EASA in a reliable and efficient way as agreed by EASA.

21L.A.44 Compliance activities for a declaration of design compliance

Regulation (EU) 2022/1358

Prior to making a declaration of design compliance in accordance with point 21L.A.43, the declarant responsible for design of that aircraft shall, for that specific aircraft design:

(a) establish a compliance demonstration plan detailing the means for compliance demonstration that shall be followed during the compliance demonstration. This document shall be updated as necessary;

(b) record the justification of compliance within compliance documents according to the compliance demonstration plan;

(c) perform testing and inspections as necessary in accordance with the compliance demonstration plan;

(d) ensure and record the conformity of the test articles and equipment and ensure that the test specimen conforms to the specifications, drawings, manufacturing processes, construction and assembly means in the design;

(e) ensure that the test and measuring equipment to be used for testing are adequate for testing and appropriately calibrated;

(f) allow the Agency to conduct or participate in any inspections or tests of aircraft in the final or suitably mature design and production configuration that are necessary to determine that the product has no feature or characteristic that makes the aircraft unsafe or environmentally incompatible for the intended use;

(g) carry out flight testing, in accordance with the methods for such flight testing specified by the Agency, to determine whether the aircraft complies with the applicable detailed technical specifications and the applicable environmental protection requirements. The flight testing shall include a period of operation in the final configuration of a sufficient duration to ensure that there will be no safety issues when the aircraft first enters service.

GM1 21L.A.44 Compliance activities for a declaration of design compliance

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VOLUNTARY INVOLVEMENT OF THE AGENCY PRIOR TO THE SUBMISSION OF THE DECLARATION

The declarant may choose to involve EASA prior to submitting the declaration of design compliance. This would allow EASA to:

(a) check that the product is within the scope of Subpart C;

(b) provide guidance on the completeness of the compliance-demonstration plan and the selection of the means of compliance;

(c) provide guidance on the selection of the applicable detailed technical specifications and applicable noise requirements;

(d) provide guidance about and witnessing and participating to noise tests;

(e) avoid any issues or delays during the first-article inspection (after submission of the declaration of design compliance).

The initiation of the project by the declarant by submitting a request to EASA may occur before starting the compliance activities or during those activities. The assignment of a dedicated project number would facilitate any subsequent communication with EASA. This will facilitate the provision of compliance documentation required by point 21L.A.43(c) which can be provided by the declarant to EASA at key stages in the compliance demonstration prior to submission of the declaration of design compliance.

The declarant should also request access to EASA's Part 21 Light database of declared noise levels referring to the given Agency project number[1] in order to provide the required data under point 21L.A.43(b)(11) (see AMC1 21L.A.43(b)).

In accordance with point 21L.B.61, the environmental protection requirements are defined in Regulation (EU) 2018/1139 to be those contained in Annex 16 to the Chicago Convention. As regards aircraft noise, noise testing is generally conducted making use of technical and equivalent procedures that are described in ICAO Doc 9501 'Environmental Technical Manual', Volume I 'Procedures for the Noise Certification of Aircraft'. The use of such procedures demands a deeper knowledge of the environmental protection requirements. In case of doubt and to minimise the risk of any re-test after the first-article inspection, the declarant is encouraged to contact EASA well before the noise flight test.

AMC1 21L.A.44(a) Compliance activities for a declaration of design compliance

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COMPLIANCE-DEMONSTRATION PLAN

The compliance-demonstration plan is a document that allows the declarant to manage and control the evolving aircraft design, as well as the process of compliance demonstration that enables EASA to investigate the root cause(s) in the event of a safety issue being discovered.

In particular, the following information should typically be expected:

— Identification of the relevant personnel that make decisions affecting airworthiness and environmental compatibility, and that will interface with EASA during the physical inspection (safety review) prior to the issuance of the flight conditions and during the first-article inspection.

— A project schedule, including major milestones.

— Subcontracting arrangements for design, environmental compatibility and/or production.

Point 21L.A.43(c)(2) 'Configurations covered by the declaration'

[1] The access to the Agency's Part 21 Light database of declared noise levels will be granted when the declarant initiates their first Part 21 Light declared project at EASA. Access to this database will also enable the declarant to use this database for future projects.

An overview of the following:

— architecture, functions, systems;

— dimensions, design weights, payloads, design speeds;

— engines and power/thrust rating;

— materials and technologies;

— cabin configuration aspects;

— options (e.g. weight variants, power/thrust rating variants, optional avionics equipment items, brake options, tyre options, floats, skids).

Point 21L.A.43(c)(2) 'Operating characteristics and limitations'

— operating speed limitations;

— service ceiling, maximum airfield elevation;

— limit load factors;

— number of passengers, payload, range;

— weight and centre-of-gravity (CG) envelope and fuel loading;

— performance;

— environmental envelope;

— runway surface conditions;

— other items, if considered to be more appropriate, that address the specific aeronautical product.

The declarant should provide detailed information about the means of compliance with the applicable requirements identified under point 21L.A.45. This should include the following:

— a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC1 21L.A.44(a) below for the relevant codes), and the related compliance document(s);

— identification of industry standards, methodology documents, handbooks and any other acceptable means of compliance, specified in the airworthiness data sheet, that have been followed in the demonstration of compliance;

— identification of methodologies and procedures laid down in Annex 16 to the Chicago Convention that have or will be followed in the demonstration of compliance with the applicable environmental protection requirements;

— when the compliance demonstration involves testing, a description of the ground-and flight-test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and

— when the compliance demonstration involves analyses/calculations, a description/ identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose.

For every aspect related to airworthiness compliance mentioned above, the declarant should clearly identify whether the demonstration of compliance involves different means than those contained in the published AMC to the relevant CSs and any method (analysis or test) which is novel or unusual for the declarant.

For every aspect related to compliance with the applicable environmental protection requirements mentioned above, the declarant should clearly identify whether the demonstration of compliance involves means that are described in ICAO Doc 9501 'Environmental Technical Manual'.

Appendix A to AMC1 21L.A.44(a) Compliance activities for a declaration of design compliance

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MEANS-OF-COMPLIANCE CODES

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analysis
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	Note: Equipment qualification is a process that may include all previous means of compliance at equipment level.

GM1 21L.A.44(a) Compliance activities for a declaration of design compliance

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UPDATES TO THE COMPLIANCE-DEMONSTRATION PLAN

The initial compliance-demonstration plan may not be fully complete, e.g. due to schedule constraints of the design, analysis and testing activities.

Furthermore, even if the initial compliance-demonstration plan is complete, it may be necessary to amend it throughout the duration of the compliance-demonstration activities.

In particular, updates to the following elements should be conducted by the declarant:

— any complementary information that was not included in the initial compliance-demonstration plan;

— any change to the intended use or kind of operation of the product;

— a change to the key characteristics of the product such as but not limited to any declared limits that are intended to be recorded in the airworthiness data sheet and noise data sheet;

— any change to the initial detailed technical specifications or environmental protection requirements, as applicable to the product;

— any change to the proposed means of compliance, including the related methodology;

— any changes to the schedule that impacts on the first-article inspection.

The declarant should submit an updated and final version of the compliance-demonstration plan when submitting the declaration of design compliance to EASA (point 21L.A.43(c)(3)).

If a declarant has chosen to involve EASA prior to the declaration (GM1 21L.A.44) and has already submitted a preliminary version of the compliance-demonstration plan to EASA, they should resubmit the updated and final version of it.

AMC1 21L.A.44(b) Compliance activities for a declaration of design compliance

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COMPLIANCE DOCUMENTATION

1. Compliance documentation comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable detailed technical specifications and environmental protection requirements has been demonstrated.

2. Each compliance document should normally contain:

    — the reference of the detailed technical specifications or environmental protection requirements addressed by the document;

    — substantiation data demonstrating compliance (except test or inspection programmes/ plans);

    — a statement by the declarant declaring that the document provides the proof of compliance for which it has been created; and

    — the declarant's signature.

3. Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7 'Record-keeping'.

AMC1 21L.A.44(c);(d);(e) Compliance activities for a declaration of design compliance

ED Decision 2023/013/R

INSPECTIONS AND TESTS

In accordance with point 21L.A.44(d), the declarant should address the conformity of the test specimen as well as of the test and measuring equipment.

Conformity of the test specimen

The recorded justification of the conformity of the test articles is intended to ensure that the manufactured test specimen adequately represents the declared applicable design data. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the originally intended design data at the time of the test. These are typically identified in the early stage of the test planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several existing or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity as early as possible, the declarant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed and justified by cross reference to the test plan or other documents. However, testing for the demonstration of compliance with the environmental protection requirements should be conducted with the final design of the product.

Compliance demonstration is typically an iterative process in which the design is under continuous evolution. If the aircraft design evolves after the time of the inspection or test, then the final aircraft design should be checked against the originally intended design (as it was at the time of the inspection or test), and the differences (if any) should be analysed to ensure that the inspection or test results are representative of the final configuration. However, such changes made to the aircraft design may lead to the invalidation of the inspection or test results and the need to repeat the inspection or test. It is recommended that the declarant should have a thorough configuration management process to track the evolving aircraft design.

Conformity of the test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

  — type/model of sensors, together with their technical characteristics;

  — position and orientation of exciters and sensors; and

  — electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through test plans and supporting documentation. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The declarant should confirm that the test and measuring equipment conform to its definition in the test plan, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This can be done either in the recorded justification of the conformity of the test articles and equipment or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test and measuring equipment is considered 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up do not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or by masking any potential failure mode or behaviour).

Changes that affect the validity of the recorded justification of the conformity of the test articles and equipment: if changes need to be introduced to the test specimen or to the test and measurement equipment after the justification has been recorded (and before the test is undertaken), then it must be updated.

Development versus compliance-demonstration tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for demonstration of compliance (known as development tests), are performed as part of a risk-control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21L.A.44(d) and (e).

Any planned test event should be classified in advance as either a development test or a compliance-demonstration test.

It is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a compliance-demonstration test as long as it meets the requirements of point 21L.A.44(d) and (e). For this reason, it is important to keep the configuration of such tests under control.

If the test specimen used for a compliance-demonstration test has already undergone a series of previous tests that may affect or ultimately invalidate its validity due to potential non-conformity to point 21L.A.44(d) as required by point 21L.A.43(c)(5), this aspect should be considered when justifying the conformity, and specific analyses or inspections may be required to support such a statement.

Because of the above aspects, declarants may wish to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as demonstration of compliance tests to establish whether EASA would wish to witness the test.

GM1 21L.A.44(f) Compliance activities for a declaration of design compliance

ED Decision 2023/013/R

INSPECTIONS AND TESTS PERFORMED BY THE AGENCY

The declarant should inform EASA sufficiently in advance about the execution of significant inspections and tests that are used for compliance-demonstration purposes in order to permit EASA the opportunity to perform or witness these inspections or tests in advance of the first-article inspection required by point 21L.A.47(a).

This would be advantageous for the declarant to avoid any issues or delays during the physical inspection (safety review) for the flight-conditions approval and during the first-article inspection.

Additionally, the declarant may propose to EASA to perform or witness flight or other tests of particular aspects of the product during its development and before the type design is fully defined. However, before EASA performs or witnesses any flight test, the declarant should first perform these tests and should ensure that no features of the product preclude the safe conduct of the evaluation requested.

A recorded justification of the conformity of the test articles and equipment as per point 21L.A.43(c)(5) is required for the above tests.

The declarant should inform EASA of its intent to conduct demonstration-of-compliance testing for the environmental protection requirements for noise in order to provide EASA with the opportunity to witness and participate to the testing. This will ensure that there are no unforeseen issues with the registration of the declaration of design compliance after the first-article inspection.

GM1 21L.A.44(g) Compliance activities for a declaration of design compliance

ED Decision 2023/013/R

FLIGHT TESTING TO ENSURE NO SAFETY ISSUES EXIST WHEN AN AIRCRAFT ENTERS INTO SERVICE

The objective of the period of operation in the final configuration is to expose the aircraft to the variety of uses, including training, that are likely to occur when in routine service to provide an assurance that it performs its intended functions without safety issues and should continue to do so in service.

The testing should cover typical routine operations and also some simulation of abnormal conditions.

It may be possible to combine flight testing with the testing required to demonstrate compliance with the applicable detailed technical specifications and environmental protection requirements.

A substantial proportion of the flying should be on a single aircraft. The flying should be carried out to a continuous schedule on an aircraft that is very close to the final type design, operated as though it were in service and should include a range of representative ambient operating conditions and airfields.

GM2 21L.A.44(g) Compliance activities for a declaration of design compliance

ED Decision 2023/013/R

FLIGHT TESTING TO ENSURE NO ENVIRONMENTAL COMPATABILITY ISSUES EXIST WHEN AN AIRCRAFT ENTERS INTO SERVICE

The objective of noise flight tests is to establish the environmental performance of the product that occurs during the in-service operation and to confirm that the aircraft is environmentally compatible in terms of aircraft noise.

21L.A.45 Detailed technical specifications and environmental protection requirements that are applicable to aircraft subject to declarations of design compliance

Regulation (EU) 2022/1358

The declarant shall demonstrate the compliance of the aircraft design with the detailed technical specifications and the applicable environmental protection requirements referred to in point 21L.B.61, which are applicable to that aircraft and which are effective on the date on which the declaration of design compliance is made to the Agency.

GM1 21L.A.45 Detailed technical specifications and environmental protection requirements that are applicable to aircraft subject to declarations of design compliance

ED Decision 2023/013/R

ENVIRONMENTAL PROTECTION REQUIREMENTS

(See GM1 21L.B.61(c)(1))

Volumes I, II and III of Annex 16 to the Chicago Convention are available at https://elibrary.icao.int/.

Since the Standards and Recommended Practices in Annex 16 Volumes I, II and III apply only to certain categories of products and as such do not necessarily apply to all products that are within the scope of Subpart C, it is recommended that the declarant may contact the Environment and Sustainability Section of EASA to confirm the environmental protection requirements that are applicable to their particular product and at any stage of the declared process for further guidance.

21L.A.46 Aircraft design data

Regulation (EU) 2022/1358

(a) The declarant shall clearly define the aircraft design to enable its unique and unambiguous identification.

(b) The aircraft design data that is used by the declarant to uniquely define the aircraft design shall include:

1. the drawings and specifications and a listing of those drawings and specifications that are necessary to define the configuration and the design features of the product;
2. information on the materials and processes used;
3. information on the methods of manufacture and assembly;

4. any airworthiness limitations;

5. any environmental compatibility requirements; and

6. any other data allowing by comparison the determination of the airworthiness and, if relevant, the environmental compatibility of later products of the same type.

21L.A.47 Obligations of the declarant of a declaration of design compliance

Regulation (EU) 2022/1358

The declarant who made a declaration of aircraft design compliance to the Agency in accordance with point 21L.A.43 shall:

(a) upon submission of the declaration, arrange for the Agency to conduct a physical inspection and flight tests of the first article of that aircraft in the final or a suitably mature configuration to ensure that the aircraft can achieve an acceptable level of safety and is environmentally compatible;

(b) retain all the supporting documents for the declaration of design compliance, and make them available to the Agency upon request;

(c) comply with all other obligations applicable to a declarant of a declaration of design compliance set forth in Subpart A of this Annex.

AMC 21L.A.47(a) Physical inspection and flight tests of the first article of that aircraft (first-article inspection) prior to registration of a declaration of design compliance

ED Decision 2023/013/R

1. Purpose

The purposes of the first-article inspection (of the article that is in conformance with the declared design) prior to the registration of a declaration of design compliance for a particular aircraft design are:

a. for EASA to ensure the completion of the demonstration-of-compliance activities conducted by the declarant under point 21L.A.44 in accordance with the information provided in accordance with point 21L.A.43 and in particular the compliance-demonstration plan;

b. for EASA to ensure[1] that the designed aircraft is capable of conducting safe flight during in-service operations and does not have any environmental incompatibilities;

c. in case the declarant is a declared design organisation, for EASA to conduct further oversight in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the declarant is able to discharge its obligations.

Note: Under Subpart C of Section A there is no obligation for a declarant of an aircraft declaration of design compliance to submit a declaration of design capability.

[1] This is limited to the scope of the activities that can be conducted under point 2 and the elements of the product that are selected for inspection based upon a risk-based approach to safety and environmental incompatibility.

2. Methodology and evidence

The first-article inspection will be conducted by EASA at an appropriate location(s) selected by the declarant where an effective review and inspection activities can take place. This (these) location(s) should:

— include the location of the aircraft for which the declaration of design compliance has been submitted under point 21L.A.43;

— be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State); and

— in case the declarant is a declared design organisation, be in a location that enables the competent authority to conduct the oversight stated in point 1(c) above.

Note: The principal place of business is defined as follows: 'The head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised.'

The Agency will conduct a physical inspection of the aircraft, engine or propeller for which the registration of a declaration of design compliance has been requested. This inspection, along with any other activity that EASA deems necessary (see point 21L.A.44(f)), should ensure that the objectives mentioned in point 1 are met.

The declarant should make the following arrangements to support the first-article inspection:

a. prepare the aircraft, engine, propeller, systems or components for live testing (including flight testing) upon EASA's request;

b. make available the final version of the compliance-demonstration plan;

c. provide access to supporting compliance documentation and test reports;

d. provide access to key design and production personnel;

e. if relevant (the declarant has opted to become a declared design organisation), make available any design processes and procedures that were used.

It will be necessary for EASA to conduct flight testing of the final configuration of the aircraft. This flight testing will be performed according to a plan proposed by the declarant prior to the first-article inspection and agreed by EASA.

Flight testing could be a combination of:

a. a predefined flight-test plan that is not specific to the particular aircraft type;

b. specific flight testing to focus on targeted aspects after a review of the declarant's flight-testing data/reports.

The above list of additional sources of evidence is not exhaustive.

It is possible that during the first-article inspection EASA may discover evidence that indicates that the declarant has:

a. misunderstood, misinterpreted or not demonstrated compliance with the applicable technical specifications or the applicable environmental protection requirements, which could lead to an unsafe or an environmentally incompatible design;

b. not fulfilled its design obligations as a declared design organisation (if applicable);

c. not utilised good design management principles to ensure compliance or control of the design.

If such evidence is discovered, the declarant should support EASA in conducting a more in-depth investigation into the compliance documentation and/or the design practices of the declarant. The purpose of this in-depth investigation should be to determine whether or not compliance was demonstrated, the root cause(s) and the corrective actions. This investigation should also serve to prevent a reoccurrence of the issue.

3. Aircraft condition and configuration

The declarant should present to EASA the aircraft, engine or propeller (if applicable) in the final configuration for which compliance has been declared by the declarant.

It is possible for the declarant to arrange inspection visits with EASA prior to the declaration of compliance (for example, for noise testing).

Any differences between the configuration presented to EASA for the first-article inspection and the final configuration in the declaration of design compliance should be justified by the declarant and may, therefore, depending upon their criticality, be subject to more focussed scrutiny during the first-article inspection. It is possible that some differences from the final configuration may delay the registration of the declaration of design compliance.

4. Findings and resolution

In the process of the activities mentioned in point 2, EASA will raise an appropriate finding or observation against the aircraft if a non-compliance is discovered. Findings will need to be resolved by the declarant before the declaration of design compliance is registered.

5. Duration and schedule

The first-article inspection may be a single visit or multiple visits depending on the complexity of the design. For example, EASA may wish to witness or participate to compliance-demonstration testing (for example, noise testing) prior to the first-article inspection.

The declarant should coordinate with the competent authority so that the first-article-inspection activities conducted under point 21L.B.143(b) or point 21L.B.251(b) are conducted as far as practical at the same time as first-article-inspection activities conducted under point 21L.B.62(b).

21L.A.48 Non-transferability of a declaration of aircraft design compliance

Regulation (EU) 2022/1358

(a) A declaration of aircraft design compliance cannot be transferred.

(b) A natural or legal person who is taking over the design of an aircraft for which compliance of the design has been previously declared shall:

1. submit a new declaration of aircraft design compliance in accordance with this Subpart;
2. demonstrate that the declarant who previously made a declaration of aircraft design compliance is no longer active or has agreed to the transfer of the aircraft design data;
3. commit to comply with all the obligations applicable to persons making a declaration of aircraft design compliance set forth in this Subpart as per point 21L.A.47.

SUBPART D — CHANGES TO TYPE CERTIFICATES

21L.A.61 Scope

Regulation (EU) 2022/1358

This Subpart establishes:

(a) the procedure for applying for the approval of changes to type certificates for products certified in accordance with this Annex, provided that the changed product is still within the scope of point 21L.A.21;

(b) the rights and obligations of the applicants for, and holders of, those approvals referred to in point (a);

(c) provisions regarding the standard changes that do not require an approval.

GM1 21L.A.61 Scope

ED Decision 2023/013/R

The term 'changes to the type certificate' is consistently used in Subparts D and E of Part 21 Light, as well as in the related AMC and GM. This term does not refer to changing the document that reflects the type certificate (TC) but to changing the elements of the TC as defined in point 21L.B.47(b). Therefore, the processes contained in Subparts D and E of Part 21 Light should be used for the approval of changes to the elements listed in point 21L.B.47(b).

21L.A.62 Standard changes

Regulation (EU) 2022/1358

(a) Standard changes are those changes to a type certificate of a product approved in accordance with Subpart B of Section B of this Annex:

1. that follow the design data included in the certification specifications issued by the Agency, containing the acceptable methods, techniques and practices for carrying out and identifying standard changes, including the associated instructions for continued airworthiness; and

2. that are not in conflict with the data of the holder of that type certificate.

(b) Points 21L.A.63 to 21L.A.70 are not applicable to standard changes.

GM1 21L.A.62 Standard changes

ED Decision 2023/013/R

APPLICABLE CERTIFICATION SPECIFICATIONS

CS-STAN[1] contains the certification specifications referred to in point 21L.A.62. Guidance on the implementation of Standard Changes and Standard Repairs may be found in AMC M.A.801 of the AMC to Part-M.

[1] https://www.easa.europa.eu/en/certification-specifications/cs-stan-standard-changes-and-standard-repairs

21L.A.63 Classification of changes to a type certificate

Regulation (EU) 2022/1358

(a) Changes to a type certificate shall be classified as minor or major.

(b) A 'minor change' is a change that has no appreciable effect on the mass, balance, structural strength, reliability, certified noise or emissions levels, operational characteristics, or other characteristics affecting the airworthiness or the environmental compatibility of the product.

(c) All other changes are 'major changes', unless the change in design, power, thrust, or mass is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis or with the applicable environmental protection requirements or with the applicable detailed technical specifications is required, in which case the design shall be certified in accordance with Subpart B of this Annex.

(d) The requirements for the approval of minor changes are those established in point 21L.A.67.

(e) The requirements for the approval of major changes are those established in point 21L.A.68.

AMC1 21L.A.63(c) Classification of changes to a type certificate

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Major changes that are classified as being 'substantial' will require a new application for a type certificate in accordance with Subpart B of Part 21 Light.

Examples of major changes that are considered substantial may be found in Appendix B to GM1 21L.A.63.

GM1 21L.A.63 Classification of changes to a type certificate

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(a) PURPOSE OF CLASSIFICATION

The purpose of classification of changes to a type certificate (TC) into 'minor' or 'major' is to determine the approval route to be followed in accordance with Part 21 Light Subpart D, i.e. either point 21L.A.67 or point 21L.A.68, or alternatively whether application and approval have to be made in accordance with Part 21 Light Subpart E.

(b) INTRODUCTION

(1) Point 21L.A.63 proposes criteria for the classification of changes to a TC as 'minor' or 'major'.

(i) This GM is intended to provide guidance on the term 'appreciable effect' that affects the airworthiness of the product, the certified noise or emissions levels or affects any of the other characteristics mentioned in point 21L.A.63, where 'airworthiness' is interpreted in the context of a product that is in conformity with type design and in condition for safe operation. It provides complementary guidelines to assess a change to the TC in order to meet the requirements of points 21L.A.63 and 21L.A.91 where classification is the first step of a procedure.

Characteristics that affect the environmental compatibility of the product are characteristics that affect the compliance of the product with the applicable environmental protection requirements.

Note: For the classification of repairs, see GM 21L.A.203(a).

(ii) Although this GM provides guidance on the classification of major changes, as opposed to minor changes as defined in point 21L.A.63, the GM and point 21L.A.63 are deemed entirely compatible.

Appendix A to GM1 21L.A.63 provides examples of major changes and a classification process.

(c) ASSESSMENT OF A CHANGE FOR CLASSIFICATION

(1) Changes to the TC

Point 21L.A.63 addresses all changes to any of the aspects of a TC. This includes changes to a type design, as defined in point 21L.A.26, as well as to the other constituents of a TC, as defined in point 21L.B.47(b).

(2) Reserved

(3) Classification process (see also the flow chart 'Classification process' in Appendix A to GM1 21L.A.63)

Point 21L.A.63 requires all changes to be classified as either 'major' or 'minor', using the criteria of point 21L.A.63.

Wherever there is doubt as to the classification of a change, EASA should be consulted for clarification.

When the strict application of the point (c)(4) criteria results in a major classification, the applicant may request reclassification, if justified, and EASA could take the responsibility for reclassifying the change.

A simple design change planned to be mandated by an airworthiness directive may be reclassified as minor due to the involvement of EASA in the continued airworthiness process when this is agreed between EASA and the design organisation.

The reasons for a classification decision should be recorded.

(4) General guidance on the classification of major changes

A change to the TC that is judged to have an 'appreciable effect on the mass, balance, structural strength, reliability, certified noise or emissions levels, operational characteristics, or other characteristics affecting the airworthiness or the environmental compatibility' is classified as major, in particular, but not only, when one or more of the following conditions are met:

(i) where the change requires an adjustment of the type-certification basis (special conditions or equivalent safety findings) other than electing to comply with later certification specifications or an adjustment to the applicable environmental protection requirements (e.g. when a new requirement becomes applicable after the type certification);

(ii) where the applicant proposes a new interpretation of the certification specifications used for the type-certification basis that has not been published as AMC material or otherwise agreed with EASA;

(iii) where the demonstration of compliance uses methods that have not been previously accepted as appropriate for the nature of the change;

(iv) where the extent of new substantiation data necessary to comply with the applicable certification specifications and the degree to which the original substantiation data has to be reassessed and re-evaluated is considerable;

(v) where the change alters the airworthiness limitations or the operating limitations;

(vi) where the change is made mandatory by an airworthiness directive or the change is the terminating action of an airworthiness directive (ref. point 21L.A.4), see *Note 1*; and

(vii) where the design change introduces or affects functions where the failure effect is classified as catastrophic or hazardous.

Note 1: A change previously classified as minor and approved prior to the decision to issue an airworthiness directive needs no reclassification. However, EASA retains the right to review the change and reclassify/reapprove it if found necessary.

Note 2: The conditions listed in points (i) through (vii) above are an explanation of the criteria noted in point 21L.A.63, and of point 21L.A.103 that refers to this point for the classification of changes in Subpart F.

For an understanding of how to apply the above conditions, it is useful to take note of the examples given in Appendix A to GM1 21L.A.63.

(5) Guidance on the classification of changes to aircraft flight manuals (AFMs)

The following changes to the AFM are deemed to be minor:

(i) revisions to the AFM associated with changes to the type design that are classified as minor in accordance with point 21L.A.63;

(ii) revisions to the AFM that are not associated with changes to the type design (also identified as stand-alone revisions) which fall into one of the following categories:

(A) changes to limitations or procedures that remain within already certified limits (e.g. weight, structural data, etc.);

(B) consolidation of two or more previously approved and compatible AFMs into one, or the compilation of different parts taken from previously approved and compatible AFMs that are directly applicable to the individual aircraft (customisation); and

(C) the introduction into a given AFM of compatible and previously approved AFM amendments, revisions, appendices or supplements; and

(D) changes that affect the certified noise or emissions levels of the product; and

(iii) administrative revisions to the AFM, defined as follows:

(A) for the AFMs issued by the TC holder:

(a) editorial revisions or corrections to the AFM;

(b) changes to parts of the AFM that do not require approval by EASA;

(c) conversions of previously Federal Aviation Administration (FAA)- or EASA-approved combinations of units of measurement added to the AFM in a previously approved manner;

(d) the addition of aircraft serial numbers to an existing AFM where the aircraft configuration, as related to the AFM, is identical to the configuration of the aircraft already covered by that AFM;

(e) the removal of references to aircraft serial numbers no longer applicable to that AFM; and

(f) the translation of an EASA-approved AFM into the official language of the State of design or State of registry;

(B) for AFM supplements issued by STC holders:

(a) editorial revisions or corrections to the AFM supplement;

(b) changes to parts of the AFM supplement that are not required to be approved by EASA;

(c) conversions of previously FAA- or EASA-approved combinations of units of measurement added to the AFM supplement in a previously approved manner;

(d) the addition of aircraft serial numbers to an existing AFM supplement where the aircraft configuration, as related to the AFM supplement, is identical to that of the aircraft already in that AFM supplement; 'identical' means here that all aircraft must belong to the same type and model/variant;

(e) the addition of a new STC to an existing AFM supplement, when this supplement is fully applicable to the new STC;

(f) the removal of references to aircraft serial numbers that are no longer applicable to that AFM supplement;

(g) the translation of an EASA-approved AFM supplement into the official language of the State of design or State of registry.

(6) Guidance on the classification of changes to certified aircraft noise levels and aircraft engine emissions levels

Volumes I and II of ICAO Doc 9501 'Environmental Technical Manual' define 'no-acoustical changes' and 'no-emissions changes' respectively as changes that would result in very small changes in the certified levels and provide criteria for their determination. These changes have 'no appreciable effect' on the certified levels. Consequently, they are classified as minor changes for environmental protection and the certified levels remain unchanged.

If the 'no-acoustical change' or 'no-emissions change' is demonstrated using an equivalent procedure to the one specified in ICAO Annex 16, the applicant should seek the agreement of EASA on the classification of the change. An equivalent procedure is a test or analysis procedure which, while differing from the one specified in ICAO Annex 16, effectively yields the same noise or emission levels as the specified procedure according to the technical judgement of EASA.

All other changes to the certified aircraft noise levels and aircraft engine emissions levels are classified as major changes.

Examples of major changes are provided in Appendix A to GM1 21L.A.63.

Appendix A to GM1 21L.A.63 Classification of changes to a type certificate

ED Decision 2023/013/R

EXAMPLES OF MAJOR CHANGES PER DISCIPLINE

The information below is intended to provide a few examples of major changes per discipline, resulting from the application of point 21L.A.63 and point 3.3 below. It is not intended to present a comprehensive list of all major changes. Examples are categorised per discipline and are applicable to all products (aircraft, engines, propellers). However, a particular change may involve more than one discipline, e.g. a change to engine controls may be covered in engines and systems (software).

Those involved in the classification of changes should always be aware of the interaction between disciplines and the consequences this will have when assessing the effects of a change (i.e. operations and structures, systems and structures, systems and systems, etc.).

Specific rules may exist which override the guidance of these examples.

In Part 21 Light, a negative definition is given of minor changes only. However, in the following list of examples, it was preferred to give examples of major changes.

Where in this list of examples the words 'has effect' or 'affect(s)' are used, they have always to be understood as being the opposite of 'no appreciable effect' as in the definition of minor change in point 21L.A.63. Strictly speaking, the phrases 'has appreciable effect' and 'appreciably affect(s)' should have been used, but this has not been done to improve readability.

1. Structure

   (i) Changes such as a change of dihedral, addition of floats.

   (ii) Changes to materials, processes or methods of manufacture of primary structural elements, such as spars, frames and critical parts.

   (iii) Changes that adversely affect fatigue or damage tolerance or life-limit characteristics.

   (iv) Changes that adversely affect aeroelastic characteristics.

2. Cabin safety

   (i) Changes which introduce a new cabin layout of sufficient change to require a reassessment of the emergency evacuation capability, or changes which adversely affect other aspects of passenger or crew safety.

   Items to consider include but are not limited to:

   — changes to or introduction of dynamically tested seats;

   — changes to cabin layouts that affect evacuation path or access to exits;

   — changes to the cabin area in striking distance of the occupant's head or torso introducing potentially injurious objects

3. Flight

   Changes which adversely affect the approved performance or brake changes that affect braking performance.

   Changes which adversely affect the flight envelope.

Changes which adversely affect the handling qualities of the product, including changes to the flight controls function (gains adjustments, functional modification to software), or changes to the flight protection or warning system.

4. Systems

For systems assessed under CS 23.2510, the classification process is based on the functional aspects of the change and its potential effects on safety.

(i) Where the failure effect is 'catastrophic' or 'hazardous', the change should be classified as 'major'.

(ii) Where the failure effect is 'major', the change should be classified as 'major' if:

— aspects of the compliance demonstration will use a means that has not been previously accepted for the nature of the change to the system; or

— the change affects the pilot–system interface (displays, controls, approved procedures); or

— the change introduces new types of functions/systems such as GPS primary, TCAS, predictive windshear, HUD.

The assessment of the criteria for software changes to systems should also be performed.

When software is involved, account should be taken also of the following guidelines:

Where a change is made to software produced in accordance with the guidelines of the latest edition of AMC 20-115 (see AMC-20 document), the change should be classified as 'major' if either of the following applies, and the failure effect is 'catastrophic', 'hazardous' or 'major':

(i) the executable code for software, determined to be Level A or Level B in accordance with the guidelines, is changed unless that change involves only a variation of a parameter value within a range already verified for the previous certification standard; or

(ii) the software is upgraded to or downgraded from Level A, Level B or Level C; or

(iii) the executable code, determined to be level C, is deeply changed, e.g. after a software re-engineering process accompanying a change of processor.

For software developed to guidelines other than the latest edition of AMC 20-115, the applicant should assess the changes in accordance with the foregoing principles.

For other codes, the principles noted above may be used. However, due consideration should be given to specific certification specifications/interpretations.

For example:

— Opening and listening on a User Datagram Protocol (UDP) port in an end system of an already certified topology.

— Activating a protocol in a point-to-point communication channel.

— The modification of a service between a system of a more closed, controlled security domain and a system of a more open, less controlled security domain.

— The modification of a security control between a system of a more closed, controlled information security domain and a system of a more open, less controlled security domain.

5. Propellers

Changes to:

— diameter,

— aerofoil,

— planform,

— material,

— blade retention system, etc.

6. Engines

Changes:

(i) that adversely affect operating speeds, temperatures, and other limitations;

(ii) that affect or introduce parts identified by CS E-510 where the failure effect has been shown to be ‘hazardous’;

(iii) that affect or introduce engine critical parts (CS E-515) or their life-limits.

(iv) to a structural part which requires a resubstantiation of the fatigue and static load determination used during certification;

(v) to any part of the engine which adversely affects the existing containment capability of the structure;

(vi) that adversely affect the fuel, oil and air systems, which alter the method of operation, or require reinvestigation against the type-certification basis;

(vii) that introduce new materials or processes, particularly on critical components.

7. Rotors and drive systems

Changes that:

(i) adversely affect fatigue evaluation unless the service life or inspection interval is unchanged; this includes changes to materials, processes or methods of manufacture of parts, such as

— rotor blades,

— rotor hubs including dampers and controls,

— gears,

— drive shafts,

— couplings;

(ii) affect systems whose failure may have ‘hazardous’ or ‘catastrophic’ effects; the design assessment should include:

— the cooling system,

— the lubrication system,

— rotor controls;

(iii) adversely affect the results of the rotor drive system endurance test, the rotor drive system being defined in CS 27.917;

(iv) adversely affect the results of the shafting critical speed analysis required by CS 27.931.

8. Noise and emissions

The examples provided below are not exhaustive and will not, in every case, result in an appreciable effect on the certified noise or emissions levels and, therefore, will not per se and in every case result in a major change classification.

(i) Examples of noise-related changes that might lead to a major change classification are:

(1) for propeller-driven aeroplanes:

— a change that might affect the aircraft's take-off performance, including:

— a change to the maximum take-off mass;

— a change to the take-off distance;

— a change to the rate of climb; or

— a change to V_Y (best rate of climb speed);

— a change that increases the aircraft's drag (e.g. the installation of external cargo pods, external fuel tanks, larger tyres to a fixed undercarriage, floats etc.);

— a change of engine or propeller type;

— a change in take-off power including a change in engine speed (tachometer 'red line') or, for piston engines, a change to the manifold pressure limitations;

— a change to the highest power in the normal operating range ('top of green arc');

— in the case of an aircraft where take-off power/engine speed is time limited, a change in the period over which take-off power/engine speed may be applied;

— a change to the engine inlet or exhaust including, if fitted, the inlet or exhaust muffler;

— a change in propeller diameter, tip shape, blade thickness or the number of blades;

— the installation of a variable or adjustable pitch propeller in place of a fixed pitch propeller and vice versa;

— a change that causes a change to the angle at which air flows into the propeller;

(2) for helicopters:

— a change that might affect the take-off and/or landing performance, including a change in take-off mass and V_Y (best rate of climb speed);

— a change to VNE (never-exceed airspeed) or to VH (airspeed in level flight obtained using the torque corresponding to minimum engine installed, maximum continuous power available for sea level pressure, 25°C ambient conditions at the relevant maximum certified mass);

— a change to the maximum take-off engine power or maximum continuous power;

— a change to the gearbox torque limits;

— a change of engine type;

— a change to the engine intake or exhaust;

— a change to the maximum normal operating rpm of the main or tail rotors;

— a change to the main or tail rotors, including a change in diameter, blade thickness or blade tip profile.

Note: The effect on the helicopter's noise characteristics of either carrying external loads or the installation of external equipment need not be considered.

(ii) Examples of smoke-engine-emissions-related changes that might lead to a major change classification are:

— a change in engine thrust rating;

— a change to the aerodynamic flow lines through the engine;

— a change that affects the engine thermodynamic cycle, specifically relevant engine cycle parameters (e.g. combustor pressure P3, combustor entry temperature T3, air fuel ratio (AFR));

— a change to the compressor that might influence the combustor inlet conditions and engine overall pressure ratio;

— a change to the combustor design (geometry);

— a change to the cooling of the combustor;

— a change to the air mass flow through the combustor;

— a change that affects the fuel spray characteristics.

9. Power plant installation

Changes which include:

(i) control system changes which affect the engine/propeller/airframe interface;

(ii) new instrumentation displaying operating limits;

(iii) modifications to the fuel system and tanks (number, size and configuration);

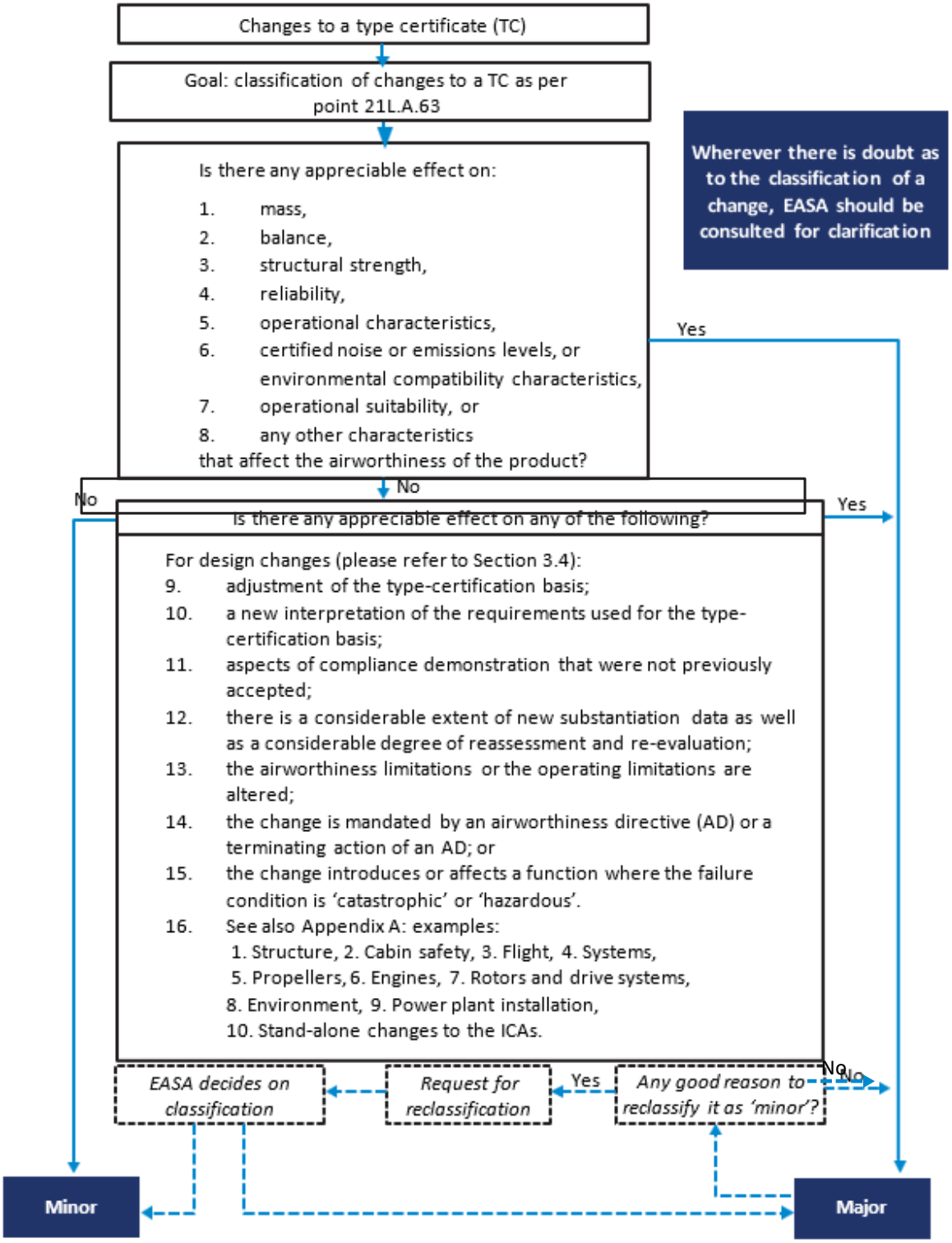
(iv) change of engine/propeller type.

10. Stand-alone changes to non-ALS ICAs that require additional work to demonstrate compliance with the applicable certification basis as follows:

(i) the introduction of novel technology for inspection purposes related to an ALS task;

(ii) changes that adversely affect the certification assumptions: e.g. some specific inspection procedures, such as inspection procedures for use after a hard landing, may include a decision-making chart based on the level of exceedance of the load in comparison with the certified limit loads; such criteria, and adverse changes, should be agreed with EASA.

Classification process



Appendix B to GM 21L.A.63 Classification of changes to a type certificate

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The following tables provide examples of 'substantial' changes. The classification may change due to cumulative effects and/or combinations of individual changes.

A.1 Examples of 'substantial' changes for small aeroplanes (CS-23)

A.1.1 *Table A-1* contains examples of changes that are 'substantial' for small aeroplanes (CS-23).

Table A-1 — Examples of 'substantial' changes for small aeroplanes (CS-23)

Example	Description of change	Notes
1.	Change to wing location (tandem, forward, canard, high/low).	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.
2.	Fixed wing to tilt wing.	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.
3.	A change to the number of engines.	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.
4.	Replacement of piston or turboprop engines with turbojet or turbofan engines.	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.
5.	Change to engine configuration (tractor/pusher).	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.
6.	Change from an all-metal to all-composite aeroplane.	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

A.2 Examples of 'substantial' changes for rotorcraft (CS-27)

A.2.1 Table A-2 contains examples of changes that are 'substantial' for rotorcraft (CS-27).

Table A-2 — Examples of 'substantial' changes for rotorcraft (CS-27)

Example	Description of change	Notes
1.	Change to the number and/or configuration of rotors (e.g. main and tail rotor system to two main rotors).	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.
2.	Change from an all-metal rotorcraft to all-composite rotorcraft.	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

A.3 Examples of 'substantial' changes for propellers (CS-P)

A.3.1 Table A-3 contains an example of a change that is 'substantial' for propellers (CS-P).

Table A-3 — Example of a 'substantial' change for propellers (CS-P)

Example	Description of change	Notes
1.	Change to the number of blades.	Proposed change to the design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

21L.A.64 Eligibility

Regulation (EU) 2022/1358

(a) Only the type-certificate holder may apply for the approval of a major change to a type certificate under this Subpart; all other applicants for a major change to a type certificate shall apply under Subpart E of this Annex.

(b) Any natural or legal person may apply for the approval of a minor change to a type certificate under this Subpart.

21L.A.65 Application for a change to a type certificate

Regulation (EU) 2022/1358

(a) An application for the approval of a change to a type certificate shall be made in a form and manner established by the Agency.

(b) For a major change to a type certificate, the applicant shall include in the application a compliance demonstration plan for the demonstration of compliance in accordance with point 21L.A.66, along with a proposal for the type-certification basis and the applicable environmental protection requirements, prepared in accordance with the requirements and options specified in point 21L.B.81.

AMC1 21L.A.65 Application for a change to a type certificate

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FORM AND MANNER

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application forms for the approval of major changes/major repair designs or for the approval of minor changes/minor repair designs, which may be downloaded from the EASA website.

The forms should be completed in accordance with the instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[2].

AMC1 21L.A.65(b) Application for a change to a type certificate

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CERTIFICATION BASIS

Point 21L.A.65(b) 'a proposal for the type-certification basis and the applicable environmental protection requirements, prepared in accordance with the requirements and options specified in point 21L.B.81'.

The proposed type-certification basis should include applicable certification specifications, proposed special conditions, proposed equivalent safety findings, as well as a proposed 'elect to comply' and proposed deviations, as applicable.

21L.A.66 Demonstration of compliance

Regulation (EU) 2022/1358

(a) The applicant for a major change to a type certificate shall demonstrate compliance with the applicable type-certification basis and the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with point 21L.B.81, and shall provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant for a major change to a type certificate shall provide the Agency with a recorded justification of the means of compliance according to the compliance demonstration plan.

(c) When carrying out testing and inspections to demonstrate compliance in accordance with point (a), the applicant shall have verified and documented this verification prior to carrying out any test:

1. for the test specimen, that:

   (i) the materials and processes adequately conform to the specifications for the proposed changed type design;

   (ii) the constituent parts of the products adequately conform to the drawings in the proposed changed type design;

   (iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed changed type design; and

[1] https://ap.easa.europa.eu (accessed: DD.MM.2023)

[2] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (accessed: 20 October 2023)

2. that the test and measuring equipment used for the test were adequate for the test and appropriately calibrated.

(d) The flight testing for the purpose of obtaining an approval of a major change to a type certificate shall be conducted in accordance with the methods for such flight testing specified by the Agency. The applicant for a major change to a type certificate shall make all the flight tests necessary to determine compliance with the applicable type-certification basis and the applicable environmental protection requirements.

(e) An applicant for a major change to a type certificate shall allow the Agency to:

1. review any data and information related to the demonstration of compliance;

2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance; and

3. if it is considered necessary, conduct a physical inspection of the first article of that product in the final changed configuration to verify the compliance of the design with the type-certification basis and the applicable environmental protection requirements.

(f) Upon completion of the compliance demonstration, the applicant shall declare to the Agency that:

1. they have demonstrated compliance with the type-certification basis and the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with point 21L.B.81, according to the compliance demonstration plan; and

2. no feature or characteristic has been identified that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested.

AMC1 21L.A.66 Demonstration of compliance

ED Decision 2023/013/R

DEMONSTRATION OF COMPLIANCE FOR A CHANGE TO A TYPE CERTIFICATE

The description of the change should include an explanation of the purpose of the change, the pre-modification and post-modification configuration(s) of the product, schematics/pictures, and any other detailed features and boundaries of the physical change (this may be supplemented by drawings or outlines of the design, if this helps to understand the design change), as well as the identification of the changes in areas of the product that are functionally affected by the change, and the identification of any changes to the approved manuals.

The applicant should identify any reinvestigations that are necessary to demonstrate compliance. This is a list of affected items of the applicable type-certification basis for which a new demonstration is necessary, together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

Before submitting the application for a change, the analysis and classification activities under point 21L.A.63 should be performed using the corresponding GM. For repair designs, the analysis under point 21L.A.63 should be performed using GM 21L.A.203.

For a major change, AMC1 21L.A.24(b)(4) should be used as applicable to the change for the development of the compliance-demonstration plan.

Compliance documentation for the demonstration of compliance under point 21L.A.66(a) comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications,

calculations, analyses, etc., and provides a record of the means by which compliance with the applicable type-certification basis and environmental protection requirements is demonstrated.

Each compliance document should typically contain:

— the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;

— substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

— the appropriate authorised signature.

Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7.

The level of detail of the compliance documentation that is referred to in point 21L.A.66(a) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

The compliance-demonstration process always takes into account the specific configuration(s) in the type certificate (TC) to which the major change under approval is applied. This (these) configuration(s) may be defined by type models/variants or by design changes to the type design. The demonstration of compliance covers this (these) applicable specific configuration(s). Consequently, the approval of the major change excludes any other configurations, in particular those that already exist but are not considered in the compliance-demonstration process, as well as those that may be certified in the future.

For major changes approved by a design organisation approval (DOA) holder on the basis of its privilege as per point 21.A.263(c)(8) of Annex I (Part 21), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

AMC1 21L.A.66(c) Demonstration of compliance

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INSPECTIONS AND TESTS

Proposed type design: this term defines the type design (or the portion of the type design) as it is determined at the time when the testing and inspections are carried out.

Verification document (also known as 'statement of conformity'): before each testing and inspection, the verification document must confirm that the test specimen conforms with the proposed design, the test and measuring equipment is adequate for the test, and the sensors and measuring system are appropriately calibrated.

Conformity of the test specimen: the documented verification is intended to ensure that the manufactured test specimen adequately represents the proposed type design. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the proposed type design at the time of the test. These are typically identified in the early stage of the testing and inspection planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity in as early as possible, the applicant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed, justified in the verification document or by cross reference to the test plan or other documents. However, testing for the demonstration of compliance with the applicable environmental protection requirements should be conducted in the final design of the product having incorporated the change.

Certification is typically an iterative process in which the design is under continuous evolution. If the type design evolves after the time of the testing and inspections, then the final type design should be checked against the proposed type design (as it was at the time of the testing and inspections), and the differences (if any) should be analysed to ensure that the testing and inspections' results are representative of the final configuration. However, such changes made to the type design may lead to the invalidation of the testing and inspections' results and the need to repeat the testing and inspections. It is recommended that the design organisation should have a thorough configuration management process to track the evolving type design.

Conformity of test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and should include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

    — type/model of sensors, together with their technical characteristics;

    — position and orientation of exciters and sensors; and

    — electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through certification test plans and supporting documentation, according to the design assurance system, if applicable. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The verification document should confirm that the test and measuring equipment conforms to its purpose, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This may be done either in the verification document or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test specimen, as well as the test and measuring equipment, is considered 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up do not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or masking any potential failure mode or behaviour).

Changes that affect the validity of the verification document: if changes need to be introduced to the test specimen or to the test and measurement equipment after the verification is documented (and

before the test is undertaken), then the verification document must be updated. The updated verification document must be made available to EASA before the test if EASA has informed the applicant that it will witness or carry out the tests or inspections.

Development versus certification tests: sometimes, tests on specimens that conform to a preliminary design, but are not intended for certification (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21L.A.66(c).

Any planned test event should be classified in advance as either a development test or a certification test. Tests that support the compliance demonstration should be classified as certification tests.

It is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a certification test as long as it meets the requirements of point 21L.A.66(c). For this reason, it is important to keep the configuration of such tests under control.

If the test specimen used for a certification test has already undergone a series of previous tests that may affect or ultimately invalidate its acceptance as required by point 21L.A.66(c), this aspect should be considered when documenting the verification, and specific analyses or inspections may be required.

Because of the above aspects, EASA advises applicants to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as certification tests to establish whether EASA would wish to witness the test(s).

GM1 21L.A.66(d) Demonstration of compliance

ED Decision 2023/013/R

FLIGHT TESTING

Detailed material on flight testing for compliance demonstration is included in the applicable CSs and GM. Information on flight testing for compliance demonstration with the applicable environmental protection requirements may be found in Volumes I, II and III of Annex 16 to the Chicago Convention and in ICAO Doc 9501 ‘Environmental Technical Manual’.

AMC1 21L.A.66(e)(1) Demonstration of compliance

ED Decision 2023/013/R

DATA AND INFORMATION REVIEW

Availability of compliance data (see point 21L.A.66(e)): data and information required to be provided by the applicant should be made available to EASA in a reliable and efficient way.

AMC1 21L.A.66(e)(2) Demonstration of compliance

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TESTS AND INSPECTIONS

The applicant should inform EASA sufficiently in advance about the execution of tests and inspections that:

— are used for compliance-demonstration purposes; and

— have been identified as being of particular interest to EASA during the review and approval of the compliance-demonstration plan

in order to permit EASA the opportunity to witness or carry out these inspections or tests.

The applicant may propose to EASA to witness or carry out flight or other tests of particular aspects of the product during its development and before the type design is fully defined.

However, in case of flight tests, the applicant should perform the tests before EASA witnesses or performs them to ensure that no feature of the product precludes the safe conduct of the evaluation requested. EASA may require any such tests to be repeated once the type design is fully defined to ensure that subsequent changes have not adversely affected the conclusions from any earlier evaluation.

A verification document as per point 21L.A.66(c) is required for the above tests.

AMC1 21L.A.66(e)(3) Demonstration of compliance

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FIRST-ARTICLE PHYSICAL INSPECTION

The applicant should be prepared for any additional investigations as notified by EASA according to point 21L.B.83(c).

Refer to AMC1 21L.A.25(e)(3) for an explanation of the activities performed under the first-article inspection.

GM1 21L.A.66(f) Demonstration of compliance

ED Decision 2023/013/R

DECLARATION OF COMPLIANCE

All compliance demonstrations in accordance with the compliance-demonstration plan, including all the testing and inspections in accordance with point 21L.A.66(c) and all flight testing in accordance with point 21L.A.66(d) and those necessary to determine compliance with the applicable environmental protection requirements, should be completed before the issuance of the final declaration of compliance.

'No feature or characteristic' that may make the changed product unsafe under point 21L.A.66(f)(2) means the following: while every effort is made to address in the applicable certification basis all the risks to product safety that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant should declare that it has not identified any such feature or characteristic.

'No feature or characteristic' that may make the changed product environmentally incompatible under point 21L.A.66(f)(2):

It is assumed that environmental compatibility is demonstrated when the changed product complies with the applicable environmental protection requirements. Therefore, the applicant, when declaring that the changed product complies with the applicable environmental protection requirements under point 21L.A.66(f)(1), should also declare that it has not identified any such feature or characteristic.

21L.A.67 Requirements for the approval of a minor change to a type certificate

Regulation (EU) 2022/1358

In order to be issued with an approval of a minor change to a type certificate, the applicant shall:

(a) demonstrate that the change and the areas affected by the change comply:

1. with the type-certification basis and the applicable environmental protection requirements incorporated by reference in the type certificate; or
2. if the applicant chooses to, with the certification specifications that are applicable to the product on the date of the application for the change;

(b) declare compliance with the type-certification basis and the applicable environmental protection requirements that apply in accordance with point (a)(1), or with the certification specifications chosen in accordance with point (a)(2), record the justifications of compliance in the compliance documents, and record that no feature or characteristic has been identified that may make the changed product unsafe for the uses for which certification is requested;

(c) submit to the Agency the justification of compliance for the change and the declaration of compliance.

AMC1 21L.A.67 Requirements for the approval of a minor change to a type certificate

ED Decision 2023/013/R

(a) Applicability of point 21L.A.67

Point 21L.A.67 should be complied with by applicants for the approval of a minor change to a type certificate (TC), and by design organisation approval (DOA) holders that approve minor changes under their own privileges.

Point 21L.A.67(c), however, only applies to projects for which an application is submitted to EASA. For DOA holders that approve minor changes under their privileges, the justification of compliance and the declaration of compliance required by point 21L.A.67(b) should be produced but do not need to be submitted to EASA. They should be, however, kept on record and submitted to EASA on request during its DOA continued surveillance process.

(b) The approval process

The approval process comprises the following steps:

Note: Steps 1, 2 and 4 should be followed only by applicants for minor changes approved by EASA. DOA holders that approve minor changes under their privileges should refer to AMC No 1 to 21.A.263(c)(2) or AMC No 2 to 21.A.263(c)(2), as applicable to their approval process.

(1) Application

When the minor change is approved by EASA, an application should be submitted to EASA as described in point 21L.A.65 and in AMC 21L.A.65.

(2) Certification basis

(3) Justification of compliance

(4) Declaration of compliance

(c) Certification basis

The certification basis for a minor change consists of a subset of the elements of the product's certification basis 'incorporated by reference in the type certificate'.

The certification basis 'incorporated by reference in the type certificate' is the certification basis for the product as recorded in the type certificate data sheet (TCDS) for the product type/model in the applicable configuration(s).

The certification basis contains the applicable airworthiness and environmental protection requirements specified by reference to their amendment level, as complemented by special conditions, equivalent safety findings, deviations, a proposed 'elect to comply', etc., as applicable.

By way of derogation from the above, CSs that became applicable after those incorporated by reference in the TC may be used for the approval of a minor change (see the guidance below on certification specifications that became applicable after those 'incorporated by reference in the type certificate').

If other changes are required for the embodiment of the minor change, the certification basis corresponding to the product modified by these other changes should also be considered when determining the certification basis for the minor change.

(d) Justification of compliance required by point 21L.A.67(c)

The applicant should justify compliance with the certification basis under point 21L.A.67(a) for all areas that are either physically changed or functionally affected by the minor change.

(1) Means of compliance: the applicant should define and record the means (calculation, test or analysis, etc.) by which compliance is demonstrated. Appendix A to AMC1 21L.A.24(b) may be used to describe how compliance is demonstrated.

(2) Compliance documents: the compliance demonstration should be recorded in compliance documents. For minor changes, one comprehensive compliance document may be sufficient, provided that it contains evidence of all aspects of the compliance demonstration.

See also the additional guidance in point (e) below.

(3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

See also additional guidance in point (f) below on embodiment/installation instructions.

(e) Definition of the change to the type certificate

The change to the type certificate should be defined in accordance with GM 21L.A.61.

(f) Embodiment/installation instructions

The instructions for the embodiment/installation of the change (e.g. service bulletin, modification bulletin, production work order, etc.) should be defined. This may include the installation procedure, the required material, etc.

(g) Certification specifications that are applicable to the product on the date of the application for the change

(1) Minor changes are those changes that do not affect the airworthiness of the product. This means that the certification basis for the minor change may consist of the items of the certification basis incorporated by reference in the TCDS of the product type/model, and normally it should not be necessary for a minor change to use certification specifications that became applicable after those that are incorporated by reference in the type certificate.

(2) On the other hand, the applicant may elect to use the certification specifications that are applicable to the product on the date of the application for the change for the compliance demonstration. This does not affect the classification of the change.

(h) Feature or characteristic that affects the airworthiness or environmental compatibility of the changed product

The term 'no feature or characteristic' applies to a minor change, in which case the effect of the change on the product safety or environmental compatibility is quite low. Minor changes should not be approved if either the design organisation approval (DOA) holder approving minor changes under its privileges or EASA is aware of a feature or characteristic that may make the changed product unsafe or environmentally incompatible for the uses for which the approval is requested.

GM1 21L.A.67(c) Requirements for the approval of a minor change to a type certificate

ED Decision 2023/013/R

The level of detail of the justification that is referred to in point 21L.A.67(c) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

21L.A.68 Requirements for the approval of a major change to a type certificate

Regulation (EU) 2022/1358

In order to be issued with an approval of a major change to a type certificate, the applicant shall:

(a) demonstrate that the change and the areas affected by the change comply with the type-certification basis and the applicable environmental protection requirements, as established and notified to the applicant by the Agency in accordance with point 21L.B.81

(b) demonstrate compliance in accordance with point 21L.A.66;

(c) demonstrate that there are no unresolved issues from the physical inspection of the first article of that product in the final changed configuration carried out by the Agency in accordance with point 21L.A.66(e)(3).

AMC1 21L.A.68 Requirements for the approval of a major change to a type certificate

ED Decision 2023/013/R

(a) For major changes approved by EASA, the applicant should use all the AMC and GM to point 21L.A.25.

(b) For major changes approved by the design organisation approval (DOA) holder on the basis of its privileges under point 21.A.263(c)(8) of Annex I (Part 21), the process described in AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

AMC1 21L.A.68(c) Requirements for the approval of a major change to a type certificate

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For the demonstration by the applicant that there are no unresolved issues, see AMC1 21L.A.27(d).

21L.A.69 Approval of a change to a type certificate under a privilege

Regulation (EU) 2022/1358

(a) The approval of a change to a type certificate that it has designed may be issued by an approved design organisation without an application according to point 21L.A.65 in accordance with the scope of its privileges provided for in points (2) and (8) of point 21.A.263(c) of Annex I (Part 21) instead of the Agency, as recorded in the terms of approval.

(b) When issuing an approval of a change to type certificate in accordance with point (a), the design organisation shall:

1. ensure that all the substantiation data and justifications are available;
2. ensure that the compliance of the change with the type-certification basis and the applicable environmental protection requirements according to point (a)(1) of point 21L.A.67 or point (a) of point 21L.A.68 has been demonstrated and declared in accordance with point 21L.A.66;
3. confirm that it has not found:
   (i) any non-compliances with the type-certification basis or, where applicable, with the applicable environmental protection requirements, or with the certification specifications chosen;
   (ii) any feature or characteristic of the change that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested;
4. limit the approval of a change to a type certificate to the specific configuration(s) in the type certificate to which the change relates.

21L.A.70 Obligations for minor changes to a type certificate

Regulation (EU) 2022/1358

The holder of an approval of a minor change to a type certificate shall ensure that the obligations for holders of minor change approvals of Subpart A of this Annex are undertaken.

SUBPART E — SUPPLEMENTAL TYPE CERTIFICATES

21L.A.81 Scope

Regulation (EU) 2022/1358

This Subpart establishes the procedure for natural or legal persons other than the holder of that type certificate for applying for the approval of major changes to type certificates, issued under Annex I (Part 21) or this Annex, of products within the scope of point 21L.A.21, provided that the changed product is still within the scope of that point, and establishes the rights and obligations of the applicants for, and holders of, those certificates.

GM1 21L.A.81 Scope

ED Decision 2023/013/R

The term 'changes to the type certificate' is consistently used in Subparts D and E of Part 21 Light, as well as in the related AMC and GM. This term does not refer to changing the document that reflects the type certificate (TC) but to changing the elements of the TC as defined in point 21L.B.47(b). Therefore, the processes contained in Subparts D and E of Part 21 Light should be used for the approval of changes to the elements listed in point 21L.B.47(b).

21L.A.82 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person who has demonstrated, or is in the process of demonstrating, or have declared, their design capability in accordance with point 21L.A.83 may apply for a supplemental type certificate under the conditions laid down in this Subpart.

21L.A.83 Demonstration of design capability

Regulation (EU) 2022/1358

An applicant for a supplemental type certificate shall demonstrate their design capability by:

(a) holding a design organisation approval with terms of approval that cover the respective category of product, issued by the Agency in accordance with Subpart J of Section A of Annex I (Part 21); or

(b) declaring their design capability for the scope of the product in accordance with Subpart J of this Annex.

GM1 21L.A.83(a) Demonstration of design capability

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TERMS OF APPROVAL COVERING THE RESPECTIVE CATEGORY OF THE PRODUCT

If an applicant has a design organisation approval (DOA) issued under Subpart J of Annex I (Part 21) and it wishes to use this approval to meet the eligibility criteria of point 21L.A.83, it will need to apply for a change to the Terms of Approval to include the new aircraft type within the list of products.

GM1 21L.A.83(b) Demonstration of design capability

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DECLARATION OF PRODUCT CATEGORY

Organisations that have declared their design capability under Subpart J of Annex Ib (Part 21 Light) should update their declaration of design capability to include the new product when submitting a new application for a type certificate (see point 21L.A.173(c) 'Declaration of design capability').

21L.A.84 Application for a supplemental type certificate

Regulation (EU) 2022/1358

(a) An application for a supplemental type certificate shall be made in a form and manner established by the Agency.

(b) When applying for a supplemental type certificate, the applicant shall:

1. include in the application the information required by point 21L.A.65(b;)
2. specify whether the certification data has been or will be prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.

AMC1 21L.A.84(a) Application for a supplemental type certificate

ED Decision 2023/013/R

FORM AND MANNER

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application form for a supplemental type certificate (STC), which may be downloaded from the EASA website.

If the form is filled in offline, it should be completed in accordance with the instructions embedded at the bottom of the application form and sent to EASA by email or regular mail following the information provided on the EASA website[2].

AMC1 21L.A.84(b)(1) Application for a supplemental type certificate

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CERTIFICATION BASIS

Point 21L.A.65(b) 'a proposal for the type-certification basis and the applicable environmental protection requirements, prepared in accordance with the requirements and options specified in point 21L.B.101'.

The proposed type-certification basis should include applicable certification specifications, proposed special conditions, proposed equivalent safety findings, as well as a proposed 'elect to comply' and proposed deviations, as applicable.

[1] https://ap.easa.europa.eu (accessed: 20 October 2023)

[2] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals https://ap.easa.europa.eu (accessed: 20 October 2023)

21L.A.85 Demonstration of compliance

Regulation (EU) 2022/1358

(a) The applicant for a supplemental type certificate shall demonstrate compliance with the applicable type-certification basis and the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with point 21L.B.101 and shall provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant for a supplemental type certificate shall provide the Agency with a recorded justification of the means of compliance within compliance documents according to the compliance demonstration plan.

(c) When carrying out testing and inspections to demonstrate compliance in accordance with point (a), the applicant shall have verified and documented this verification prior to carrying out any test:

1. for the test specimen, that:

(i the materials and processes adequately conform to the specifications for the proposed changed type design;

(ii) the constituent parts of the products adequately conform to the drawings in the proposed changed type design;

(iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed changed type design; and

2. that the test and measuring equipment used for the test were adequate for the test and appropriately calibrated.

(d) The flight testing for the purpose of obtaining a supplemental type certificate shall be conducted in accordance with the methods for such flight testing specified by the Agency. The applicant for a supplemental type certificate shall make all the flight tests necessary to determine compliance with the applicable type-certification basis.

(e) An applicant for a supplemental type certificate shall allow the Agency to:

1. review any data and information related to the demonstration of compliance;

2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance; and

3. conduct a physical inspection of the first article of that product in the final changed configuration to verify the compliance of the design with the type-certification basis and the applicable environmental protection requirements.

(f) Upon completion of the compliance demonstration, the applicant for a supplemental type certificate shall declare to the Agency that:

1. it has demonstrated compliance with the type-certification basis and the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with points 21L.B.101, according to the compliance demonstration plan; and

2. no feature or characteristic has been identified that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested.

AMC1 21L.A.85 Demonstration of compliance

ED Decision 2023/013/R

DEMONSTRATION OF COMPLIANCE FOR A SUPPLEMENTAL TYPE CERTIFICATE

The description of the design change should include an explanation of the purpose of the change, the pre-modification and post-modification configuration(s) of the product, schematics/pictures, and any other detailed features and boundaries of the physical change (this may be supplemented by drawings or outlines of the design, if this helps to understand the design change), as well as the identification of the changes in areas of the product that are functionally affected by the change, and the identification of any changes to the approved manuals.

The applicant should identify any reinvestigations that are necessary to demonstrate compliance. This is a list of any affected items of the applicable certification basis for which a new demonstration is necessary, together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

(a) Compliance documentation for the demonstration of compliance under point 21L.A.85(a) comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable type-certification basis and environmental protection requirements is demonstrated.

(b) Each compliance document should typically contain:

— the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;

— substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

— the appropriate authorised signature.

(c) Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7.

The level of detail of the compliance documentation that is referred to in point 21L.A.85(a) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

For major changes (STCs) approved by a design organisation approval (DOA) holder on the basis of its privileges as per point 21.A.263(c)(8) of Annex I (Part 21), the process described in AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

AMC1 21L.A.85(b) Demonstration of compliance

ED Decision 2023/013/R

COMPLIANCE-DEMONSTRATION PLAN

The compliance-demonstration plan is a document that allows the applicant and EASA to manage and control the evolving supplemental type certificate design, as well as the process of compliance demonstration by the applicant and its verification by EASA when required.

In particular, the following information should typically be expected:

— identification of the relevant personnel that make decisions affecting airworthiness and environmental protection, and that will interface with EASA during the critical design review prior to issuance of the flight conditions and during the first-article inspection (if required), unless otherwise identified to EASA (e.g. within the design organisation procedures);

— a project schedule, including major milestones;

— subcontracting arrangements for design, environmental protection and/or production.

The applicant should provide detailed information about the proposed means of compliance with the applicable airworthiness and environmental protection requirements identified under point 21L.B.101. The information provided should be sufficient for EASA to easily determine the means of compliance used.

This should include the following:

— a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC1 21L.A.85 below for the relevant codes), and the related compliance document(s);

— identification of industry standards (Society of Automotive Engineers (SAE), American Society for Testing and Materials (ASTM), European Organisation for Civil Aviation Equipment (EUROCAE), AeroSpace and Defence Industries Association of Europe (ASD), etc.), methodology documents, handbooks, technical procedures, technical documents and specifications specified in the type certificate data sheet, certification memoranda, policy statements, guidance material, etc., that are proposed in the demonstration of compliance;

— when the compliance demonstration involves testing (point 21L.A.85(c) and (d)), a description of the ground- and flight-test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and

— when the compliance demonstration involves analyses/calculations, a description/ identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose; furthermore, the validation and verification of such tools and methods should be addressed.

For every aspect mentioned above, the applicant should clearly identify whether the demonstration of compliance involves any method (analysis or test) which is novel or unusual for the applicant. In addition, the applicant should identify any deviations from the published AMC to the relevant CSs.

Appendix A to AMC1 21L.A.85 Demonstration of compliance

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MEANS-OF-COMPLIANCE CODES

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analyses
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	*Note*: Equipment qualification is a process that may include all previous means of compliance at equipment level.

AMC1 21L.A.85(a);(b) Demonstration of compliance

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COMPLIANCE DOCUMENTATION

(a) Compliance documentation comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable type-certification basis and environmental protection requirements is demonstrated.

(b) Each compliance document should typically contain:

— the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;

— substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

— the appropriate authorised signature.

(c) Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7.

AMC1 21L.A.85(c) Demonstration of compliance

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INSPECTIONS AND TESTS

Proposed type design: this term defines the type design (or the portion of the type design) as it is determined at the time when the testing and inspections are carried out.

Verification document (also known as 'statement of conformity'): before each testing and inspection, the verification document must confirm that the test specimen conforms with the proposed design, the test and measuring equipment is adequate for the test, and the sensors and measuring system are appropriately calibrated.

Conformity of the test specimen: the documented verification is intended to ensure that the manufactured test specimen, even in the presence of non-conformities, adequately represents the proposed type design. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the proposed type design at the time of the test. These are typically identified in the early stage of the testing and inspection planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity as early as possible, the applicant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed, justified in the verification document or by cross reference to the test plan or other documents. However, testing for the demonstration compliance with the applicable environmental protection requirements should be conducted in the final design of the product having incorporated the change.

Type certification is typically an iterative process in which the design is under continuous evolution. If the type design evolves after the time of the testing and inspections, then the final type design should be checked against the proposed type design (as it was at the time of the testing and inspections), and the differences (if any) should be analysed to ensure that the testing and inspection results are representative of the final configuration. However, such changes made to the type design may lead to the invalidation of the testing and inspection results and the need to repeat the testing and inspections. It is recommended that the design organisation should have a thorough configuration management process to track the evolving type design.

Conformity of test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

  — type/model of sensors, together with their technical characteristics;

  — position and orientation of exciters and sensors; and

  — electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through certification test plans and supporting documentation, according to the design assurance system, if applicable. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The verification document should confirm that the test and measuring equipment conforms to its purpose, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This may be done either in the verification document or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test specimen, as well as the test and measuring equipment, is considered 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up do not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or masking any potential failure mode or behaviour).

Changes that affect the validity of the verification document: if changes need to be introduced to the test specimen or to the test and measurement equipment after the verification is documented (and before the test is undertaken), then the verification document must be updated. The updated verification document must be made available to EASA before the test if EASA has informed the applicant that it will witness or carry out the tests or inspections.

Development versus certification tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for certification (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21L.A.85(c).

Any planned test event should be classified in advance as either a development test or a certification test. Tests that support the compliance demonstration should be classified as certification tests.

It is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a certification test as long as it meets the requirements of point 21L.A.85(c). For this reason, it is important to keep the configuration of such tests under control.

If the test specimen used for a certification test has already undergone a series of previous tests that may affect or ultimately invalidate its acceptance as required by point 21L.A.85(c), this aspect should be considered when documenting the verification, and specific analyses or inspections may be required.

Because of the above aspects, EASA advises applicants to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as certification tests to establish whether EASA would wish to witness the tests.

GM1 21L.A.85(d) Demonstration of compliance

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FLIGHT TESTING

Detailed material on flight testing for compliance demonstration is included in the applicable CSs and GM. Information on flight testing for compliance demonstration with the applicable environmental protection requirements, especially in terms of aircraft noise, may be found in Volumes I, II and III of Annex 16 to the Chicago Convention and in ICAO Doc 9501 'Environmental Technical Manual'.

AMC1 21L.A.85(e)(1) Demonstration of compliance

ED Decision 2023/013/R

REVIEW OF DATA AND INFORMATION RELATED TO THE DEMONSTRATION OF COMPLIANCE

Availability of compliance data (see point 21L.A.85(e): data and information required to be provided by the applicant should be made available to EASA in a reliable and efficient way as agreed with EASA.

AMC1 21L.A.85(e)(2) Demonstration of compliance

ED Decision 2023/013/R

TESTS AND INSPECTIONS

The applicant should inform EASA sufficiently in advance about the execution of tests and inspections that:

— are used for compliance demonstration purposes; and

— have been identified as being of particular interest to EASA during the review and approval of the compliance demonstration plan

in order to permit EASA the opportunity to witness or carry out these inspections or tests.

The applicant may propose to EASA to witness or carry out flight or other tests of particular aspects of the product during its development and before the type design is fully defined.

However, in case of flight tests, the applicant should perform the tests before EASA witnesses or performs them to ensure that no features of the product preclude the safe conduct of the evaluation requested. EASA may require any such tests to be repeated once the type design is fully defined to ensure that subsequent changes have not adversely affected the conclusions from any earlier evaluation.

A verification document as per point 21L.A.85(c) is required for the above tests.

AMC1 21L.A.85(e)(3) Demonstration of compliance

ED Decision 2023/013/R

PHYSICAL INSPECTION OF THE FIRST ARTICLE

The applicant should be prepared for any additional investigations as notified by EASA according to point 21L.B.102(c).

Refer to AMC1 21L.A.25(e)(3) for the description of the compliance activities of the first-article inspection.

GM1 21L.A.85(f) Demonstration of compliance

ED Decision 2023/013/R

DECLARATION OF COMPLIANCE

All compliance-demonstration activities conducted in accordance with the compliance-demonstration plan, including all the testing and inspections conducted in accordance with point 21L.A.85(c) and all flight testing conducted in accordance with point 21L.A.85(d) and those necessary to determine compliance with the applicable environmental protection requirements should be completed before the issuance of the final declaration of compliance.

'No feature or characteristic' that may make the product unsafe in point 21L.A.85(f)(2) means the following: while every effort is made to address in the applicable certification basis all the risks to product safety that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant should declare that it has not identified any such feature or characteristic.

'No feature or characteristic' that may make the changed product environmentally incompatible (point 21L.A.85(f)(2)):

It is assumed that environmental compatibility is demonstrated when the changed product complies with the applicable environmental protection requirements. Therefore, the applicant, when declaring that the changed product complies with the applicable environmental protection requirements under point 21L.A.85(f)(1), should also declare that they have not identified any such feature or characteristic.

21L.A.86 Requirements for approval of a supplemental type certificate

Regulation (EU) 2022/1358

(a) In order to be issued with a supplemental type certificate, the applicant shall:

1. demonstrate their design capability in accordance with point 21L.A.83;
2. demonstrate that the change to a type certificate and the areas affected by the change comply with the type-certification basis and the applicable environmental protection requirements, as established by the Agency in accordance with point 21L.B.101;
3. demonstrate compliance in accordance with point 21L.A.85;
4. if the applicant has specified that they provided certification data on the basis ofan arrangement with the owner of the type-certification data in accordance with point 21L.A.84(b), demonstrate that the type-certificate holder:
   (i) has no technical objection to the information submitted under point 21L.A.65; and
   (ii) has agreed to collaborate with the applicant to ensure the discharge of all the obligations for continued airworthiness of the changed product through compliance with points 21L.A.28 and 21L.A.88;
5. demonstrate that there are no unresolved issues from the physical inspection of the first article of that product in the final changed configuration carried out by the Agency in accordance with point 21L.A.85(e)(3).

(b) A supplemental type certificate shall be limited to the specific configuration(s) in the type certificate to which the related major change relates.

AMC1 21L.A.86 Requirements for approval of a supplemental type certificate

ED Decision 2023/013/R

(a) For supplemental type certificates (STCs) approved by EASA, the AMC and GM to point 21L.A.25 should be followed by the applicant.

(b) In accordance with point 21L.A.86(b), the compliance-demonstration process must always cover the specific configuration(s) in the type certificate (TC) to which the STC under approval is applied. This (these) configuration(s) should be defined by the change to the type certificate considering the type certificate data sheet (TCDS) and the relevant optional installations. The demonstration of compliance covers this (these) applicable specific configuration(s). Consequently, the approval of the STC excludes any other configurations, in particular those that already exist, but are not considered in the compliance-demonstration process, as well as those that may be certified in the future.

(c) For STCs approved by the design organisation approval (DOA) holder under its privilege as per point 21.A.263(c)(9) of Annex I (Part 21), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

AMC1 21L.A.86(a)(5) Requirements for approval of a supplemental type certificate

ED Decision 2023/013/R

For the demonstration by the applicant that there are no unresolved issues, see AMC1 21L.A.27(d).

21L.A.87 Approval of a supplemental type certificate under a privilege

Regulation (EU) 2022/1358

(a) The approval of a supplemental type certificate for a major change it has designed may be issued by an approved design organisation without an application according to point 21L.A.84 in accordance with the scope of its privileges provided for in point (9) of point 21.A.263(c) of Annex I (Part 21) instead of the Agency, as recorded in the terms of approval.

(b) When issuing a supplemental type certificate in accordance with point (a), the design organisation shall:

1. ensure that all the substantiation data and justifications are available;
2. ensure that the compliance of the change with the type-certification basis and the applicable environmental protection requirements has been demonstrated and declared;
3. confirm that it has not found:
   (i) any non-compliances with the type-certification basis or, where applicable, with the applicable environmental protection requirements, or with the certification specifications chosen;

(ii) any feature or characteristic of the change that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested;

4. limit the approval of the supplemental type certificate to the specific configuration(s) in the type certificate to which the change relates.

21L.A.88 Obligations of a holder of a supplemental type certificate

Regulation (EU) 2022/1358

Each holder of a supplemental type certificate shall undertake the obligations of a supplemental type-certificate holder set forth in Subpart A of this Annex and shall continue to comply with the eligibility requirement under point 21L.A.82.

21L.A.89 Transferability of a supplemental type certificate

Regulation (EU) 2022/1358

A supplemental type certificate may be transferred to a new holder, provided that the Agency has verified that the natural or legal person to whom the certificate is intended to be transferred is eligible in accordance with point 21L.A.83 to hold a supplemental type certificate and is able to undertake the obligations of a supplemental type-certificate holder under point 21L.A.88.

21L.A.90 Continued validity of a supplemental type certificate

Regulation (EU) 2022/1358

(a) A supplemental type certificate shall remain valid as long as:

1. the supplemental type certificate is not surrendered by the holder;

2. the holder of the supplemental type certificate remains in compliance with the relevant requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, taking into account the provisions related to the handling of findings as specified under point 21L.B.21;

3. the supplemental type certificate is not revoked by the Agency in accordance with point 21L.B.22.

(b) Upon surrender or revocation, the type certificate shall be returned to the Agency.

21L.A.91 Changes to a part of a product covered by a supplemental type certificate

Regulation (EU) 2022/1358

(a) A minor change to a part of a product covered by a supplemental type certificate shall be approved in accordance with Subpart D of this Annex.

(b) A major change to that part of a product covered by a supplemental type certificate shall be approved as a separate supplemental type certificate in accordance with this Subpart.

(c) By way of derogation from point (b), a major change to that part of a product covered by a supplemental type certificate submitted by the supplemental type-certificate holder may be approved as a change to the existing supplemental type certificate in accordance with points 21L.A.63 to 21L.A.69.

SUBPART F — CHANGES TO AIRCRAFT FOR WHICH DESIGN COMPLIANCE HAS BEEN DECLARED

21L.A.101 Scope

Regulation (EU) 2022/1358

This Subpart establishes:

(a) the procedure for declaring the compliance of a change to the design of an aircraft which was subject to a declaration made in accordance with Subpart C of this Annex;

(b) the rights and obligations of the declarant making a declaration of compliance of the change referred to in point (a); and

(c) provisions regarding the standard changes that do not require a declaration of design compliance.

GM1 21L.A.101 Scope

ED Decision 2023/013/R

The term 'change to the design of an aircraft which was subject to a declaration' is used in Part 21 Light Subpart F, as well as in the related AMC and GM, to refer to any changes to the elements of the aircraft design data as defined in point 21L.A.46. Therefore, a declaration of design compliance should be required for any changes to the aircraft design data defined in point 21L.A.46.

21L.A.102 Standard changes

Regulation (EU) 2022/1358

(a) Standard changes are changes to the design of an aircraft which was subject to a declaration made in accordance with Subpart C of this Annex and which:

1. follow the design data included in the certification specifications issued by the Agency, containing the acceptable methods, techniques and practices for carrying out and identifying standard changes, including the associated instructions for continued airworthiness; and

2. are not in conflict with the design data covered by the declaration of aircraft design compliance made in accordance with Subpart C of this Annex.

(b) Points 21L.A.103 to 21L.A.108 are not applicable to standard changes.

GM1 21L.A.102 Standard changes

ED Decision 2023/013/R

APPLICABLE CERTIFICATION SPECIFICATIONS

CS-STAN[1] contains the certification specifications referred to in point 21L.A.102(a)(1). Guidance on the implementation of Standard Changes and Standard Repairs may be found in AMC M.A.801 of the AMC to Part-M.

[1] https://www.easa.europa.eu/en/certification-specifications/cs-stan-standard-changes-and-standard-repairs

21L.A.103 Classification of changes to the design of an aircraft for which design compliance has been declared

Regulation (EU) 2022/1358

(a) Changes to the design of an aircraft which was subject to a declaration made in accordance with Subpart C of this Annex shall be classified as minor or major, using the criteria laid down in points 21L.A.63 (b) and (c).

(b) The design compliance of a minor change shall be declared in accordance with point 21L.A.105.

(c) The design compliance of a major change shall be declared in accordance with point 21L.A.107.

GM1 21L.A.103 Classification of changes to the design of an aircraft for which design compliance has been declared

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Major changes that are classified as being 'substantial' should require a new declaration of design compliance to be submitted in accordance with Subpart C of Annex Ib (Part 21 Light).

Examples of major changes that are considered substantial may be found in Appendix B to GM1 21L.A.103.

(a) PURPOSE OF CLASSIFICATION

The purpose of the classification of changes to the design of an aircraft that was subject to a declaration made in accordance with point 21L.A.63 of Subpart C is to allow the declarants to determine the route to be followed for the declaration and whether they need to submit the declaration to EASA (major change) or to maintain it in order to make it available to EASA upon request (minor change).

Point 21L.A.63, as referenced by point 21L.A.103(a), requires that all changes be classified as either 'major' or 'minor' using the criteria in point 21L.A.63.

(b) INTRODUCTION

(1) Point 21L.A.63(b) and (c), as referenced by point 21L.A.103(a), proposes criteria for the classification of design changes as either 'minor' or 'major'.

This GM is intended to provide guidance on the term 'appreciable effect' affecting the airworthiness of the product, the declared noise or emissions levels or affecting any of the other characteristics mentioned in point 21L.A.63, where 'airworthiness' is interpreted in the context of a product in conformity with the applicable detailed technical specifications and is in condition for safe operation. It provides complementary guidelines to assess a change to the declared aircraft in order to meet the requirements of point 21L.A.103 where classification is the first step of a procedure.

Characteristics affecting the environmental compatibility of the product are characteristics affecting the compliance of the product with the applicable environmental protection requirements.

Note: For classification of repairs, see GM 21L.A.223.

Although this GM provides guidance on the classification of major changes, as opposed to minor changes as defined in point 21L.A.103, the GM and point 21L.A.103 are deemed entirely compatible.

Appendix A to GM1 21L.A.103 provides examples of major changes and a classification process.

(c) ASSESSMENT OF A CHANGE FOR CLASSIFICATION

(1) Changes to the declared design

Point 21L.A.103 addresses all changes to any of the aspects of a declaration of design compliance that was submitted under Subpart C.

(2) Reserved

(3) Classification process (see also the flow chart 'Classification process' in Appendix A to GM 21L.A.103)

Point 21L.A.103 requires all changes to be classified as either 'major' or 'minor', using the criteria of point 21L.A.63.

Wherever there is doubt as to the classification of a change, EASA should be consulted for clarification.

When the strict application of the point (c)(4) criteria results in a major classification, the declarant may request reclassification by EASA.

A simple design change planned to be mandated by an airworthiness directive may be reclassified as minor due to the involvement of EASA in the continued airworthiness process when this is agreed between EASA and the declarant.

The reasons for a classification decision should be recorded.

(4) General guidance on the classification of major changes

A change that is judged to have an 'appreciable effect on the mass, balance, structural strength, reliability, declared noise or emissions levels, operational characteristics, or other characteristics affecting the airworthiness or the environmental compatibility' is classified as major, in particular, but not only, when one or more of the following conditions are met:

(i) where the change requires an adjustment of the detailed technical specifications other than electing to comply with later certification specifications;

(ii) where the declarant proposes a new interpretation of the certification specifications used to define the applicable detailed technical specifications;

(iii) where the demonstration of compliance uses methods that have not been previously determined as appropriate for the nature of the change;

(iv) where the extent of new substantiation data necessary to comply with the applicable detailed technical specifications and the degree to which the original substantiation data has to be reassessed and re-evaluated is considerable;

(v) where the change alters the airworthiness limitations or the operating limitations;

(vi where the change is made mandatory by an airworthiness directive or the change is the terminating action of an airworthiness directive (ref. point 21L.A.4), see *Note* 1; and

(vii) where the design change introduces or affects functions where the failure effect is classified as 'catastrophic' or 'hazardous'.

Note 1: A change previously classified as minor and approved prior to the decision to issue an airworthiness directive needs no reclassification. However, EASA retains the right to review the change and reclassify/reapprove it if found necessary.

Note 2: The conditions listed in points (i) through (vii) above are an explanation of the criteria noted in point 21L.A.63 as referenced by point 21L.A.103.

For an understanding of how to apply the above conditions, it is useful to take note of the examples given in Appendix A to GM 21L.A.103.

(5) Guidance on the classification of changes to aircraft flight manuals (AFMs)

The following changes to the AFM are deemed to be minor:

(i) revisions to the AFM associated with changes to the design that are classified as minor in accordance with point 21L.A.103;

(ii) revisions to the AFM that are not associated with changes to the design (also identified as stand-alone revisions) which fall into one of the following categories:

(A) changes to limitations or procedures that remain within already declared limits (e.g. weight, structural data, etc.);

(B) consolidation of two or more previously declared and compatible AFMs into one, or the compilation of different parts taken from previously declared and compatible AFMs that are directly applicable to the individual aircraft (customisation); and

(C) the introduction into a given AFM of compatible and previously declared AFM amendments, revisions, appendices or supplements; and

(iii) administrative revisions to the AFM, defined as follows:

(A)

(a) editorial revisions or corrections to the AFM;

(b) conversions of previously Federal Aviation Administration (FAA)- or EASA-approved combinations of units of measurement added to the AFM in a previously approved manner;

(c) the addition of aircraft serial numbers to an existing AFM where the aircraft configuration, as related to the AFM, is identical to the configuration of aircraft already covered by that AFM;

(d) the removal of references to aircraft serial numbers no longer applicable to that AFM; and

(e) the translation of an AFM into the official language of the State of design or State of registry.

(6) Guidance on the classification of changes to declared aircraft noise levels

(i) Volume I of ICAO Doc 9501 'Environmental Technical Manual' defines 'no-acoustical changes' as changes that would result in very small changes in the declared noise level(s) and provide criteria for their determination. These changes have 'no appreciable effect' on the declared noise levels. Consequently, they are classified as minor changes and the declared noise level(s) remain unchanged.

(ii) All other changes to the declared aircraft noise levels are classified as major changes.

(iii) Examples of major changes are provided in Appendix A to GM1 21L.A.103.

Appendix A to GM1 21L.A.103 Classification of changes to the design of an aircraft for which design compliance has been declared

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EXAMPLES OF MAJOR CHANGES PER DISCIPLINE

The information below is intended to provide a few examples of major changes per discipline, resulting from the application of point 21L.A.103. It is not intended to present a comprehensive list of all major changes. Examples are categorised per discipline and are applicable to all products (aircraft, engines, propellers). However, a particular change may involve more than one discipline, e.g. a change to engine controls may be covered in engines and systems (software).

The persons that assess the change for its classification should always be aware of the interaction between disciplines and the consequences this will have when assessing the effects of a change (i.e. operations and structures, systems and structures, systems and systems, etc.).

Specific rules may exist which override the guidance of these examples.

In Part 21 Light, a negative definition is given of minor changes only. However, in the following list of examples, it was preferred to give examples of major changes.

Where in this list of examples the words 'has effect' or 'affect(s)' are used, they should always be understood as being the opposite of 'no appreciable effect' as in the definition of minor change in point 21L.A.63. Strictly speaking, the phrase 'has appreciable effect' and 'appreciably affect(s)' should have been used, but this has not been done to improve readability.

1. Structure

(i) Changes such as a change of dihedral, addition of floats.

(ii) Changes to materials, processes or methods of manufacture of primary structural elements, such as spars, frames and critical parts.

(iii) Changes that adversely affect fatigue or damage tolerance or life-limit characteristics.

(iv) Changes that adversely affect aeroelastic characteristics.

2. Cabin safety

(i) Changes which introduce a new cabin layout of sufficient change to require a reassessment of the emergency evacuation capability, or changes which adversely affect other aspects of passenger or crew safety.

Items to consider include but are not limited to:

— changes to or introduction of dynamically tested seats;

— changes to cabin layouts that affect evacuation path or access to exits;

— changes to the cabin area in striking distance of the occupant's head or torso introducing potentially injurious objects.

3. Flight

Changes which adversely affect the approved performance or brake changes that affect braking performance.

Changes which adversely affect the flight envelope.

Changes which adversely affect the handling qualities of the product, including changes to the flight controls function (gains adjustments, functional modification to software), or changes to the flight protection or warning system.

4. Systems

For systems assessed under CS 23.2510, the classification process is based on the functional aspects of the change and its potential effects on safety.

(i) Where the failure effect is 'catastrophic' or 'hazardous', the change should be classified as 'major'.

(ii) Where the failure effect is 'major', the change should be classified as 'major' if:

— aspects of the compliance demonstration will use a means that has not been previously utilised for the nature of the change to the system; or

— the change affects the pilot–system interface (displays, controls, approved procedures); or

— the change introduces new types of functions/systems such as GPS primary, TCAS, predictive windshear, HUD.

The assessment of the criteria for software changes to systems should also be performed.

When software is involved, account should be taken also of the following guidelines:

Where a change is made to software produced in accordance with the guidelines of the latest edition of AMC 20-115 (see AMC-20 document), the change should be classified as 'major' if either of the following applies, and the failure effect is 'catastrophic', 'hazardous' or 'major':

(i) the executable code for software, determined to be Level A or Level B in accordance with the guidelines, is changed unless that change involves only a variation of a parameter value within a range already verified for the previous certification standard; or

(ii) the software is upgraded to or downgraded from Level A, Level B or Level C; or

(iii) the executable code, determined to be level C, is deeply changed, e.g. after a software re-engineering process accompanying a change of processor.

For software developed to guidelines other than the latest edition of AMC 20-115, the declarant should assess the changes in accordance with the foregoing principles.

For other codes the principles noted above may be used. However, due consideration should be given to specific certification specifications/interpretations.

5. Propellers

Changes to:

(i) diameter,

(ii) aerofoil,

(iii) planform,

(iv) material,

(v) blade retention system, etc.

6. Engines

Changes:

(i) that adversely affect operating speeds, temperatures, and other limitations;

(ii) that affect or introduce parts identified by CS E-510 where the failure effect has been shown to be 'hazardous';

(iii) that affect or introduce engine critical parts (CS E-515) or their life-limits;

(iv) to a structural part which requires a resubstantiation of the fatigue and static load determination used during the original compliance demonstration;

(v) to any part of the engine which adversely affects the existing containment capability of the structure;

(vi) that adversely affect the fuel, oil and air systems, which alter the method of operation, or require reinvestigation against the original detailed technical specifications;

(vii) that introduce new materials or processes, particularly on critical components.

7. Noise

The examples provided below are not exhaustive and will not, in every case, result in an appreciable effect on the declared noise levels and, therefore, will not per se and in every case result in a major change classification.

Examples of noise-related changes for aeroplanes that might lead to a major change classification are:

(i) a change that might affect the aircraft's take-off performance including:

— a change to the maximum take-off mass;

— a change to the take-off distance;

— a change to the rate of climb; or

— a change to V_Y (best rate of climb speed);

(ii) a change that increases the aircraft's drag (e.g. the installation of external cargo pods, external fuel tanks, larger tyres to a fixed undercarriage, floats etc.);

(iii) a change of engine or propeller type;

(iv) a change in take-off power including a change in engine speed (tachometer 'red line') or, for piston engines, a change to the manifold pressure limitations;

(v) a change to the highest power in the normal operating range ('top of green arc');

(vi) in the case of an aircraft where take-off power/engine speed is time limited, a change in the period over which take-off power/engine speed may be applied;

(vii) a change to the engine inlet or exhaust including, if fitted, the inlet or exhaust muffler;

(viii) a change in propeller diameter, tip shape, blade thickness or the number of blades;

(ix) the installation of a variable or adjustable pitch propeller in place of a fixed pitch propeller and vice versa;

(x) a change that causes a change to the angle at which air flows into the propeller.

8. Power plant installation

Changes which include:

(i) control system changes which affect the engine/propeller/airframe interface;

(ii) new instrumentation displaying operating limits;

(iii) modifications to the fuel system and tanks (number, size and configuration);

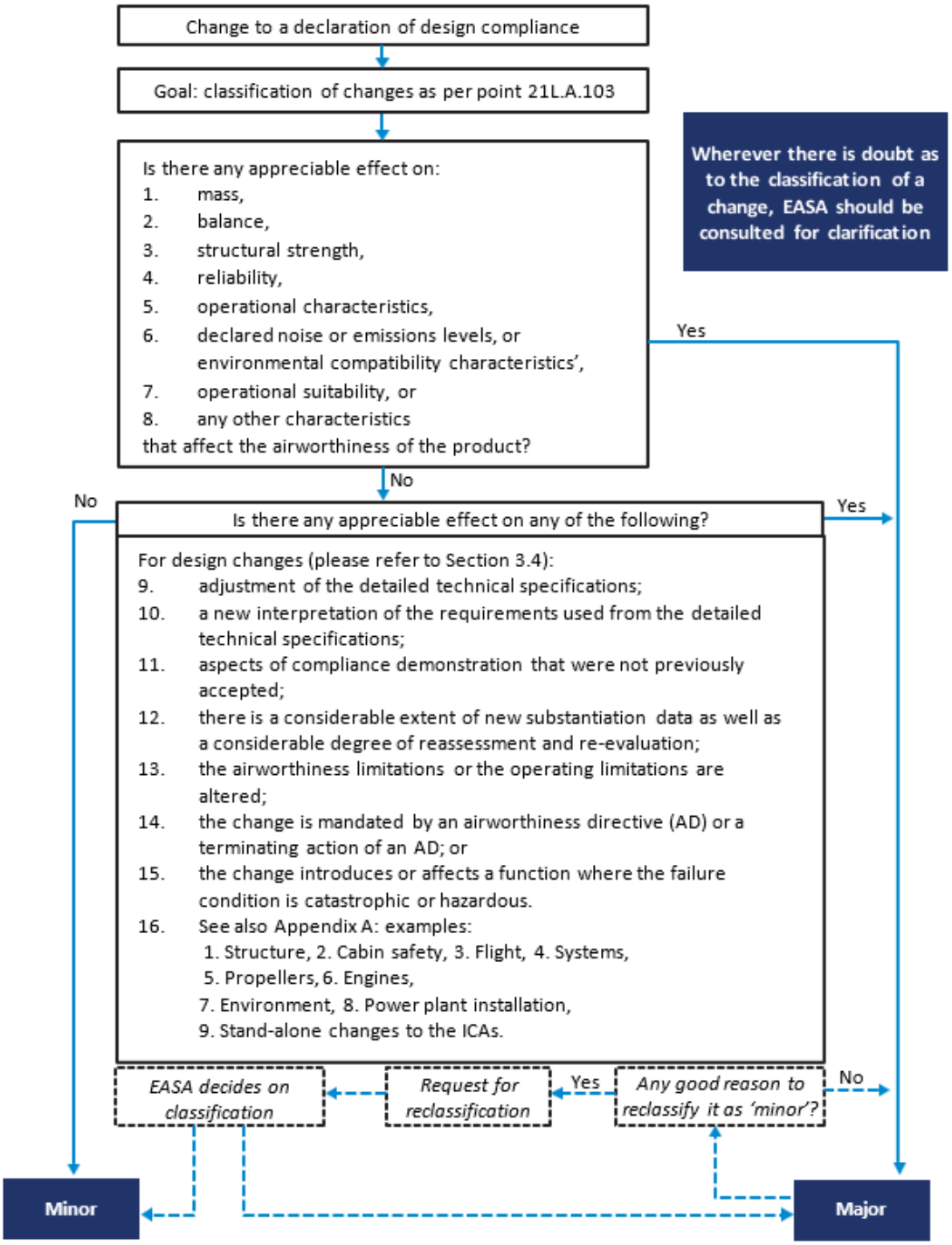
(iv) change of engine/propeller type.

9. Stand-alone changes to non-ALS ICAs that require additional work to demonstrate compliance with the applicable detailed technical specifications as follows:

(i) the introduction of novel technology for inspection purposes related to an ALS task;

(ii) changes that adversely affect the assumptions made during the original demonstration of compliance: e.g. some specific inspection procedures, such as inspection procedures for use after a hard landing, may include a decision-making chart based on the level of exceedance of the load in comparison with the limit loads; such criteria, and adverse changes, should be taken into consideration.

Declaration process



Appendix B to point 21L.A.103 Classification of changes to the design of an aircraft for which design compliance has been declared

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The following tables provide examples of 'substantial' changes. The classification may change due to cumulative effects and/or combinations of individual changes.

A.1 Examples of 'substantial' changes for small aeroplanes (CS-23)

A.1.1 Table A-1 contains examples of changes that are 'substantial' for small aeroplanes (CS-23).

Table A-1 — Examples of when a new declaration of design compliance would be required under Subpart C for substantial changes for small aeroplanes (CS-23)

Example	Description of change	Notes
1.	Change to wing location (tandem, forward, canard, high/low).	Proposed change to the design is so extensive that a substantially complete demonstration of compliance with the applicable detailed technical specifications is required.
2.	Change to engine configuration (tractor/pusher).	Proposed change to the design is so extensive that a substantially complete demonstration of compliance with the applicable detailed technical specifications is required.
3.	Change from an all-metal to all-composite aeroplane.	Proposed change to the design is so extensive that a substantially complete demonstration of compliance with the applicable detailed technical specifications is required.

21L.A.104 Eligibility

Regulation (EU) 2022/1358

(a) A declarant who made a declaration of aircraft design compliance in accordance with Subpart C of this Annex may declare compliance of a minor change to the design of that aircraft under the conditions laid down in this Subpart. In addition, such a declaration of compliance may also be made, under the conditions laid down in this Subpart, by a design organisation approved in accordance with point (c)(3) of point 21.A.263 of Annex I (Part 21) .

(b) Only the declarant who made a declaration of aircraft design compliance in accordance with Subpart C of this Annex may declare the compliance of a major change to the design of an aircraft for which design compliance has been declared in accordance with Subpart C of this Annex, under the conditions laid down in this Subpart.

(c) By derogation from point (b) of point 21L.A.104, if the declarant who made a declaration of aircraft design compliance in accordance with Subpart C of this Annex is no longer active or is unresponsive to requests for design changes, the compliance of a changed aircraft design may also be declared in accordance with Subpart C of this Annex by a design organisation approved in accordance with point (c)(4) of point 21.A.263 of Annex I (Part 21) within the scope of their terms of approval, or by any other natural or legal person who is able to undertake the obligations laid down in point 21L.A.47 with respect to that changed aircraft.

21L.A.105 Declaration of design compliance for minor changes

Regulation (EU) 2022/1358

(a) Prior to installing or incorporating or agreeing with a production organisation to install or incorporate a minor change to the design of an aircraft for which design compliance has been declared in accordance with Subpart C of this Annex the organisation that has designed that minor change shall declare that the design of that minor change complies with:

1. either the detailed technical specifications incorporated by reference in the declaration of design compliance of the aircraft, unless those detailed technical specifications or parts of them are no longer applicable in accordance with point 21L.B.61 because the Agency has determined that experience from other similar products in service or products that have similar design features has shown that unsafe conditions may develop, and the detailed technical specifications that were referenced in the declaration of design compliance of the aircraft do not address this unsafe condition, or

2. the detailed technical specifications applicable, on the date on which the declaration is made in accordance with point 21L.B.61, if chosen by the declarant; and

3. the applicable environmental protection requirements referred to in point 21L.B.61 which are applicable on the date on which the declaration is made.

(b) The declaration of design compliance shall be made in a form and manner established by the Agency.

(c) The declarant or the organisation that has designed the minor change shall maintain a register of minor changes to the design of aircraft for which design compliance has been declared, and make any declaration made in accordance with point (a) available to the Agency upon request.

AMC1 21L.A.105(a) Declaration of design compliance for minor changes

ED Decision 2023/013/R

REQUIREMENTS FOR THE DECLARATION OF A MINOR CHANGE

(a) Applicability of point 21L.A.105

Point 21L.A.105 should be complied with by declarants for the declaration of compliance of a minor change, including design organisation approval (DOA) holders that declare compliance of minor changes under their privileges as per point (c)(3) of point 21.A.263 of Annex I (Part 21).

In accordance with point 21L.A.105(c) for declarations of compliance for minor changes, the substantiating data and the declaration of compliance required by point 21L.A.105(a) should be produced but does not need to be submitted to EASA. They should be, however, kept on record and made available to EASA upon request during any oversight visit.

(b) The declaration process

The declaration process comprises the following steps:

(1) classification of the change;

(2) applicable detailed technical specifications;

(3) determination of compliance;

(4) declaration of design compliance.

(c) Detailed technical specifications

The detailed technical specifications for a minor change consist of the detailed technical specifications that were incorporated by reference in the declaration of design compliance that was submitted for the particular aircraft under Subpart C unless EASA has determined that these are no longer appropriate, and the latest detailed technical specifications should be complied with or the declarant elects to comply with these detailed technical specifications.

(d) Determination of compliance required by point 21L.A.105(a)

The declarant should determine compliance with the applicable detailed technical specifications established for the minor change for all areas that are either physically changed or functionally affected by the minor change.

(1) Means of compliance: the declarant should define and record the means (calculation, test or analysis, etc.) by which compliance is determined. Appendix A to AMC1 21L.A.108(a) may be used for this purpose.

(2) Compliance documents: the compliance determination should be recorded in compliance documents. For minor changes, one comprehensive compliance document may be sufficient, provided that it contains evidence of all aspects for compliance. AMC1 21L.A.108(b) may also be used, where applicable.

(3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

See also additional guidance below (point (e)) on embodiment/installation instructions.

(e) Embodiment/installation instructions

The instructions for the embodiment/installation of the change (e.g. service bulletin, modification bulletin, production work order, etc.) should be defined. This may include the installation procedure, the required material, etc.

AMC1 21L.A.105(b) Declaration of design compliance for minor changes

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FORM AND MANNER

The declarant should complete and file a declaration of compliance for the minor change using the form which can also be downloaded from the EASA website for the declaration of minor changes/minor repair designs.

If there are any changes to the data (e.g. propeller or engine designation) that was provided in the EASA Part 21 Light database of declared noise levels as a result of the minor change, then this data should be added by the declarant.

The justification of the classification of the change should also be recorded.

EASA Form 201

Declaration of design compliance for a Minor Change / Minor Repair Design

1. Designation	
Minor Change ☐	Minor Repair ☐

2. Product Identification	
☐ Small Aeroplane with a MTOM of 1200Kg or less and a max seating configuration of 2 persons.	☐ Sailplane with a MTOM of 1200kg or less ☐ Powered Sailplane with a MTOM of 1200kg or less ☐ Balloon designed for no more than 4 persons ☐ Hot Airship designed for no more than 4 persons.

2.2 Applicability		
2.2.1 Design details	Registered Declaration Number for the original product	
	Original Declarant	
	Type Name	
	Model(s)	
2.3 Applicable technical specifications	Please specify the applicable airworthiness code, e.g. CS-23 (if these are not the original technical specifications against which compliance was originally declared in accordance with Part 21 Light Subpart C due to the reasons stated in 21L.A.105 (a)(1) or (2) then this should be indicated here).	

3. Description	
3.1 Title	Please limit to 40 characters
3.2 Description	
3.3 Affected Areas (including manuals)	

3.4 Re-Investigations	

4. Declarants' declaration and acceptance of the General Conditions		
I declare that I have the legal capacity to make this declaration and that all information provided in this declaration is correct and complete. I hereby declare that the design of the minor change/repair described in Section 3 is in compliance with the applicable detailed technical specifications detailed in Section 2.3 and the applicable environmental protection requirements. I hereby declare that no features or characteristics have been identified that may make the aircraft after the minor change or repair has been incorporated unsafe or environmentally incompatible for the intended use. I hereby commit to undertake the obligations of a declarant of a declaration of design compliance as detailed in point 21L.A.106 of Annex Ib to Regulation (EU) 748/2012. I declare that I have provided the required information and that it is accurate and complete and indicated where it is not applicable.		
Date/Location	Name	Signature
This Declaration should be retained by the declarant and made available upon request by EASA		

AMC1 21L.A.105(c) Declaration of design compliance for minor changes

ED Decision 2023/013/R

REGISTER OF DECLARATIONS FOR MINOR CHANGES

The register that is used by the declarant to record the declarations of design compliance for minor changes should also comply with point 21L.A.7 and be easily accessible in case EASA requests the details of a specific minor change during oversight.

21L.A.106 Obligations of the person making a declaration of compliance of the design of a minor change

Regulation (EU) 2022/1358

Any person that has made a declaration of compliance of a minor change to an aircraft design in accordance with point 21L.A.105 shall:

(a) maintain a register of those declarations and shall make those declarations available to the Agency upon request;

(b) retain all supporting documents for a declaration of design compliance, and make them available to the Agency upon request;

(c) undertake all other obligations of a declarant of a declaration of design compliance set forth in Subpart A of this Annex.

21L.A.107 Declaration of design compliance for a major change

Regulation (EU) 2022/1358

(a) Prior to installing or incorporating or agreeing with a production organisation to install or incorporate a major change to the design of an aircraft for which design compliance has been declared in accordance with Subpart C of this Annex, the organisation that has designed that major change shall declare that the design of that major change and the areas affected by that change comply with:

1. either the detailed technical specifications incorporated by reference in the declaration of design compliance of the aircraft, unless those detailed technical specifications or parts of them are no longer applicable in accordance with point 21L.B.61 because the Agency has determined that experience from other similar products in service or products that have similar design features has shown that unsafe conditions may develop and the detailed technical specifications that were referenced in the declaration of design compliance of the aircraft do not address this unsafe condition, or

2. the detailed technical specifications applicable on the date on which the declaration is made in accordance with point 21L.B.61, if chosen by the declarant; and

3. the applicable environmental protection requirements referred to in point 21L.B.61 which are applicable on the date on which the declaration is made.

(b) The declaration of design compliance shall be made in a form and manner established by the Agency.

(c) The declaration shall contain at least the following information:

1. the name of the person submitting the declaration, and their address/place of business;
2. the declaration reference number of the aircraft to which the major change relates;
3. a unique reference for identifying the major change;
4. indication of the detailed technical specifications and the applicable environmental protection requirements with which the declarant declares compliance;
5. a signed statement made under the sole responsibility of the person making the declaration that the design of the major change is in compliance with the detailed technical specifications and the applicable environmental protection requirements referred to in point (4), according to the compliance demonstration plan referred to in point (d)(3);
6. a signed statement made under the sole responsibility of the person making the declaration that no features or characteristics have been identified by that person that may make the aircraft unsafe or environmentally incompatible for the intended use;
7. a signed commitment that the person making the declaration will undertake the obligations referred to in point 21L.A.47 in respect of the changed aircraft design;
8. the instructions for continued airworthiness;
9. the operating limitations, if changed;
10. the data sheet for airworthiness and, if applicable, the record of emissions compliance;
11. the data sheet for noise, if applicable;
12. any other conditions or limitations prescribed for the aircraft in the applicable detailed technical specifications and the applicable environmental protection requirements with which the declarant declares compliance.

(d) The declarant that designs a major change shall submit the declaration referred to in point (c) to the Agency. Together with this declaration, the declarant shall provide to the Agency:

1. a description of the major change;
2. basic data about the major change, including the operating characteristics, design features and any limitations;
3. a compliance demonstration plan detailing the means for compliance demonstration that was followed during the compliance demonstration;
4. recorded justifications of compliance within the compliance data obtained from the compliance activities that have been conducted according to the compliance demonstration plan;
5. the means by which such compliance with the applicable detailed technical specifications and applicable environmental protection requirements in point 21L.B.61 has been demonstrated;

6. where compliance is demonstrated by carrying out tests, recorded justification of the conformity of the test articles and equipment, demonstrating:

(i) for the test specimen, that:

(A) the materials and processes adequately conformed to the specifications for the design;

(B) the constituent parts of the products adequately conformed to the drawings in the design; and

(C) the manufacturing processes, construction and assembly adequately conformed to those specified in the design;

(ii) that the test and measuring equipment used for the test were adequate for the test and appropriately calibrated;

7. reports, results of inspections or tests that the declarant found necessary to determine that the aircraft complies with the applicable detailed technical specifications and applicable environmental protection requirements.

(e) The declaration of a major change to a declaration of design compliance shall be limited to the specific configuration(s) in the declaration of design compliance to which the change relates.

AMC1 21L.A.107(b) Declaration of design compliance for a major change

ED Decision 2023/013/R

FORM AND MANNER

The request for registration should be completed along with the declaration of design compliance and sent to EASA by email or regular mail following the information provided on the EASA website[1].

If the data sheet for airworthiness needs to be adapted, then an amended version should also be provided.

If there are any changes to the data that was provided in the EASA Part 21 Light database of declared noise levels as a result of the major change, then this data should be added by the declarant as a new record within the EASA Part 21 Light database identifying that it is applicable after the major change.

EASA Form 202

PART 1 – REQUEST FOR REGISTRATION AND DECLARATION OF DESIGN COMPLIANCE FOR A MAJOR CHANGE/ MAJOR REPAIR

1. Identification of Activity			
Major Change	☐	Major Repair	☐

2. Product Identification		
2.1 Applicability	Declared Type Name (this must be a unique means to identify the aircraft)	

[1] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (accessed: 20 October 2023).

	Declared Model Name(s)	
	Original Declarant	
	Registered Declaration No	
2.2 Product Category	☐ Small Aeroplane with a MTOW of 1 200 kg or less and a max. seating configuration of 2 persons ☐ Sailplane with a MTOW of 1 200 kg or less ☐ Powered Sailplane with a MTOW of 1 200 kg or less ☐ Balloon designed for no more than 4 persons ☐ Hot Air Airship designed for no more than 4 persons	
2.3 Technical Specifications	Please specify the applicable technical specifications, e.g. CS-23 (if these are not the original technical specifications against which compliance was originally declared in accordance with Part 21 Light Subpart C due to the reasons stated in 21L.A.107 (a)(1) or (2) then this should be indicated here).	
2.4 Environmental Protection Requirements (if applicable)	Please specify the environmental protection requirements with which compliance has been determined	

3. Description	
3.1 Title	Please limit to 40 characters
3.2 Description	
3.3 Affected Areas including manuals	
3.4 Re-Investigations	Compliance Demonstration Plan – doc. Ref.: (Please provide the reference of the Compliance Demonstration Plan required by 21L.A.107(d)(3) or 21L.A.226(d)(3), respectively) Documentation, if changed, to submit with the Declaration in accordance 21L.A.107(c): • Airworthiness Data Sheet

	• Aircraft Flight Manual including any limitations • Instructions for Continued Airworthiness • Any other conditions/limitations which the declarant wishes to declare • EASA Noise Record Number

4. Declarant's Statement		
4.1. Declaration of Compliance		
I declare that I have the legal capacity to submit this Declaration to EASA and that all information provided in this Declaration form is correct and complete. I hereby declare that the design of the major change/repair described in Section 3 is in compliance with the applicable detailed technical specifications detailed in Section 2.3 and the applicable environmental protection requirements (if applicable) in Section 2.4 in accordance with the compliance demonstration plan detailed in Section 3.4. I hereby declare that no features or characteristics have been identified that, after the major change or repair has been incorporated, may make the aircraft unsafe or environmentally incompatible for the intended use. I hereby commit to undertake the obligations of a Declarant of a Declaration of Design Compliance as detailed in point 21L.A.47 and for major repairs (if applicable) point 21L.A.228 of Annex Ib to Regulation (EU) 748/2012. I declare that I have provided the required information in 3.4 and that it is accurate and complete and indicated where it is not applicable.		
Date/Location	Name	Signature
Important Note: EASA cannot accept Declarations without signature. Please make sure that you sign the Declaration.		
This declaration should be sent by email to: applicant.services@easa.europa.eu		

GM1 21L.A.107(c) Declaration of design compliance for a major change

ED Decision 2023/013/R

INFORMATION TO BE PROVIDED TO EASA

The documents and information that are required to be provided to EASA under point 21L.A.107(c) may be provided to EASA by the declarant in advance of the submission of the declaration of design compliance for the major change. This would be advantageous for the declarant to facilitate EASA's investigations and to determine the need for the first-article inspection under point 21L.B.121(b).

AMC1 21L.A.107(e) Declaration of design compliance for a major change

ED Decision 2023/013/R

SPECIFIC CONFIGURATION(S)

The compliance-demonstration process always takes into account the specific configuration(s) in the declaration of design compliance to which the major change relates. This (these) configuration(s) may be defined by product models/variants or by design changes to the declaration. The demonstration of compliance applies to this (these) applicable specific configuration(s). Consequently, the declaration of the major change excludes any other configurations, in particular those that already exist but are not considered in the compliance-demonstration process, as well as those that may be declared in the future.

21L.A.108 Compliance activities for declaring compliance of a major change

Regulation (EU) 2022/1358

Prior to making a declaration of compliance in accordance with point 21L.A.107, the declarant shall, for that specific design:

(a) establish a compliance demonstration plan detailing the means for compliance demonstration that shall be followed during the compliance demonstration. This document shall be updated as necessary;

(b) record the justification of compliance within compliance documents according to the compliance demonstration plan;

(c) perform testing and inspections as necessary in accordance with the compliance demonstration plan;

(d) ensure and record the conformity of the test articles and equipment and ensure that the test specimen conforms to the specifications, drawings, manufacturing processes, construction and assembly means in the design;

(e) ensure that the test and measuring equipment to be used for testing are adequate for testing and appropriately calibrated;

(f) allow the Agency to conduct or participate in any inspections or tests of aircraft in the final or suitably mature design and production configuration that are necessary to determine that the changed product has no feature or characteristic that makes the aircraft unsafe or environmentally incompatible for the intended use;

(g) carry out flight testing, in accordance with the methods for such flight testing specified by the Agency, as necessary to determine that the aircraft complies with the applicable detailed technical specifications and the applicable environmental protection requirements.

GM1 21L.A.108 Compliance activities for declaring compliance of a major change

ED Decision 2023/013/R

VOLUNTARY INVOLVEMENT OF EASA PRIOR TO THE SUBMISSION OF DECLARATION

The declarant may choose to involve EASA prior to submitting the declaration of design compliance for a major change. This would allow EASA to:

(f) check the scope of the product is still within the scope of Subpart C;

(g) provide guidance on the completeness of the compliance-demonstration plan and the selection of means of compliance;

(h) advise on the selection of the applicable detailed technical specifications and applicable noise requirements;

(i) provide guidance about noise tests (if applicable) and witness them;

(j) avoid any issues or delays during the the physical inspection and assessment of the aircraft (if considered necessary prior to issuing flight conditions under point 21L.B.242(a)4) or if considered to be necessary under point 21L.B.121(b)).

The initiation of the project may occur before starting the compliance activities or during those activities. The assignment of a dedicated project number would facilitate any subsequent communication with EASA. This will facilitate the provision of compliance documentation required by point 21L.A.107(d), which may be provided by the declarant to EASA at key stages in the compliance demonstration prior to the submission of the declaration of design compliance for the major change.

AMC1 21L.A.108(a) Compliance activities for declaring compliance of a major change

ED Decision 2023/013/R

COMPLIANCE-DEMONSTRATION PLAN FOR A MAJOR CHANGE

The compliance-demonstration plan for a major change is a document that allows the declarant to manage and control the design of the major change, as well as the process of compliance demonstration, and that enables EASA to investigate the root cause(s) in the event of a safety issue being discovered.

The description of the change should include an explanation of the purpose of the change, the pre-modification and post-modification configuration(s) of the aircraft, schematics/pictures, and any other detailed features and boundaries of the physical change (this may be supplemented by drawings or outlines of the design, if this helps to understand the design change), as well as the identification of the changes in areas of the aircraft that are functionally affected by the change, and the identification of any changes to the approved manuals.

The items of the declaration of aircraft design compliance made in accordance with Subpart C that are affected by the change and for which a new demonstration of compliance is necessary should be identified together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

The compliance demonstration should include the analysis for the classification of the change in accordance with GM1 21L.A.103.

In particular, the following information should typically be expected:

— identification of the relevant personnel that make decisions affecting airworthiness and environmental compatibility, and that will interface with EASA during any physical inspection and assessment of the changed product if required under point 21L.B.121(b);

— subcontracting arrangements for design, environmental compatibility and/or production (if applicable).

Point 21L.A.107(d)(1) 'Description of the major change'

An overview of the:

— architecture, functions, systems;

— dimensions, design weights, payloads, design speeds;

— engines and power/thrust rating;

— materials and technologies;

— cabin configuration aspects;

— options (e.g. weight variants, power/thrust rating variants, optional avionics equipment items, brake options, tyre options, floats, skids).

Point 21L.A.107(d)(2) 'Operating characteristics, design features and limitations'

— operating speed limitations;

— service ceiling, maximum airfield elevation;

— cabin pressure;

— limit load factors;

— number of passengers, minimum crew, payload, range;

— weight and centre-of-gravity (CG) envelope and fuel loading;

— performance;

— environmental envelope;

— runway surface conditions;

— other items, if considered to be more appropriate, which address the specific aeronautical product.

The declarant should provide detailed information about the means of compliance with the applicable requirements identified under point 21L.A.107(a). This should include the following:

— a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC1 21L.A.107(a) below for the relevant codes), and the related compliance document(s);

— identification of industry standards, methodology documents, handbooks and any other acceptable means of compliance, specified in the airworthiness or noise data sheet, which have been followed in the demonstration of compliance;

— when the compliance demonstration involves testing, a description of the ground- and flight-test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and

— when the compliance demonstration involves analyses/calculations, a description/ identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose.

For every aspect mentioned above, the declarant should clearly identify whether the demonstration of compliance involves different means than those contained in the published AMC to the relevant CSs and any method (analysis or test) which is novel or unusual for the declarant.

For every aspect related to compliance with the applicable environmental protection requirements mentioned above, the declarant should clearly identify whether the demonstration of compliance involves means that are described in ICAO Doc 9501 'Environmental Technical Manual'.

Appendix A to AMC1 21L.A.108(a) Compliance activities for declaring compliance of a major change

ED Decision 2023/013/R

MEANS-OF-COMPLIANCE CODES

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analyses
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	*Note*: Equipment qualification is a process that may include all previous means of compliance at equipment level.

AMC1 21L.A.108(b) Compliance activities for declaring compliance of a major change

ED Decision 2023/013/R

COMPLIANCE DOCUMENTATION

(a) Compliance documentation comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable detailed technical specifications and environmental protection requirements has been demonstrated.

(b) Each compliance document should typically contain:

— the reference of the detailed technical specifications or environmental protection requirements addressed by the document;

— substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the declarant declaring that the document provides the proof of compliance for which it has been created; and

— the declarant's signature.

(c) Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7.

AMC1 21L.A.108(c);(d);(e) Compliance activities for declaring compliance of a major change

ED Decision 2023/013/R

INSPECTIONS AND TESTS

In accordance with point 21L.A.108(d), the declarant must address the conformity of the test specimen, as well as of the test and measuring equipment.

Conformity of the test specimen

The recorded justification of the conformity of the test articles is intended to ensure that the manufactured test specimen adequately represents the declared applicable design data. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the originally intended design data at the time of the test. These are typically identified in the early stage of the test planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity as early as possible, the declarant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed and justified by cross reference to the test plan or other documents. However, testing for the demonstration compliance with the applicable environmental protection requirements should be conducted with the final design of the product having incorporated the change.

Compliance demonstration is typically an iterative process in which the design is under continuous evolution. If the aircraft design evolves after the time of the inspection or test, then the final major change design should be checked against the originally intended design (as it was at the time of the inspection or test), and the differences (if any) should be analysed to ensure that the inspection or test results are representative of the final configuration. However, such changes made to the design may lead to the invalidation of the inspection or test results and the need to repeat the inspection or test. It is recommended that the declarant should have a thorough configuration management process to track the evolving design of the major change.

Conformity of the test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

  — type/model of sensors, together with their technical characteristics;

  — position and orientation of exciters and sensors; and

  — electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through test plans and supporting documentation. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The declarant should confirm that the test and measuring equipment conforms to its definition in the test plan, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This may be done either in the recorded justification of the conformity of the test articles and equipment or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test and measuring equipment is considered 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up do not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or by masking any potential failure mode or behaviour).

Changes that affect the validity of the recorded justification of the conformity of the test articles and equipment: if changes need to be introduced to the test specimen or to the test and measurement equipment after the justification has been recorded (and before the test is undertaken), then it must be updated.

Development versus compliance-demonstration tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for demonstration of compliance (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21L.A.108(d) and (e).

Any planned test event should be classified in advance as either a development test or a compliance-demonstration test.

It is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a compliance-demonstration test as long as it meets the requirements of point 21L.A.108(d) and (e). For this reason, it is important to keep the configuration of such tests under control.

If the test specimen used for a compliance-demonstration test has already undergone a series of previous tests that may affect or ultimately invalidate its validity due to potential non-conformity to 21L.A.108(d) as required by point 21L.A.107(d)(6), this aspect should be considered when justifying the conformity, and specific analyses or inspections may be required to support such a statement.

Because of the above aspects, declarants may wish to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as demonstration-of-compliance tests to establish whether EASA would wish to witness the tests.

AMC1 21L.A.108(f) Compliance activities for declaring compliance of a major change

ED Decision 2023/013/R

PHYSICAL INSPECTION OF THE FIRST ARTICLE

The declarant should be prepared for any additional investigations as notified by EASA according to point 21L.B.121(b).

Refer to AMC 21L.A.47(a) for an explanation of the activities performed under the first-article inspection.

GM1 21L.A.108(f) Compliance activities for declaring compliance of a major change

ED Decision 2023/013/R

INSPECTIONS AND TESTS PERFORMED BY EASA

The declarant should inform EASA sufficiently in advance about the execution of significant inspections and tests that are used for compliance-demonstration purposes in order to permit EASA the opportunity to perform or witness these inspections or tests in advance of any physical inspection and assessment of the changed product if required by point 21L.B.121(b).

This would be advantageous for the declarant to avoid any issues or delays if a physical inspection and assessment of the changed product is required (see point 21L.B.121(b)).

Additionally, the declarant may propose to EASA to perform or witness flight or other tests of particular aspects of the product during its development and before the design of the major change is fully defined. However, before EASA performs or witnesses any flight test, the declarant should perform these tests and should ensure that no features of the product preclude the safe conduct of the evaluation requested.

A recorded justification of the conformity of the test articles and equipment as per point 21L.A.107(d)(6) is required for the above tests.

SUBPART G — DECLARED PRODUCTION ORGANISATIONS

21L.A.121 Scope

Regulation (EU) 2022/1358

(a) This Subpart establishes:

1. the procedures for declaring the production capability of natural and legal persons showing the conformity of products and parts with the applicable design data;
2. the rights and obligations of the natural and legal persons making a declaration of production capability referred to in point (1).

(b) The following categories of products and parts may be produced by organisations which have made a declaration of production capability in accordance with this Subpart:

1. products and parts the design of which has been certified in accordance with this Annex;
2. aircraft the design of which is covered by a declaration made in accordance with this Annex, and their engines, propellers and parts.

GM1 21L.A.121(a) Scope

ED Decision 2023/013/R

APPLICABLE DESIGN DATA

Applicable design data is defined as all necessary drawings, specifications and other technical information provided by the applicant for, or holder of, a design approval to be issued in accordance with this Annex or by a natural or legal person that has declared or intends to declare the compliance of the aircraft design in accordance with this Annex, and has released it in a controlled manner to a declared production organisation. This should be sufficient for the development of production data to enable repeatable manufacture to take place in conformity with the applicable design data.

Prior to the issuance of the type certificate (TC), supplemental type certificate (STC), approval of the changes to the TC/STC or approval of the repair design, design data is defined as ‘non- approved’ but parts may be released with an EASA Form 1 as a certificate of conformity.

After the issuance of the TC, STC, approval of the changes to the TC/STC or approval of the repair design, the design data is defined as ‘approved’ and items manufactured in conformity with this data are eligible for release on an EASA Form 1 for airworthiness purposes.

When the compliance of the aircraft design and any subsequent compliance of any changes to the design or the repair design are subject to a declaration according to the requirements of Subparts C, F or N respectively of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012, the design data is considered ‘non-approved’. However, a distinction can be made between the status of the data before the issuance of the declaration and after. This will be indicated in Block 12 ‘Remarks’ of the EASA Form 1.

Note: For the EASA Form 1 layout, contents and instructions for completion, please refer to Appendix I to Annex I (Part 21) to Regulation (EU) No 748/2012.

For the purpose of Subpart G of Part 21 Light, the term ‘applicable design data’ includes the information related to the applicable environmental protection requirements.

21L.A.122 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person ('organisation') may declare their production capability under this Subpart, if that person:

(a) has applied or intends to apply for the approval of the design of the product or part in accordance with this Annex; or

(b) has declared or intends to declare the compliance of an aircraft design in accordance with this Annex; or

(c) is collaborating with the applicant for, or holder of, an approval of the design of the product to be issued or issued in accordance with this Annex, or with the organisation that has declared or intends to declare the compliance of that aircraft design in accordance with this Annex, in order to ensure that the manufactured product or part is in conformity to that design, and to ensure the continued airworthiness of the product or part.

GM1 21L.A.122(a);(b) Eligibility

ED Decision 2023/013/R

INTERFACE BETWEEN DESIGN AND PRODUCTION

In the natural or legal person that declares the production capability there is a need for an interface between staff responsible for design and staff responsible for production. This interface may be achieved through common design and production procedures.

Other ways to document this interface may be also used. For example, by defining simple flow charts supported by self-explanatory forms, or by task descriptions of the responsible functions in the organisation. IT-based enterprise resource planning (ERP) systems may be used to ensure and to demonstrate that there is a correct flow of information on the basis of defined and visible workflows with assigned roles and release gates.

Such interface normally covers the following aspects:

— the transfer of applicable design data from design to production (including their status: approved / non-approved);

— the development of own manufacturing data;

— the management of continued airworthiness matters and required actions;

— the cooperation in compliance-demonstration activities (e.g. manufacturing and testing prototype models and test specimens);

— the management of production deviations and non-conforming parts; and

— the configuration control of manufactured parts.

AMC1 21L.A.122(c) Eligibility

ED Decision 2023/013/R

ARRANGEMENTS BETWEEN DESIGN AND PRODUCTION ORGANISATIONS

In accordance with point 21L.A.122(c), the natural or legal person that declares their production capability (referred to as 'declared production organisation' in this AMC and in GM1 21L.A.122(c)) must collaborate with the applicant for, or holder of, an approval of the design of the product, or with the organisation that has declared or intends to declare the compliance of that aircraft design

(referred to as 'design organisation' in this AMC and in GM1 21L.A.122(c)) to ensure that the manufactured product or part is in conformity to that design, and to ensure the continued airworthiness of the product or part.

An acceptable means of compliance with point 21L.A.122(c) is an arrangement documented between the declared production organisation and the design organisation that are separate legal entities.

GM1 21L.A.122(c) Eligibility

ED Decision 2023/013/R

ARRANGEMENT BETWEEN DESIGN AND PRODUCTION ORGANISATIONS — FORMAT

To define such a design–production interface, the following sample form is offered:

ARRANGEMENT SAMPLE FORM

<table>
<tr><td colspan="2">ARRANGEMENT
in accordance with point 21L.A.122(c) of Annex Ib (Part 21 Light)</td></tr>
<tr><td>- The undersigned agree to commit to the following:</td><td>- Relevant interface procedures</td></tr>
<tr><td>The design organisation [NAME] takes responsibility to:
assure the correct and timely transfer of up-to-date applicable design data (e.g. drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the declared production organisation [NAME];
provide visible statement(s) of approved or declared design data.</td><td></td></tr>
<tr><td>The declared production organisation [NAME] takes responsibility to:
assist the design organisation [NAME] in dealing with continuing airworthiness matters and for required actions;
assist the design organisation [NAME] in case of products prior to type certification in demonstrating compliance with the applicable certification specifications and environmental protection requirements;
develop, where applicable, its own manufacturing data in compliance with the airworthiness data package.</td><td></td></tr>
<tr><td>The design organisation [NAME] and the declared production organisation [NAME] take joint responsibility to:
deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the declared production organisation;
achieve adequate configuration control of manufactured parts to enable the declared production organisation to make the final determination and identification for conformity.</td><td></td></tr>
<tr><td colspan="2">The scope of production covered by this arrangement is detailed in [DOCUMENT REFERENCE / ATTACHED LIST].</td></tr>
<tr><td colspan="2">- Transfer of applicable design data:
- (keep only the text relevant for either a design-approval case or a declaration-of-design-compliance case)
-
The design approval holder [NAME] acknowledges that the approved data provided, controlled, and modified in accordance with the arrangement is recognised as approved by the competent authority and, therefore, the parts manufactured in accordance with this data and found in a condition for safe operation may be released certifying that the item(s) has (have) been manufactured in conformity to approved design data and is in a condition for safe operation.
When indicated so by the applicant for design approval [NAME], before the issuance of the design approval, the design data provided is considered not approved and, therefore, the parts manufactured in accordance with this data may be released certifying only their conformity.</td></tr>
</table>

The declarant of the design compliance *[NAME]* acknowledges that the declared data provided, controlled and modified in accordance with the arrangement is recognised as declared by the competent authority and, therefore, the parts manufactured in accordance with this data and found in a condition for safe operation may be released certifying that the parts have been manufactured in accordance with the design data of a declaration of design compliance in accordance with Subpart C, F or N of Section A of Annex Ib (Part 21 Light). When indicated so by *[NAME]* that intends to submit a declaration of design compliance, before the declaration of design compliance, the design data provided is considered not approved and, therefore, the parts manufactured in accordance with this data may be released certifying only their conformity.	
- **Direct delivery authorisation:** This acknowledgment includes also [OR does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts.	
For the *[NAME of the design organisation]* - - **Date:** **Signature:** xx.xx.xxxx [NAME in block letters]	For the *[NAME of the declared production organisation]* - **Date:** **Signature:** xx.xx.xxxx [NAME in block letters]

21L.A.123 Declaration of production capability

Regulation (EU) 2022/1358

(a) Prior to producing any products or parts, an organisation intending to show the conformity of those products or parts with the applicable design data shall declare its production capability.

(b) The declaration, and any subsequent changes thereto, shall be made in a form and manner established by the competent authority.

(c) The declaration shall include the information necessary for the competent authority to become familiar with the organisation and the intended scope of work, and shall include at least the following:

1. the registered name of the organisation;
2. the contact details of the organisation's registered address of their principal place of business and, where applicable, the contact and the operating sites of the organisation;
3. the names and contact details of the accountable manager of the organisation nominated in accordance with point (c)(1) of point 21L.A.125;
4. the intended scope of work;
5. the date of the intended commencement of production;
6. a statement confirming that the organisation:
   (i) has a management system for production in accordance with point (a) of point 21L.A.124; and
   (ii) will maintain the management system for production in compliance with this Subpart;
7. a statement confirming that the organisation will adhere to the processes and procedures established in accordance with point (d) of point 21L.A.124;
8. a statement that the organisation agrees to undertake the obligations of a declared production organisation in accordance with point 21L.A.127.

(d) The declaration of production capability shall be submitted to the competent authority.

AMC1 21L.A.123(c) Declaration of production capability

ED Decision 2023/013/R

DECLARATION FORM

The natural or legal person that declares their production capability should provide the information required by point 21L.A.123(c) in the declaration form defined below.

EASA Form 203

<table>
<tr><td colspan="3">DECLARATION OF PRODUCTION CAPABILITY
pursuant to Commission Regulation (EU) No 748/2012
Annex Ib (Part 21 Light)
Subpart G — DECLARED PRODUCTION ORGANISATIONS</td></tr>
<tr><td colspan="3">☐ Initial declaration
☐ Notification of changes — Declared production organisation (DPO) registered number:</td></tr>
<tr><td>1.</td><td colspan="2">Declared production organisation (DPO)
Registered name:</td></tr>
<tr><td>2.</td><td colspan="2">Place of business
Contact details (registered address, phone, email) of the DPO’s principal place of business:</td></tr>
<tr><td>3.</td><td colspan="2">Operating sites
Where applicable, contact details (address, phone, email) of the operating site(s) where manufacturing activities are taking place:
(may be left blank if same as in point 2 ‘Place of business’)</td></tr>
<tr><td>4.</td><td colspan="2">Accountable manager
Name and contact details (address, phone, email) of the DPO’s representative:</td></tr>
<tr><td rowspan="6">5.</td><td colspan="2">Intended scope of work</td></tr>
<tr><td colspan="2">5.1. Category of products</td></tr>
<tr><td>Products certified under Part 21 Light Subpart B</td><td>Products declared under Part 21 Light Subpart C</td></tr>
<tr><td>☐ Aeroplanes with a maximum take-off mass (MTOM) of 2 000 kg or less with a seating configuration of maximum 4 persons</td><td>☐ Aeroplanes with a maximum take-off mass (MTOM) of 1 200 kg or less that is not jet powered, and has a seating configuration of maximum 2 persons.</td></tr>
<tr><td>☐ Sailplanes or powered sailplanes with a MTOM of 2 000 kg or less</td><td>☐ Sailplanes or powered sailplanes with a MTOM of 1 200 kg or less</td></tr>
<tr><td>☐ Balloons</td><td>☐ Balloons designed for not more than 4 persons</td></tr>
<tr><td>☐ Hot-air airships</td><td>☐ Hot-air airships designed for not more than 4 persons</td></tr>
</table>

	☐ Passenger gas airships designed for not more than 4 persons	
	☐ Rotorcraft with a MTOM of 1 200 kg or less and a maximum seating configuration of 4 persons	
	☐ Piston engines	
	☐ Fixed pitch propellers	
	☐ Gyroplanes	
	5.2. Conformity documents	
	☐ For complete aircraft, issue EASA Form 52B for new aircraft	
	☐ For other products or parts, issue EASA Form 1	
	☐ Maintain a new aircraft and issue EASA Form 53B	
	5.3. Detailed description of the scope of work *(aircraft type …)* *(parts for aircraft type …)*	
6.	**Date of intended commencement of production:**	
7.	**Statements** The DPO has established and implemented a management system for production in accordance with point 21L.A.124. This management system will be maintained in compliance with Subpart G of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012. The references of the elements of the management system for production are included in the annex to this declaration. All the personnel of the DPO must adhere to the processes and procedures referred to in the annex to this declaration. [Company Name] agrees to undertake the obligations of a declared production organisation in accordance with point 21L.A.127. I confirm that all the information contained in this declaration, including its annex, is complete and correct.	
8.		
	Date / Location	Signature of the accountable manager

ANNEX TO THE DECLARATION OF PRODUCTION CAPABILITY			
This annex includes references to the DPO documentation showing compliance with the requirements of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012.			
No	**Part 21 Light**	**Subject**	**DPO reference** (DPOE reference, as relevant)
Quality system			
1.	21L.A.124(b)(2)(i)	Document issue, approval, or change	
2.	21L.A.124(b)(2)(ii)	Vendor and subcontractor assessment, audit and control	
3.	21L.A.124(b)(2)(iii)	Verification that incoming products, parts, materials, and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data	
4.	21L.A.124(b)(2)(iv)	Identification and traceability	
5.	21L.A.124(b)(2)(v)	Manufacturing processes	
6.	21L.A.124(b)(2)(vi)	Inspection and testing	
7.	21L.A.124(b)(2)(vi)	Production flight tests, flight test operations manual (FTOM) (if relevant)	
8.	21L.A.124(b)(2)(vii)	Calibration of tools, jigs, and test equipment	
9.	21L.A.124(b)(2)(viii)	Non-conforming item control	
10.	21L.A.124(b)(2)(ix) 21L.A.5	Collaboration with the applicant for, or holder of, the design approval or the declarant of a declaration of design compliance	
11.	21L.A.124(b)(2)(x)	Completion and retention of records	
12.	21L.A.124(b)(2)(xi) 21L.A.125(a)	Competence and qualifications of personnel	
13.	21L.A.124(b)(2)(xii)	Issue of airworthiness release documents	
14.	21L.A.124(b)(2)(xiii)	Handling, storage and packing	
15.	21L.A.124(b)(2)(xiv) 21L.A.124(c)	Internal quality audits and the resulting corrective actions	
16.	21L.A.124(b)(2)(xv)	Work performed at any location other than the operating sites included in the declaration	
17.	21L.A.124(b)(2)(xvi) 21L.A.124(e)	Work carried out after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation	
18.	21L.A.124(b)(2)(xvii)	Request for the issuance of permits to fly and the approval of associated flight conditions	

No	**Part 21 Light**	**Subject**	**DPO reference (DPOE reference, as relevant)**
Airworthiness and environmental compatibility data			
20.	21L.A.125(b)(2)	Procedure to ensure that airworthiness and environmental compatibility data is correctly incorporated into production data	
21.	21L.A.125(b)(3)	Such data is kept up to date and made available to all personnel that need access to such data to perform their duties	
Organisation, key personnel and certifying staff			

22.	21L.A.125(c)(4)	Organisational structure documented and kept updated	
23.	21L.A.125(c)(2)	Identification of key personnel nominated by the accountable manager to ensure that the organisation is in compliance with the requirements of Subpart G of Part 21 Light	
24.	21L.A.125(c)(2)	Nomination process for key personnel ensuring they have the appropriate knowledge, background and experience to discharge their responsibilities	
25.	21L.A.125(c)(3)	Staff at all levels have been given appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the declared production organisation in respect of airworthiness and environmental compatibility data matters	
26.	21L.A.125(d)(1)	Nomination procedure for certifying staff	
27.	21L.A.125(d)(2)	List of certifying staff	
Changes to the DPO			
28.	21A.L.128	Procedure for the notification of organisational changes to the competent authority according to point 21L.A.128	
Obligations			
29.	21L.A.3	Reporting system	
30.	21L.A.6	Marking	
31.	21L.A.7	Record-keeping	

Instructions: If the DPO, for the purpose of compliance with point 21L.A.124(d), has produced a declared production organisation exposition (DPOE), then the DPOE sections should be referenced in the right-hand column of the form.

21L.A.124 Management system for production

Regulation (EU) 2022/1358

(a) The declared production organisation shall establish, implement, and maintain a management system for production with clear accountability and lines of responsibility throughout the organisation that:

1. corresponds to the nature and complexity of its activities and the size of the organisation, and takes into account the hazards and associated risks inherent in these activities;

2. is established under the accountability of an accountable manager nominated according to point (c)(1) of point 21L.A.125.

(b) The management system for production shall include a means to manage quality by maintaining a quality system that shall:

1. ensure that each product or part produced by the declared production organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in a condition for safe operation;

2. establish, implement, and maintain, as appropriate, within the scope of their activities, control procedures for:

(i) document issue, approval, or change;

(ii) vendor and subcontractor assessment, audit and control;

(iii) verification that incoming products, parts, materials, and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;

(iv) identification and traceability;

(v) manufacturing processes;

(vi) inspection and testing, including production flight tests;

(vii) calibration of tools, jigs, and test equipment;

(viii) non-conforming item control;

(ix) the collaboration with the applicant for, or holder of, the design approval or the declarant of a declaration of design compliance;

(x) the completion and retention of records;

(xi) ensuring the competence and qualifications of personnel;

(xii) the issue of airworthiness release documents;

(xiii) handling, storage and packing;

(xiv) internal quality audits and the resulting corrective actions;

(xv) work performed at any location other than the operating sites included in the declaration;

(xvi) work carried out after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;

(xvii) the request for the issuance of permits to fly and the approval of associated flight conditions;

3. include specific provisions in the control procedures for any critical parts.

(c) The declared production organisation shall establish, as part of their management system for production, an independent function to monitor the compliance of the organisation with the relevant requirements, and compliance with, and the adequacy of, the production management system. This monitoring shall include a system to provide feedback to the person or group of persons referred to in points (c)(1) and (2) of point 21L.A.125 to ensure, as necessary, corrective action.

(d) The declared production organisation shall establish, maintain and keep updated, as part of their management system for production, processes and procedures that ensure the compliance of products that are produced with the applicable design data. The declared production organisation shall make documentary evidence of these processes and procedures available to the competent authority upon request.

(e) The declared production organisation shall have procedures in place to ensure that newly manufactured aircraft are maintained in accordance with the applicable maintenance instructions and are kept in an airworthy condition and, if applicable, that a certificate of release to service is issued for any maintenance that has been completed.

(f) If the declared production organisation holds (an)other organisation certificate(s) issued on the basis of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, the production organisation may integrate the production management system with the management system that is required for the issuance of the other certificate(s).

GM1 21L.A.124(b) Management system for production

ED Decision 2023/013/R

QUALITY SYSTEM DOCUMENTATION

The quality system is an organisational structure, included in the management system for production, with responsibilities, procedures, processes, and resources, which implements a management function to determine and enforce quality principles.

The quality system should be documented in such a way that the documentation can be made easily available to personnel that need to use the material for performing their normal duties, in particular:

— the procedures, instructions and data to cover the issues of point 21L.A.124(b)(2) are available in a written form;

— the distribution of relevant procedures to offices/staff is made in a controlled manner;

— the job descriptions (or equivalent) providing staff with a clear list of their tasks and responsibilities; and

— the updating process is clearly described.

The person or group of persons responsible for ensuring that the quality system is implemented and maintained should be identified.

Other methods to document the quality system may be used if they ensure that members of the organisation can obtain the actual and relevant information in a reasonable way. Such other methods may include the provision of such information by electronic means, for example, on the intranet of the organisation, by the use of an electronic database such as document management system (DMS), on paper, by illustration, by using workflow definitions within IT-based enterprise resource planning (ERP) systems, etc.

GM2 21L.A.124(b) Management system for production

ED Decision 2023/013/R

USE OF RECOGNISED STANDARDS

An organisation that has a quality system designed to meet a recognised standard such as ISO 9001, EN 9100, or ASTM F2972 (relevant to the scope of work of the declared production organisation), should ensure that the existing quality system covers all the aspects defined in point 21L.A.124(b).

For example, if the standard that is used is ISO 9001, the quality system should be expanded to include at least the following additional topics, as appropriate, in order to demonstrate compliance with the requirements of this Annex:

— mandatory and voluntary reporting system as required by point 21L.A.3;

— control of work occasionally performed outside the operating sites included in the declaration;

— collaboration with the applicant for, or holder of, an approved design, or with the organisation that has declared or intends to declare the compliance of a particular aircraft design as required by point 21L.A.122(c);

— issue certificates within the scope of work of point 21L.A.126;

— incorporation of airworthiness data in production and inspection data as required by point 21L.A.125(b);

— when applicable, ground test and/or production flight test of products in accordance with the procedures defined by the applicant for, or holder of, the design approval or the declarant of a declaration of design compliance;

— procedures for traceability including the definition of clear criteria of which items require such traceability; traceability is defined as a means of establishing the origin of an article by reference to historical records for the purpose of providing evidence of conformity; and

— personnel training and qualification procedures especially for certifying staff as required by point 21L.A.125(d).

GM1 21L.A.124(b)(1);(b)(2)(iii) Management system for production

ED Decision 2023/013/R

QUALITY SYSTEM — CONFORMITY OF SUPPLIED ITEMS

The declared production organisation is responsible for determining and applying acceptance standards for the physical condition, configuration status and conformity of supplied products, parts, materials or equipment, whether to be used in production or delivered to customers as spare parts. This responsibility also includes items of buyer-furnished equipment (BFE).

To discharge this responsibility, the quality system needs an organisational structure and procedures to adequately verify the supplied items.

The below list provides examples of verification techniques to be used as appropriate to ensure conformity of the product or part:

— qualification and auditing (desktop and on-site audits) of the supplier's quality system;

— evaluation of the supplier's capability in performing all the manufacturing activities, inspections and tests necessary to establish the conformity of parts, materials or equipment to the applicable design data;

— first-article inspections of supplied parts, including destruction, if necessary, to verify that the article conforms to the applicable data for a new production line or a new supplier;

— incoming inspections and tests of supplied parts, materials or equipment that can be satisfactorily inspected on receipt;

— identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents; and

— any additional work, tests or inspection which may be needed for parts that are to be delivered as spare parts and which are not subjected to the checks normally provided by subsequent production or inspection stages.

The declared production organisation could for example rely on the results of inspections/tests performed by the supplier, if the supplier can establish that:

— the personnel responsible for these tasks satisfy the competency standards of the declared production organisation quality system;

— quality measurements are clearly identified; and

— the records or reports showing evidence of conformity are available for review.

For the purpose of showing conformity, a declared production organisation could for example rely upon an EASA Form 1 issued by the supplier.

If the items are not delivered with an EASA Form 1, the supplier is considered a subcontractor under the direct control of the quality system of the declared production organisation.

Since the declared production organisation is responsible for the verification of the supplied items, it retains direct responsibility for inspections/tests carried out either at its own facilities or at the supplier's facilities.

GM1 21L.A.124(b)(2)(vi) Management system for production

ED Decision 2023/013/R

INSPECTION OF PARTS IN PROCESS

The purpose of the inspection is to check at suitable points during production and provide objective evidence that the correct specifications are used, and that processes are carried out strictly in accordance with those specifications.

During the manufacturing process, each part should be inspected in accordance with a plan that identifies the nature of all inspections required and the production stages at which they occur. The plan should also identify any particular skills or qualification required of person(s) carrying out the inspections (e.g. NDT personnel). This plan should be considered part of the documentation required by point 21L.A.124(d).

If the parts are such that, if damaged, they could compromise the safety of the aircraft, additional inspections for such damage should be performed at the completion of each production stage.

GM1 21L.A.124(b)(2)(vi) Management system for production

ED Decision 2023/013/R

TESTS

If relevant, the declared production organisation will have to perform functional, ground and flight tests for the manufactured products.

The production ground and flight tests for new aircraft are specified by the aircraft design organisation. These tests typically include:

— a check on handling qualities;

— a check on flight performance (using normal aircraft instrumentation);

— a check on the proper functioning of all aircraft equipment and systems;

— a determination that all instruments are properly marked, and that all placards and required flight manuals are installed before flight test;

— a check of the operational characteristics of the aircraft on the ground;

— a check on any other items peculiar to the aircraft being tested.

The functional test required for a new engine will be specified by the engine design organisation and are normally including the following:

— Break-in runs that include a determination of fuel and oil consumption and a determination of power characteristics at rated maximum continuous power or thrust and, if applicable, at rated take-off power or thrust.

— A period of operation at rated maximum continuous power or thrust. For engines that have a rated take-off power or thrust, part of that period should be at rated take-off power or thrust.

The test equipment used for the test run should be capable of output determination of a level of accuracy sufficient to assure that the engine output delivered complies with the specified rating and operation limitations.

The functional tests required for a new propeller will be specified by the propeller design organisation and are normally including several complete cycles of control throughout the propeller pitch and rotational speed ranges. In addition, for feathering and/or reversing propellers, several cycles of feathering operation and reversing operation from the lowest normal pitch to the maximum reverse pitch should normally be required.

Following functional testing, each engine or propeller will need to be inspected to determine that the engine or propeller is in condition for safe operation. Such inspections are specified by the design organisation and are normally including internal inspection and examination. The degree of internal inspections should normally be determined on the basis of the positive results of previous inspections conducted on the first production engines or propeller, and on the basis of in-service experience.

GM1 21L.A.124(b)(2)(viii) Management system for production

ED Decision 2023/013/R

NON-CONFORMING ITEM CONTROL

All parts, materials and equipment that have been identified at any stage in the manufacturing process as not conforming to the specific design data should be suitably identified by clearly marking or labelling to indicate their non-conforming status.

All such non-conforming material or parts should be removed from the production area and held in a segregated area with restricted access until their appropriate disposition is determined.

The non-conformities, which cannot be solved by restoring full conformity with the design data, should be recorded and presented to the relevant design organisation for review and disposition. The results of the review and actions taken consequently as regards the part/product should be recorded as well.

GM1 21L.A.124(b)(2)(xiii) Management system for production

ED Decision 2023/013/R

HANDLING, STORAGE AND PACKING

Storage areas should be protected from dust, dirt or debris, and adequate blanking and packaging of stored items should be practised. All parts should be protected from extremes of temperatures and humidity and, where needed, environment-controlled facilities should be provided.

Racking and handling equipment should be provided such as to allow storage, handling and movement of parts without damage.

Lighting should be such as to allow safe and effective access and handling, but should also cater for items which are sensitive to light (e.g. rubber items).

Care should be taken to segregate and shield items which can emit fumes (e.g. wet batteries), substances or radiation (e.g. magnetic items) which are potentially damaging to other stored items.

Particular attention should be paid to shelf life-limited items (e.g. sealants, adhesives) to ensure the storage conditions and monitor the expiry date.

Procedures should be in place to maintain and record stored parts' identities and batch information.

Access to storage areas should be restricted to authorised personnel that are fully trained to understand and maintain the storage control arrangements and procedures.

Provisions should be made for segregated storage of non-conforming items pending their disposition (see AMC1 21L.A.124(b)(2)(viii)).

GM1 21L.A.124(c) Management system for production

ED Decision 2023/013/R

INDEPENDENT MONITORING FUNCTION

The purpose of the independent monitoring function is to ensure that:

— the management system for production remains compliant with the applicable requirements of the Part 21 Light and with any additional requirements as established by the production organisation;

— the staff of the production organisation follow the documented procedures of the management system when performing their tasks; and

— the management system for production is adequate and enables the organisation through the use of its procedures to meet the conformity objectives identified in point 21L.A.124.

An objective review of the complete set of production-management-related activities is provided through independent monitoring activities, such as audits, inspections and reviews. The independence of the monitoring activities is established by always ensuring that those activities are performed by staff that are not involved in the function, procedure or products that they monitor and that are independent from the operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring.

The monitoring is usually performed based on a monitoring plan. This plan is established to show when and how often the activities required by this Subpart will be audited. This plan normally includes, in a defined period of time, all the elements of the management system, including all workshops and subcontractors. The defined period of time for the audit planning is typically not exceeding 24 months.

When a non-compliance is found, the root cause(s) and contributing factor(s) should be identified and corrective actions should be defined and followed up. When providing feedback, the compliance-monitoring function should define who is required to address any non-compliance in each particular case, and the procedure to be followed if the corrective action is not completed within the defined time frame.

Also, as required in point 21L.A.124(c), feedback has to be regularly provided to the accountable manager on the overall status of the compliance and adequacy of the management system for production, including main issues identified and cases where corrective actions have not been satisfactorily implemented.

The staff that perform an independent monitoring function should have access to all the parts of the production organisation and, as necessary, to any subcontracted organisations.

GM1 21L.A.124(d) Management system for production

ED Decision 2023/013/R

DOCUMENTATION

Point 21L.A.124 (d) requires the declared production organisation to document its processes and procedures.

In order to do so, the declared production organisation may consider to establish a declared production organisation exposition (DPOE). The purpose of a DPOE is to set forth in a concise document format the organisational relationships, responsibilities, terms of reference, and the associated authority, procedures, means and methods of the organisation.

If utilised, the DPOE typically contains the following:

(a) a statement signed by the accountable manager confirming that the DPOE and any associated manuals/procedures/instructions which define the organisation's compliance with this Subpart will be complied with at all times;

(b) the title(s) and name(s) of the person(s) nominated in accordance with point 21L.A.125(c)(2);

(c) the duties and responsibilities of the accountable manager and the persons as specified by points 21L.A.125(c)(1) and (2), including matters on which they may deal directly with the competent authority on behalf of the organisation;

(d) an organisational chart showing associated chains of responsibility of the managers as required by point 21L.A.125(c)(4);

(e) the list of certifying staff as referred to in point 21L.A.125(d)(2);

(f) a general description of manpower;

(g) a general description of the facilities located at each address specified in the declaration of production capability;

(h) a general description of the declared production organisation's scope of work as defined in the declaration of production capability (see also point 21L.A.126);

(i) the procedure for the notification of changes to the competent authority according to point 21L.A.128;

(j) the amendment procedure for the DPOE;

(k) a procedure to develop, where applicable, the production organisation's own manufacturing data in compliance with the airworthiness and environmental compatibility data package;

(l) a description of the quality system and the procedures as required by point 21L.A.124(b);

(m) a list of those outside parties referred to in point 21L.A.124(b)(1); and

(n) if flight tests are to be conducted, a flight test operations manual (FTOM) defining the organisation's policies and procedures in relation to flight testing; for the contents of the FTOM, refer to AMC1 21L.A.127(b).

If this information is documented and integrated in manuals, procedures and instructions, the DPOE may provide a summary of the information and an appropriate cross reference.

When changes to the organisation occur, the DPOE should be kept up to date. Changes to the organisation shall be notified to the competent authority as required by point 21L.A.128.

If the organisation holds one or more additional organisation certificates (DOA, MOA, POA, etc.) within the scope of Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, so that the organisation is required to establish another exposition, the organisation may combine the documents by producing a separate manual or supplement that covers the differences between the DPOE and the other exposition. In that case, the separate manual or supplement should identify where in the other exposition the remaining information on the declared production organisation is covered. That remaining information then formally becomes part of the exposition.

GM1 21L.A.124(e) Management system for production and 21L.A.126(e) Scope of work

ED Decision 2023/013/R

MAINTENANCE ACTIVITIES

Point 21L.A.124(e) requires the declared production organisation to have procedures that cover maintenance activities for new aircraft it has manufactured, as necessary to keep them in an airworthy condition. The declared production organisation shall not maintain newly manufactured aircraft beyond the point at which the applicable operational rules require maintenance to be performed by an approved maintenance organisation (point 21L.A.126(e)). If the declared production organisation intends to maintain aircraft beyond that point, it would have to apply for and obtain an appropriate maintenance approval (see Articles 3 and 4 of Regulation (EU) No 1321/2014).

MAINTENANCE OF AIRCRAFT

Examples of maintenance activities within the scope of work of a declared production organisation are:

— preservation, periodic inspection visits, etc.;

— embodiment of a service bulletin (SB);

— application of airworthiness directives;

— repairs;

— maintenance tasks resulting from special flights; and

— maintenance tasks to maintain airworthiness during flight training, demo flights and other non-revenue flights.

Any package of maintenance activities should be recorded in the aircraft logbook. It should be signed by certifying staff for attesting the conformity of the maintenance work with the applicable airworthiness data.

If the aircraft logbook is not available or if the production organisation prefers to use a separate form (for instance, for a large work package or for delivery of the aircraft to the customer), the production organisation should use EASA Form 53B which should subsequently become part of the aircraft maintenance records.

MAINTENANCE OF COMPONENTS OUTSIDE THE DPO CAPABILITY

Such a maintenance activity outside the capability of the aircraft declared production organisation may still be accomplished under the original release organisation. In such circumstances, the engine(s), propeller(s), parts and appliances will require re-release in accordance with point 21.A.163(c) or point 21L.A.126(c) (EASA Form 1).

21L.A.125 Resources of the declared production organisation

Regulation (EU) 2022/1358

The declared production organisation shall ensure that:

(a) the facilities, working conditions, equipment and tools, processes and associated materials, the number and competence of staff, and the general organisation are adequate to discharge its obligations under point 21L.A.127;

(b) with regard to all necessary airworthiness and environmental protection data:

1. it is in receipt of such data from the Agency, and from the declarant of design compliance or the holder of, or the applicant for, the type certificate, or design approval, to determine its conformity with the applicable design data;

2. it has established a procedure to ensure that airworthiness and environmental compatibility data is correctly incorporated into its production data;

3. such data is kept up to date and made available to all personnel who need access to such data to perform their duties;

(c) with regard to management and staff:

1. an accountable manager has been nominated by the declared production organisation with authority to ensure that, within the organisation, all production is performed to the required standards and that the declared production organisation is continuously in compliance with the requirements of the management system for production referred to in point (a) of point 21L.A.124, and the processes and the procedures identified in point (d) of point 21L.A.124;

2. a person or group of persons has or have been nominated by the accountable manager to ensure that the organisation is in compliance with the requirements of this Subpart, and is (are) identified, together with the extent of their authority. Such a person or group of persons shall be responsible to the accountable manager and have direct access to them. They shall have the appropriate knowledge, background and experience to discharge their responsibilities;

3. staff at all levels have been given appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the declared production organisation in respect of airworthiness and environmental compatibility data matters;

4. the organisational structure of the organisation along with the key personnel who are responsible for ensuring that the organisation is in compliance with this Subpart is documented and kept updated;

(d) with regard to certifying staff, authorised by the declared production organisation to sign the documents issued under point 21L.A.126 within the scope of declared production activities:

1. the knowledge, background (including other functions in the organisation), and experience of the certifying staff are appropriate to discharge their allocated responsibilities;

2. certifying staff are provided with evidence of the scope of their authorisation. A list of certifying staff shall be maintained by the declared production organisation.

GM1 21L.A.125(a) Resources of the declared production organisation

ED Decision 2023/013/R

GENERAL

1. FACILITIES AND WORKING CONDITIONS

A facility is a working area where the working conditions and the environment are controlled as appropriate in respect of cleanliness, temperature, humidity, ventilation, lighting, space/access, noise, and air pollution.

2. EQUIPMENT AND TOOLS

The organisation's equipment and tools enables all the specified tasks to be accomplished in a repeatable manner without any detrimental effects. The calibration control of the equipment and tools that affect the dimensions and values of products makes it possible for the organisation to demonstrate compliance with, and be traceable to, national or international standards.

3. NUMBER OF STAFF

Sufficient staff means that, for each function, according to the nature of the work and the production rate, the organisation has a sufficient number of qualified staff to accomplish all the specified manufacturing tasks and to attest the conformity of such task. The number of staff should be such that the relevant airworthiness considerations may be applied in all areas without any undue pressure.

4. COMPETENCE OF STAFF

An evaluation of the competence of the staff is performed as part of the quality system. This should include, where appropriate, verification that specific qualification standards have been implemented, for example, for NDT, welding, etc.

Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. That training should be adapted based on experience that is gained within the organisation.

GM1 21L.A.125(b) Resources of the declared production organisation

ED Decision 2023/013/R

MANUFACTURING DATA

When a declared production organisation develops its own manufacturing data, such as computer-based data, from the design data package that is delivered by a design organisation, procedures are required to ensure the correct transcription of the original design data.

Procedures are required to define the manner in which airworthiness and environmental compatibility data is used to issue and update the production/quality data, which determines the conformity of products and parts. The procedure should also define the traceability of such data to each individual product or part for the purpose of certifying their condition for safe operation and issuing a statement of conformity or an EASA Form 1.

AMC1 21L.A.125(c)(1) Resources of the declared production organisation

ED Decision 2023/013/R

ACCOUNTABLE MANAGER

The term 'accountable manager' refers to the manager that is responsible and has corporate authority for ensuring that all production work is carried out to the required standards. This function may be performed by the chief executive officer or by another person in the organisation, nominated by the chief executive officer to fulfil the function, provided that the position and authority of that person in the organisation allows that person to discharge the associated responsibilities.

The accountable manager should:

(a) have sufficient knowledge and authority to be able to respond to the competent authority regarding major issues concerning the declared production organisation, and to implement any necessary improvements;

(b) have an understanding of this Annex, sufficient to discharge the relevant responsibilities.

AMC1 21L.A.125(c)(2) Resources of the declared production organisation

ED Decision 2023/013/R

NOMINATED MANAGERS

The person or group of persons nominated in accordance with point 21L.A.125(c)(2) should represent the management structure of the organisation and be responsible for all the functions specified in Subpart G. Depending on the size of the declared production organisation, the functions may be subdivided among individual managers (and, in fact, may be further subdivided) or combined in a variety of ways.

The responsibilities and the duties of each individual manager should be clearly defined in such a way that all the responsibilities are covered.

Where a declared production organisation chooses to appoint managers for all or for any combination of the functions identified in Part 21 Light because of the size of the undertaking, those managers should ultimately report to the accountable manager nominated in accordance with point 21L.A.125(c)(1). Where a manager does not directly report to the accountable manager, that manager should have direct access to the accountable manager formally established.

One such manager, normally known as the 'quality manager', should be responsible for the independent monitoring function as defined in point 21L.A.124(c). The independent monitoring function should be independent from other functions. As such, the quality manager should not be at the same time one of the other persons that are referred to in point 21.A.125(c)(2). The role of the quality manager should be to ensure that:

(a) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21L.A.125(c)(2);

(b) an audit plan is properly implemented, maintained, and continually reviewed and improved; and

(c) corrective actions are requested, as necessary, and their implementation is followed up.

GM1 21L.A.125(c)(4) Resources of the declared production organisation

ED Decision 2023/013/R

DOCUMENTATION OF ORGANISATIONAL STRUCTURE AND KEY PERSONNEL

Point 21L.A.125(c)(4) requires that the organisational structure together with the key personnel are documented. The key personnel are those managers nominated according to point 21L.A.125(c)(1) and (c)(2).

This could be achieved through the information included in the declared production organisation exposition (DPOE) (see AMC1 21L.A.124(d)).

The above information should be kept updated to reflect changes made within the organisation.

AMC1 21L.A.125(d)(1) Resources of the declared production organisation

ED Decision 2023/013/R

CERTIFYING STAFF

(a) Certifying staff should be nominated by the declared production organisation to ensure that each of the products and/or parts that are produced within the organisation's scope of work, qualifies for a statement of conformity or a release certificate. The position and number of certifying staff should be appropriate to the complexity of the product and the production rate.

(b) The qualifications of certifying staff should be based on their knowledge, background and experience and on specific training (or testing) that is established by the organisation appropriate to the product or part to be released.

(c) Training should be given to develop a satisfactory level of knowledge of product/part specifications, the organisation's procedures, the management system for production (including compliance monitoring), aviation legislation, and the associated regulations, AMC and GM that are relevant to their particular role. Training should include on-the-job training, as relevant.

(d) For that purpose, in addition to the general training policy, the organisation should define its own standards for training, including pre-qualification standards, for personnel to be identified as certifying staff.

(e) The training policy is part of the quality system.

(f) The training should be updated in response to experience gained and changes in technology.

(g) A feedback system to ascertain that the required standards are being maintained should be put in place to ensure the continuing compliance of personnel with authorisation requirements.

(h) For the release of products or parts, the responsibilities to issue statements of conformity or authorised release certificates (EASA Form 1) are allocated to the certifying staff that is identified in point 21L.A.125(d)(2).

AMC1 21L.A.125(d)(2) Resources of the declared production organisation

ED Decision 2023/013/R

EVIDENCE OF AUTHORISATION

(a) Certifying staff should be provided with evidence of their authorisation. This should be done through an internal authorisation document. That document should be in a style that makes its scope clear to the certifying staff and any entitled person that may require to examine the authorisation. It should include the privileges that are granted to the certifying staff and the category of products upon which they may exercise those privileges. Where codes are used to define the scope, an interpretation document should be readily available.

(2) Certifying staff are not required to carry the authorisation document at all times, but they should be able to make it available within a reasonable time following a request from an entitled person, which includes the competent authority.

(3) The list of certifying staff should be included in the declared production organisation exposition (DPOE) (see AMC 21L.A.124(d)), if utilised, or in equivalent processes and procedures.

21L.A.126 Scope of work

Regulation (EU) 2022/1358

(a) A declared production organisation is entitled to show the conformity of the products and parts that are within the scope of this Section and that it has produced within the declared scope of work, with the applicable design data.

(b) A declared production organisation is entitled, for a complete aircraft, after presentation of an aircraft statement of conformity (EASA Form 52B), to apply:

1. for an aircraft that conforms to a type design approved in accordance with Subpart B of Section B of this Annex, for a certificate of airworthiness and a noise certificate;

2. for an aircraft that conforms to a design for which compliance has been declared in accordance with Subpart C of this Annex, for a restricted certificate of airworthiness and a restricted noise certificate.

(c) A declared production organisation is entitled to issue authorised release certificates (EASA Form 1) for engines, propellers and parts that either conform to:

1. approved design data issued in accordance with Subparts B, D, E or M of Section B of this Annex;

2. declared design data for which design compliance has been declared in accordance with Subparts C, F or N of this Annex;

3. production data based upon all the necessary approved design data as provided by a repair design approval holder.

(d) A declared production organisation is entitled to recommend the conditions for an aircraft that it has produced and for which it has attested conformity with the applicable design data, under which a permit to fly can be issued by the competent authority under Subpart P of Annex I (Part 21).

(e) A declared production organisation is entitled to maintain a new aircraft that it has produced, as necessary to keep it in an airworthy condition, unless Regulation (EU) No 1321/2014 requires the maintenance to be performed under such rules, and to issue a certificate of release to service (EASA Form 53B) in respect of that maintenance.

GM1 21L.A.126(a) Scope of work

ED Decision 2023/013/R

CONFORMITY OF PROTOTYPE MODELS AND TEST SPECIMENS

Points 21L.A.25(c) and 21L.A.44(d) require the determination of conformity of prototype models and test specimens to the applicable design data.

The EASA Form 1 may be used as a conformity certificate as part of the assistance that a declared production organisation provides to a design approval holder/applicant or a declarant of a declaration of design compliance.

The EASA Form 1 should only be used for conformity release purposes when it is possible to indicate (in Block 12) the reason that prevents its issuance for airworthiness release purposes.

GM1 21L.A.126(d) Scope of work

ED Decision 2023/013/R

FLIGHT CONDITIONS

The need to recommend flight conditions for an aircraft is related to the performance of the production flight tests.

Production flight tests of a newly manufactured aircraft should be performed under the conditions specified in point 21L.A.241 and under Subpart P of Annex I (Part 21) to this Regulation.

For this purpose, the declared production organisation should apply for a permit to fly to the competent authority. EASA Form 21 (see AMC 21.B.520(b)) should be obtained from the competent authority.

Where the flight conditions are not approved at the time of application for a permit to fly, the declared production organisation should also apply for approval of the flight conditions (refer to point 21L.A.241(a) (and by inference to point 21.A.709 of Annex I (Part 21))).

GM1 21L.A.124(e) Management system for production and 21L.A.126(e) Scope of work

ED Decision 2023/013/R

MAINTENANCE ACTIVITIES

Point 21L.A.124(e) requires the declared production organisation to have procedures that cover maintenance activities for new aircraft it has manufactured, as necessary to keep them in an airworthy condition. The declared production organisation shall not maintain newly manufactured aircraft beyond the point at which the applicable operational rules require maintenance to be performed by an approved maintenance organisation (point 21L.A.126(e)). If the declared production organisation intends to maintain aircraft beyond that point, it would have to apply for and obtain an appropriate maintenance approval (see Articles 3 and 4 of Regulation (EU) No 1321/2014).

MAINTENANCE OF AIRCRAFT

Examples of maintenance activities within the scope of work of a declared production organisation are:

— preservation, periodic inspection visits, etc.;

— embodiment of a service bulletin (SB);

— application of airworthiness directives;

— repairs;

— maintenance tasks resulting from special flights; and

— maintenance tasks to maintain airworthiness during flight training, demo flights and other non-revenue flights.

Any package of maintenance activities should be recorded in the aircraft logbook. It should be signed by certifying staff for attesting the conformity of the maintenance work with the applicable airworthiness data.

If the aircraft logbook is not available or if the production organisation prefers to use a separate form (for instance, for a large work package or for delivery of the aircraft to the customer), the production organisation should use EASA Form 53B which should subsequently become part of the aircraft maintenance records.

MAINTENANCE OF COMPONENTS OUTSIDE THE DPO CAPABILITY

Such a maintenance activity outside the capability of the aircraft declared production organisation may still be accomplished under the original release organisation. In such circumstances, the engine(s), propeller(s), parts and appliances will require re-release in accordance with point 21.A.163(c) or point 21L.A.126(c) (EASA Form 1).

21L.A.127 Obligations of the declared production organisation

Regulation (EU) 2022/1358

(a) The declared production organisation shall work in accordance with clearly defined procedures, practices and processes.

(b) If the declared production organisation intends to conduct flight tests, then it shall prepare, maintain and keep updated an operations manual that includes a description of the organisation's policies and processes for flight testing. The declared production organisation shall make this manual available to the competent authority upon request.

(c) For completed aircraft, prior to submitting an aircraft statement of conformity (EASA Form 52B) to the competent authority, the declared production organisation shall ensure that the aircraft is in a condition for safe operation and conforms to:

1. the approved type design of a type-certified product issued in accordance with Subpart B of Section B of this Annex, or

2. the design data of an aircraft for which design compliance has been declared in accordance with Subpart C of this Annex.

(d) For products (other than complete aircraft) and parts, the declared production organisation shall ensure prior to issuing an authorised release certificate (EASA Form 1) that the product or part is in a condition for safe operation and conforms to the approved type design of a type-certified product issued in accordance with Subpart B, D, E or M of Section B of this Annex or conforms to the design data of an aircraft for which design compliance has been declared in accordance with Subpart C, F or M of this Annex.

(e) For engines, the declared production organisation shall ensure that the completed engine is in compliance with the applicable engine exhaust emissions requirements applicable on the date of production of the engine.

(f) The declared production organisation shall include, in any authorised release certificates (EASA Form 1) that are issued by it, the reference number issued by the competent authority in accordance with point 21L.B.142 for this declared production organisation.

(g) The declared production organisation shall ensure that the organisation records the details of any work that is completed.

(h) The declared production organisation shall provide, to the design holder or the declarant of a declaration of design compliance, continuing airworthiness support for any products or parts that they have produced.

(i) The declared production organisation shall have an archiving system that records the requirements that have been placed on other organisations, such as suppliers and subcontractors. The declared production organisation shall make the archived data available to the competent authority for continuing airworthiness purposes.

(j) For the production of new aircraft, the declared production organisation shall ensure that the aircraft is kept in an airworthy condition and that maintenance is performed, including any necessary repairs in accordance with the applicable design data, prior to the issuance of an aircraft statement of conformity (EASA Form 52B).

(k) Where the declared production organisation issues a certificate of release to service after such maintenance, it shall determine that each completed aircraft has been subjected to the necessary maintenance and is in a condition for safe operation, prior to issuing that certificate.

(l) The declared production organisation shall comply with the requirements in Subpart A of this Annex applicable to a declared production organisation.

GM1 21L.A.127(a) Obligations of the declared production organisation

ED Decision 2023/013/R

WORK CARRIED OUT IN ACCORDANCE WITH DEFINED PROCEDURES, PRACTICES AND PROCESSES

The establishment of a declared production organisation exposition (DPOE) (if chosen to be utilised by the organisation (see AMC1 21L.A.124(d))) or the equivalent processes and procedures are a prerequisite for the registration of a declaration for production capability and for maintaining such registration.

The declared production organisation should make the DPOE or the equivalent processes and procedures available to its personnel, where necessary, for the performance of their duties. A distribution list should, therefore, be established. If utilised, and if the DPOE mainly refers to separate manuals or procedures, the distribution of the DPOE could be limited.

The declared production organisation should ensure that personnel have access to and are familiar with that part of the content of the DPOE or the referenced documents, at the latest revision level, which covers their activities.

Monitoring of compliance with the DPOE or the equivalent processes and procedures is normally the responsibility of the independent monitoring function.

AMC1 21L.A.127(b) Obligations of the declared production organisation and AMC1 21L.A.177(b) Obligations of the declared design organisation

ED Decision 2023/013/R

FLIGHT TEST OPERATIONS MANUAL (FTOM)

(a) General

(1) Scope: The FTOM covers flight-test operations.

The FTOM complexity should be proportionate to the organisation complexity's as well as to the complexity of a particular aircraft.

(2) Format

The FTOM may:

be included in the declared production organisation's (DPO) / declared design organisation's (DDO) documents; or

be a separate manual.

The FTOM may make reference to other documents to cover the contents listed in point (b) below (e.g. for record-keeping).

(3) Use by subcontractors

When flight tests are performed by subcontractors, they should comply with the FTOM of the declared production or design organisations, unless they have established an FTOM in compliance with Part 21 or Part 21 Light, the use of which has been agreed between the two organisations.

(b) The FTOM should contain the following elements:

(1) Exposition

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the staff in charge of flight-test activities. It should also mention the coordination between all departments affecting flight test, e.g. design office, production and maintenance, in particular the coordination for the establishment and update of flight-test programmes.

(2) Risk and safety management

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation, and associated methodologies.

(e.g. see additional guidance on the EASA webpage at https://www.easa.europa.eu/en/domains/general-aviation/documents-guidance-and-examples)

(3) Crew members

According to the flight-test category, the FTOM should describe the organisation's policy on the composition of the crew and the competence and currency of its flight-test pilots, including procedures for appointing crew members for each specific flight.

Note: For flight tests performed for demonstration-of-compliance activities required by points 21L.A.25 and 21L.A.44, the flight crew conditions or restrictions are part of the flight conditions approved by EASA. As part of the investigations required under point 21L.B.242, EASA will also check the flight crew qualifications to ensure that the flight testing can be conducted safely.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

(4) Carriage of persons other than crew members

According to the flight-test category, the FTOM should describe the organisation's policy in relation to the presence and safety onboard of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests (for the definition of the flight categories, refer to Appendix XII to Annex I (Part 21) to this Regulation).

(5) Instruments and equipment

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

(6) Documents

The FTOM should list the documents to be produced for flight testing, and include (or refer to) the procedures for their issuance, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a flight-test programme:

- flight order for a given flight, which should include:
  - a list of the tests to be performed and associated conditions;
  - safety considerations relevant to the flight;
  - category of the flight (e.g. certification flight, production flight);
  - composition of the crew;
  - names of persons other than crew members;
  - aircraft configuration items relevant to the test to be highlighted to the crew;
  - loading of the aircraft;
  - reference to approved flight conditions; and
  - restrictions relevant to the flight to be highlighted to the crew;

— flight crew report;

(ii) documentation and information to be carried on board the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

(7) Permit to fly

The FTOM should describe the involvement of the flight-test organisation or flight-test team (as appropriate) in the process for the approval of flight conditions and the issuance of permits to fly in accordance with Part 21 Light Subpart P (and by reference to Part 21 Subpart P).

(8) Currency and training

The FTOM should describe how training for flight test is organised.

Currency of the flight-test crew may be ensured either through recent experience or refresher training.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight-test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, may be an acceptable means of compliance to demonstrate currency for a pilot that holds a flight-test rating.

GM1 to 21L.A.127(c) Obligations of the declared production organisation

ED Decision 2023/013/R

CONFORMITY WITH APPROVED OR DECLARED DESIGN DATA

Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type-certificate holder or the declarant of a declaration of design compliance. There are also likely to be unintentional deviations (concessions or non-conformances) during the manufacturing process. All these changes should be subject to approval by the design approval holder or the declarant, as relevant, or, when necessary, by EASA.

GM2 21L.A.127(c) Obligations of the declared production organisation

ED Decision 2023/013/R

AIRCRAFT — CONDITION FOR SAFE OPERATION

Before submitting the aircraft statement of conformity (EASA Form 52B) to the competent authority of the Member State of registry, the declared production organisation should make an investigation so as to be satisfied in respect of items listed below (as applicable for the respective type of aircraft). The documented results of this investigation should be kept on file by the declared production organisation. Some of these items may be required to be provided (or made available) to the operator or owner of the aircraft (and in some cases the competent authority of the Member State of registry):

1. Equipment or design changes that do not meet the requirements of the State of manufacture but have been accepted by the competent authority of the importing country.
2. Identification of products or parts that:
   (a) are not new;
   (b) are furnished by the buyer or future operator (including those identified in point 21L.A.252(b)(1)).
3. Technical records which identify the location and serial numbers of components for which special traceability requirements apply for continued-airworthiness purposes, including those identified in point 21L.A.252(b)
4. Logbook and a modification record book for the aircraft as required by EASA.
5. Logbooks for products identified in point 21L.A.252(b)(1) installed as part of the type design as required by EASA.
6. A weight and balance report for the completed aircraft.
7. A record of missing items or defects which do not affect airworthiness. These, for example, could be furnishings or buyer-furnished equipment (BFE) (items of equipment may be recorded in a technical log or other suitable arrangement such that the operator and EASA are formally aware of).
8. Product support information required by other implementing rules and associated CSs or GM, such as a maintenance manual, a parts catalogue, all of which should reflect the actual build standard of the particular aircraft. Also, an electrical load analysis and a wiring diagram.
9. Records which demonstrate completion of maintenance tasks appropriate to the test flight flying hours recorded by the aircraft. These records should show the relationship of the maintenance status of a particular aircraft to the manufacturer's recommended maintenance task.
10. Details of the serviceability state of a particular aircraft in respect of:
    (a) the fuel and oil contents;
    (b) provision of operationally required emergency equipment.
11. An approved flight manual which conforms to the build standard and modification state of a particular aircraft shall be available.
12. Show that inspections for foreign objects at all appropriate stages of manufacture have been satisfactorily performed.
13. The registration has been marked on the exterior of the aircraft as required by national legislation. Where required by national legislation, affix a fireproof owner's nameplate.
14. Where applicable, there should be a certificate for noise and for the aircraft radio station.
15. The installed compass and/or compass systems have been adjusted and compensated, and a deviation card displayed in the aircraft.
16. A record of rigging and control surface movement measurements.
17. Where maintenance work has been performed under point 21L.A.126(e), issue a release to service that includes a statement that the particular aircraft is in a condition for safe operation.
18. List of all applicable service bulletins (SBs) and airworthiness directives (ADs) that have been implemented.

GM1 21L.A.127(l) Obligations of the declared production organisation

ED Decision 2023/013/R

APPLICABLE SUBPART A REQUIREMENTS

The following requirements in Subpart A are applicable to declared production organisations:

— points 21L.A.3(b), (c), (d), (e) and (f) Reporting system

— point 21L.A.5 Collaboration between design and production

— point 21L.A.6(b) Marking

— points 21L.A.7(b), (c) and (d) Record-keeping

— point 21L.A.10 Access and investigation

— point 21L.A.11 Findings and observations

— point 21L.A.12 Means of compliance

21L.A.128 Notification of changes and cessation of activities

Regulation (EU) 2022/1358

The declared production organisation shall notify the competent authority without undue delay of the following:

(a) any changes to the information that has been declared in accordance with point (c) of point 21L.A.123;

(b) any changes to the management system for production that are significant to the showing of conformity or to the airworthiness and environmental compatibility characteristics of the product or part;

(c) the cessation of some of or all the activities covered by the declaration.

AMC1 21L.A.128 Notification of changes and cessation of activities

ED Decision 2023/013/R

CHANGES AND THEIR TIMELY NOTIFICATION

The declared production organisation should notify the competent authority of the following changes:

(a) Changes to the information that has been declared in accordance with point (c) of point 21L.A.123v (according to point 21L.A.128(a)):

— change of the registered name of the organisation;

— change of the registered address of the organisation's principal place of business and, where applicable, change of the operating sites and/or their addresses;

— change of the accountable manager and/or their contact details; and

— change of the scope of work.

These changes are notified to the competent authority by submitting a revised declaration of production capability.

(b) Significant changes to the management system for production (according to point 21L.A.128(b)):

— significant changes to production capacity;

— change to the manufacturing methods;

— changes in the organisation structure, especially to those parts of the organisation in charge of quality;

— change of the managers nominated according to point 21L.A.125(c)(2);

— changes in the management system for production or quality system that may have an important impact on the conformity/airworthiness of each product or part; and

— changes in the placement or control of significant subcontracted work or supplied parts.

— These changes are notified without revising the declaration of production capability.

Timely notification: The declared production organisation should notify the change(s) as soon as it has taken the decision to introduce the respective change(s) but no later than 10 working days after the change(s) became effective.

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

21L.A.141 Scope

Regulation (EU) 2022/1358

This Subpart establishes the procedure for applying for a certificate of airworthiness or a restricted certificate of airworthiness for an aircraft whose design has been certified or declared in accordance with this Annex, and establishes the rights and obligations of the applicants for, and holders of, those certificates.

21L.A.142 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person under whose name an aircraft is registered or will be registered in a Member State ('Member State of registry') may apply for a certificate of airworthiness or for a restricted certificate of airworthiness for that aircraft under the conditions laid down in this Subpart.

21L.A.143 Application for a certificate of airworthiness or a restricted certificate of airworthiness

Regulation (EU) 2022/1358

(a) A natural or legal person shall apply for a certificate of airworthiness or a restricted certificate of airworthiness in a form and manner established by the competent authority of the Member State of registry.

(b) A natural or legal person may apply for:

1. a certificate of airworthiness for aircraft which conform to a type certificate that has been issued by the Agency in accordance with Subpart B of Section B of this Annex; or
2. a restricted certificate of airworthiness for aircraft which conform to a declaration of design compliance in accordance with Subpart C of this Annex which is registered by the Agency in accordance with point 21L.B.63 at the time of application.

(c) For a new aircraft that conforms to a type certificate issued by the Agency, the applicant shall include in the application:

1. an aircraft statement of conformity (EASA Form 52 or EASA Form 52B)
   (i) a production organisation that has declared their production capability under Subpart G of this Annex and has been registered by the competent authority in accordance with point 21L.B.142; or
   (ii) a production organisation approval holder under the privileges of point (b) of point 21.A.163 of Annex I (Part 21) ;
2. a weight and balance report with a loading schedule;
3. the flight manual if required by the applicable type-certification basis.

(d) For a new aircraft that conforms to a declaration of design compliance which is registered by the Agency, the applicant shall include in the application:

1. an aircraft statement of conformity (EASA Form 52B) that is either issued or signed by:

(i) a natural or legal person in accordance with Subpart R of this Annex;

(ii) a production organisation that has declared their production capability under Subpart G of this Annex and has been registered by the competent authority in accordance with point 21L.B.142; or

(iii) a production organisation approval holder under the privileges of point (d) of point 21.A.163 of Annex I (Part 21) ;

2. a weight and balance report with a loading schedule;

3. the flight manual if required by the applicable detailed technical specifications for the declaration of design compliance.

(e) For a used aircraft originating from a Member State, the applicant shall include in the application an airworthiness review certificate issued in accordance with Annex I (Part-M) or Annex Vb (Part-ML) to Regulation (EU) No 1321/2014.

(f) For a used aircraft originating from a non-Member State, the applicant shall include in the application:

1. a statement from the competent authority of the State where the aircraft is, or was, registered, reflecting the airworthiness status of the aircraft at the time of transfer;

2. the historical records to establish the production, modification, and maintenance standard of the aircraft;

3. a weight and balance report with a loading schedule;

4. the flight manual;

5. a recommendation for the issuance of a certificate of airworthiness or restricted certificate of airworthiness and for an airworthiness review certificate pursuant to an airworthiness review in accordance with Annex I (Part-M) to Regulation (EU) No 1321/2014 or an airworthiness review certificate in accordance with Annex Vb (Part-ML) to Regulation (EU) No 1321/2014.

(g) Unless otherwise agreed, the statements referred to in points (c)(1), (d)(1) and (f)(1) shall be issued no more than 60 days before the presentation of the aircraft to the competent authority of the Member State of registry.

GM1 21L.A.143(c)(1)(ii) Application for a certificate of airworthiness or a restricted certificate of airworthiness

ED Decision 2023/013/R

APPROVED PRODUCTION ORGANISATIONS THAT APPLY FOR A CERTIFICATE OF AIRWORTHINESS

The holder of a production organisation approval issued under Subpart G of Annex I (Part 21) to Regulation (EU) No 748/2012 should use EASA Form 52 (and not EASA Form 52B) when it uses its privileges under point 21.A.163(b) and applies for a certificate of airworthiness for an aircraft with a type certificate. This indicates to the competent authority that the production organisation utilises its privileges to apply for a certificate of airworthiness without further showing.

GM1 21L.A.143(d)(1)(iii) Application for a certificate of airworthiness or a restricted certificate of airworthiness

ED Decision 2023/013/R

APPROVED PRODUCTION ORGANISATIONS THAT APPLY FOR A RESTRICTED CERTIFICATE OF AIRWORTHINESS

The holder of a production organisation approval issued under Subpart G of Annex I (Part 21) to Regulation (EU) No 748/2012 should use EASA Form 52B (and not EASA Form 52) when it uses its privileges under point 21.A.163(b) and applies for a restricted certificate of airworthiness for an aircraft with a registered declaration of design compliance (declared aircraft). Only EASA Form 52B may be used for declared aircraft because references to the declaration are included in that form. The holder of a production organisation approval should include its approval number on EASA Form 52B and indicate that this is an approved organisation so that the competent authority is made aware that the production organisation utilises its privileges to apply for a restricted certificate of airworthiness without further showing.

21L.A.144 Obligations of the applicant for a certificate of airworthiness or a restricted certificate of airworthiness

Regulation (EU) 2022/1358

The applicant for a certificate of airworthiness or for a restricted certificate of airworthiness shall:

(a) present the manuals, placards, listings, and instrument markings and other necessary information required by the applicable type-certification basis or by the applicable detailed technical specifications for declarations of design compliance in one or more of the official language(s) of the European Union acceptable to the competent authority of the Member State of registry;

(b) demonstrate that their aircraft is identified in accordance with Subpart Q of this Annex;

(c) arrange for inspections of the competent authority of the Member State of registry to assess whether the aircraft has any non-conformities that could affect the safety of the aircraft.

21L.A.145 Transferability and re-issuance of a certificate of airworthiness and of a restricted certificate of airworthiness within Member States

Regulation (EU) 2022/1358

Where the ownership of an aircraft has changed:

(a) if it remains on the same register, the certificate of airworthiness, or the restricted certificate of airworthiness issued in accordance with Subpart H of Section B of this Annex, shall be transferred together with the aircraft;

(b) if the aircraft is intended to be registered in another Member State, the natural or legal person under whose name the aircraft will be registered shall apply to the competent authority of the new Member State of registry for a new certificate of airworthiness or a restricted certificate of airworthiness and shall include in this application the former certificate of airworthiness or restricted certificate of airworthiness issued in accordance with Subpart H of Section B of this Annex and a valid airworthiness review certificate issued in accordance with Annex I (Part-M) or Annex Vb (Part-ML) to Regulation (EU) No 1321/2014.

21L.A.146 Continued validity of a certificate of airworthiness and of a restricted certificate of airworthiness

Regulation (EU) 2022/1358

(a) A certificate of airworthiness or a restricted certificate of airworthiness shall remain valid as long as:

1. the aircraft remains on the same register;
2. the certificate has not been surrendered by the holder;
3. the aircraft remains in compliance with the relevant requirements of Regulation (EU) and the delegated and implementing acts adopted on the basis thereof and with the applicable type design or with the applicable design data of an aircraft for which design compliance has been declared, and with the continuing airworthiness requirements, taking into account the provisions related to the handling of findings as specified under point 21L.B.21;
4. the certificate has not been revoked by the competent authority of the Member State of registry under point 21L.B.22.

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority of the Member State of registry.

SUBPART I — NOISE CERTIFICATES AND RESTRICTED NOISE CERTIFICATES

21L.A.161 Scope

Regulation (EU) 2022/1358

This Subpart establishes the procedure for applying for a noise certificate or a restricted noise certificate for an aircraft whose design has been certified or declared in accordance with this Annex and establishes the rights and obligations of the applicants for, and holders of, those certificates.

21L.A.162 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person under whose name an aircraft is registered or will be registered in a Member State may apply for a noise certificate or a restricted noise certificate for that aircraft under the conditions laid down in this Subpart.

21L.A.163 Application

Regulation (EU) 2022/1358

(a) A natural or legal person shall apply for a noise certificate or a restricted noise certificate in a form and manner established by the competent authority of the Member State of registry.

(b) A natural or legal person may apply for:

1. a noise certificate for aircraft which conform to a type certificate that has been issued by the Agency in accordance with Subpart B of Section B of this Annex; or
2. a restricted noise certificate for aircraft which conform to a declaration of design compliance submitted in accordance with Subpart C of this Annex which is registered by the Agency in accordance with point 21L.B.63 at the time of application.

(c) The applicant shall include in the application:

1. with regard to new aircraft:
   - (i) an aircraft statement of conformity (EASA Form 52 or EASA Form 52B)
     - (A) a natural or legal person in accordance with Subpart R of this Annex;
     - (B) a production organisation that has declared their production capability under Subpart G of this Annex and has been registered by the competent authority in accordance with point 21L.B.142; or
     - (C) a production organisation approval holder under the privileges of point (b) of point 21.A.163 of Annex I (Part 21) ;
   - (ii) the reference to the noise record within the Agency database of noise levels reflecting the noise information determined in accordance with the applicable noise requirements;

2. with regard to used aircraft:

(i) the reference to the noise record within the Agency database of noise levels reflecting the noise information determined in accordance with the applicable noise requirements; and

(ii) the historical records to establish the production, modification, and maintenance standard of the aircraft.

(d) Unless otherwise agreed, the statements referred to in point (c)(1)(i) shall be issued no more than 60 days before the presentation of the aircraft to the competent authority of the Member State of registry.

GM1 21L.A.163(b)(2) Application

ED Decision 2023/013/R

RESTRICTED NOISE CERTIFICATE

In accordance with Article 18(2)(a) of Regulation (EU) 2018/1139, a restricted noise certificate is issued for individual aircraft for which noise requirements apply and which conform to a design that has been subject to a declaration of design compliance in accordance with Subpart C of Annex Ib (Part 21 Light).

GM1 21L.A.163(c)(1)(ii) Application

ED Decision 2023/013/R

NOISE RECORDS FOR A NOISE CERTIFICATE

The applicant for a noise certificate to be issued for an aircraft within the scope of Subpart B of Annex Ib (Part 21 Light) should find the supporting noise data in the EASA database of noise levels[1].

GM2 21L.A.163(c)(1)(ii) Application

ED Decision 2023/013/R

NOISE RECORDS FOR A RESTRICTED NOISE CERTIFICATE

The applicant for a restricted noise certificate to be issued for an aircraft within the scope of Subpart C of Annex Ib (Part 21 Light) should find the supporting noise data in the EASA Part 21 Light database of declared noise levels.

21L.A.164 Transferability and re-issuance of noise certificates and restricted noise certificates within Member States

Regulation (EU) 2022/1358

Where the ownership of an aircraft has changed:

(a) if the aircraft remains on the same register, the noise certificate, or the restricted noise certificate issued in accordance with Subpart I of Section B of this Annex, shall be transferred together with the aircraft;

[1] https://www.easa.europa.eu/en/domains/environment/easa-certification-noise-levels

(b) if the aircraft is intended to be registered in another Member State, the natural or legal person under whose name the aircraft will be registered shall apply to the competent authority of the new Member State of registry for a new noise certificate or restricted noise certificate and shall include in this application the former noise certificate or restricted noise certificate issued in accordance with Subpart I of Section B of this Annex.

GM1 21L.A.164(b) Transferability and re-issuance of noise certificates and restricted noise certificates within Member States

ED Decision 2023/013/R

When applying for aircraft registration, the aircraft owner should declare to the Member State of registry that the configuration of the individual aircraft serial number has not been changed or should provide the Member State of registry with information about any changes that might influence the certified or declared noise level.

21L.A.165 Continued validity of a noise certificate and of a restricted noise certificate

Regulation (EU) 2022/1358

(a) A noise certificate or a restricted noise certificate shall remain valid as long as:

1. the aircraft remains on the same register;
2. the certificate has not been surrendered by the holder;
3. the aircraft remains in compliance with the applicable environmental protection requirements of Regulation (EU)2018/1139 and the delegated and implementing acts adopted on the basis thereof and with the applicable type design or with the applicable design data of an aircraft for which design compliance has been declared, taking into account the provisions related to the handling of findings as specified under point 21L.B.21;
4. the certificate has not been revoked by the competent authority of the Member State of registry under point 21L.B.22.

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority of the Member State of registry.

SUBPART J — DECLARED DESIGN ORGANISATIONS

21L.A.171 Scope

Regulation (EU) 2022/1358

This Subpart establishes:

(a) the procedure for declaring the design capability by natural and legal persons who design products under this Section; and

(b) the rights and obligations of the persons making declarations of design capability referred to in point (a).

21L.A.172 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person ('organisation' in this Subpart) required by point 21L.A.22, point 21L.A.82 or point 21L.A.204 to demonstrate their design capability may declare their capability under the conditions laid down in this Subpart.

21L.A.173 Declaration of design capability

Regulation (EU) 2022/1358

(a) Prior to or at the same time as applying for a design approval under this Section, or prior to submitting the application for the approval of flight conditions in accordance with point 21.A.710 of Annex I (Part 21) of a product designed by it, whatever comes first, the organisation shall submit a declaration of design capability to the Agency.

(b) The declaration, and any subsequent changes thereto, shall be made in a form and manner established by the Agency.

(c) The declaration shall include the information necessary for the Agency to become familiar with the organisation and the intended scope of work, and shall include at least the following:

1. the registered name of the organisation;
2. the contact details of the organisation's registered address of the principal place of business and, where applicable, of the operating sites of the organisation;
3. the names and contact details of the head of the design organisation;
4. the intended scope of work;
5. a statement confirming that the organisation:
   (i) has a management system for design in accordance with point (a) of point 21L.A.174; and
   (ii) will maintain the management system for design in compliance with this Subpart;
6. a statement confirming that the organisation will adhere to the processes and procedures established in accordance with point (d) of point 21L.A.174;
7. a statement that the organisation agrees to undertake the obligations of a declared design organisation in accordance with point 21L.A.177.

(d) The declaration of design capability shall be submitted to the Agency.

GM1 21L.A.173(b) Declaration of design capability

ED Decision 2023/013/R

SUBMISSION OF THE DECLARATION

The EASA form to request the registration of the declaration of design capability is available on the EASA website. The documents to be sent with the request are indicated in the form and include the Declaration of Design Capability — see AMC1 21L.A.173(c) / EASA Form 204.

AMC1 21L.A.173(c) Declaration of design capability

ED Decision 2023/013/R

DECLARATION FORM

The natural or legal person that declares its design capability should provide the information required by point 21L.A173(c) in the declaration form that is available on the EASA Website.

EASA Form 204

PART 1 – REQUEST FOR REGISTRATION AND DECLARATION OF DESIGN CAPABILITY

1. Design Organisation Details		
1.1 Head of Design Organisation	Title	☐ Mr ☐ Ms
	Name	
	First name	
	Phone	
	Email	
1.2 Operating Sites where design and testing activities are taking place - may be left blank if same as in 2.1 Declarant Data	Address(es), Phone, Email	

2. Intended Scope of Work	
2.1 Product Category	☐ Aeroplane with a MTOM of 2 000 kg or less and a max. seating configuration of 4 persons ☐ Sailplane with a MTOM of 2 000 kg or less ☐ Powered Sailplane with a MTOM of 2 000 kg or less ☐ Rotorcraft with a MTOM of 1 200 kg or less and a max. seating configuration of 4 persons ☐ Gyroplanes ☐ Balloons

	☐ Hot Air Airships ☐ Passenger gas airships designed for no more than 4 persons ☐ Piston engines ☐ Fixed pitch propellers
2.2 Certification Activities	☐ Type Certification under Part 21 Light Subpart B ☐ Supplemental Type Certification (STC) under Part 21 Light Subpart E ☐ Major Repair approval under Part 21 Light Subpart M

2.3 Detailed Scope of Work Description

For Type Certification activities:

Aircraft type(s): - [product 1]

- [product 2]

Note: In the case of type-certification activities, all relevant technical areas are included.

For STC activities:

[N/A or see below]

A. Technical areas:

	Aeroplanes	(Powered) Sailplanes	Balloons	Hot-air airships	Gas airships	Rotorcraft	Gyroplanes	Engines	Propellers
Flight									
Structures									
Cabin									
Hydromechanical systems									
Environmental control systems									
Electrical systems									
Avionics									
Powerplant and fuel systems									
Rotor drive systems									

	Propulsion									

B. Limitations

2.3 Detailed Scope of Work Description continued	**For Major Repair activities:**

[N/A or see below]

A. Technical areas:

	Aeroplanes	(Powered) Sailplanes	Balloons	Hot-air airships	Gas airships	Rotorcraft	Gyroplanes	Engines	Propellers
Flight									
Structures									
Cabin									
Hydromechanical systems									
Environmental control systems									
Electrical systems									
Avionics									
Powerplant and fuel systems									
Rotor drive systems									

	Propulsion B. Limitations

3. Declarant's Statements		
3.1. Declaration of Compliance		
The Declared Design Organisation (DDO) has established and implemented a management system for design in accordance with point 21L.A.174. This management system will be maintained in compliance with Subpart J of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012. The references of the elements of the management system for design are included in the Annex to this Declaration. All the personnel of the DDO must adhere to the processes and procedures referred to in the Annex to this Declaration. I hereby commit to undertake the obligations of a Declared Design Organisation in accordance with point 21L.A.177. **I confirm that all information contained in this Declaration, including its Annex, is complete and correct.**		
Date/Location	Name (Head of Design Organisation)	Signature
Important Note: EASA cannot accept Declarations without signature. Please make sure that you sign the Declaration.		
This Declaration should be sent by email to: applicant.services@easa.europa.eu		

ANNEX TO THE DECLARATION OF DESIGN CAPABILITY

This Annex includes references to the Declared Design Organisation's (DDO) documentation showing compliance with the requirements of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012.

No	Part 21 Light	Subject	DDO reference DDOE* reference, as relevant
1.	**General**		
1.1	21L.A.174(d)	Process and procedure documentation issuance, approval or change	
2.	**Organisation, key personnel and compliance verification staff**		
2.1	21L.A.175(e)	Organisational structure documented and kept updated	
2.2	21L.A.175(b)	Identification of key personnel nominated by the head of design organisation to ensure that the organisation is in compliance with the requirements of Part 21 Light Subpart J: — head of airworthiness function, — head of independent monitoring function, — others	
2.3	21L.A.175(c)	Nomination process for key personnel ensuring they have the appropriate knowledge, background and experience to discharge their responsibilities	
2.4	21L.A.174(b)(2)	List of authorised staff to perform compliance verification and the criteria and process for their initial nomination and maintenance of their authorisation	
2.5	21L.A.175(d)	The numbers of staff in all technical departments and their level of experience are sufficient, and staff have been given the appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the declared design organisation in respect of airworthiness and environmental compatibility matters	
3.	**System monitoring**		
3.1	21L.A.174(c)	System monitoring procedure	
4.	**Subcontracting**		
4.1	21.A.174(b)(3) 21L.A.174(e)	Subcontracting procedure and a list of subcontractors	
5.	**Changes to the DDO**		

5.1	21L.A.178	Procedure for the notification of organisational changes to EASA according to point 21L.A.178

No	Part 21 Light	Subject	DDO reference DDOE* reference, as relevant
6.	**Design and certification processes**		
6.1	21L.A.26	Identification and issuance of type design documentation and configuration control	
6.2	21L.A.24	Type-certificate application (including: type-certification basis, environmental-protection requirements and certification plan)	
6.3	21L.A.25	Compliance demonstration (preparation, verification and issuance of compliance documentation)	
6.4	21L.A.25(c)	Testing procedure and conformity of test specimen/prototype	
6.5	21L.A.25(d)	Flight-testing procedure and flight test operations manual (FTOM)	
6.6	21L.A.241	Procedure for requesting the issuance of permits to fly and the approval of associated flight conditions	
6.7	21L.A.25(e) 21L.A.241(c) 21L.B.46 21L.B.242	Preparing and supporting EASA in conducting its investigations (critical design review, pre-flight inspection, first-article inspection)	
6.8	21L.A.241(b) 21L.B.241	Preparing and supporting the competent authority in conducting its inspections	
6.9	21L.A.25(f)	Issuance of compliance declaration	
6.10	21L.A.63	Classification of changes to a type certificate	
6.11	21L.A.67	Approval of minor changes to a type certificate (TC)	
6.12	21L.A.68	Approval of major changes to a type certificate (TC)	
6.13	21L.A.86	Approval of a supplemental type certificate (STC)	
6.14	21L.A.203	Classification of repair designs	
6.15	21L.A.207	Approval of minor repair designs	
6.16	21L.A.208	Approval of major repair designs	
7.	**Obligations**		
7.1	21L.A.3	Reporting system	
7.2	21L.A.4	Airworthiness directives	

7.3	21L.A.5	Collaboration between design and production
7.4	21L.A.6	Marking
7.5	21L.A.7	Record-keeping
7.6	21L.A.8	Manuals
7.7	21L.A.9	Instructions for continued airworthiness

***Instructions:** If the DDO, for the purpose of compliance with point 21L.A.174(d), has produced a Declared Design Organisation Exposition (DDOE), then the DDOE sections should be referenced in the right-hand column of the form.

21L.A.174 Management system for design

Regulation (EU) 2022/1358

(a) The declared design organisation shall establish, implement, and maintain a management system for design with clear accountability and lines of responsibility throughout the organisation that:

1. corresponds to the nature and complexity of its activities and the size of the organisation, and takes into account the hazards and associated risks inherent in these activities;
2. is established under the accountability of a single manager nominated as the head of the design organisation according to point (a) of point 21L.A.175.

(b) The declared design organisation shall have, as part of their management system for design, a means to provide design assurance by establishing, implementing and maintaining a system for the control and supervision of the design, and of design changes and repairs, of products. This system shall:

1. include an airworthiness function responsible for ensuring that the designs of products and the designs of changes and repairs thereto comply with the applicable type-certification basis and the applicable environmental protection requirements;
2. establish, implement and maintain an independent function to verify the demonstration of compliance on the basis of which the organisation declares compliance with the applicable type-certification basis and with the applicable environmental protection requirements;
3. specify the manner in which the design assurance system accounts for the acceptability of the parts that are designed or the tasks that are performed by partners or subcontractors according to methods which are the subjects of written procedures.

(c) The declared design organisation shall establish, as part of their management system for design, an independent function to monitor the compliance of the organisation with the relevant requirements, and compliance with, and adequacy of, the management system for design. This monitoring shall include a system to provide feedback to the person or a group of persons referred to in point (b) of point 21L.A.175, and to the accountable manager referred to in point (a) of point 21L.A.175 to ensure, as necessary, corrective action.

(d) The declared design organisation shall establish, maintain and keep updated processes and procedures that ensure the design compliance of products with the applicable type-certification basis, applicable detailed technical specifications and applicable environmental protection requirements. The declared design organisation shall make documentary evidence of these processes and procedures available to the Agency upon request.

(e) Where any parts or any changes to the products are designed by partner organisations or subcontractors, the processes and procedures in point (d) shall include a description of how the design organisation is able to give, for all parts, the assurance of compliance required by point (b)(2), and shall contain, directly or by cross-reference, descriptions and information on the design activities and organisation of those partners or subcontractors.

(f) If the declared design organisation holds (an)other organisation certificate(s) issued on the basis of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, the declared design organisation may integrate the design management system with the management system that is required for the issuance of the other certificate(s).

GM1 21L.A.174(b) Management system for design

ED Decision 2023/013/R

DESIGN ASSURANCE SYSTEM

(a) Purpose

This GM outlines some basic principles and objectives of the design assurance system.

(b) Definitions

(1) 'Design assurance system'

The design assurance system includes the organisational structure, responsibilities, procedures, and resources to ensure the proper functioning of the design organisation.

(2) 'Design assurance' refers to all planned and systematic actions necessary to provide adequate confidence that the organisation has the capability to:

— design products or parts in accordance with the applicable type-certification basis and environmental protection requirements;

— demonstrate and verify compliance with the type-certification basis and environmental protection requirements; and

— demonstrate compliance to EASA.

(3) 'Type investigation' refers to the tasks of the organisation in support of the type certificate (TC), supplemental type certificate (STC), or other design approval processes necessary to demonstrate, verify, and maintain compliance with the applicable type-certification basis and environmental protection requirements.

The complete design process, starting with the type-certification basis, environmental protection requirements and product specifications, and culminating with the issuance of a type certificate (TC), is shown in the diagram in Figure 1. This identifies the relationship between the design, the type investigation and the design assurance processes.

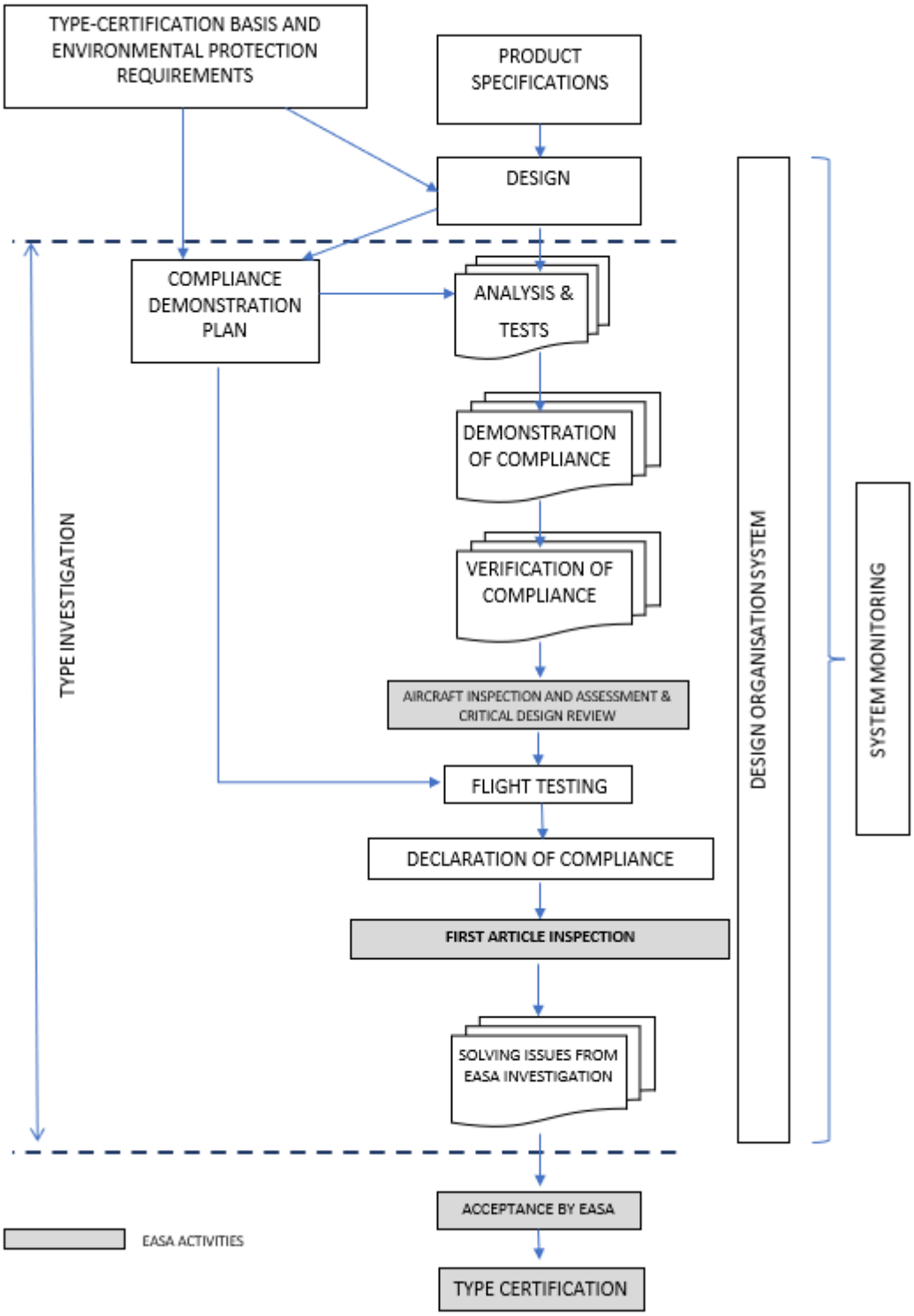

Figure 1 — Relationship between design, design assurance and type investigation

PLANNED AND SYSTEMATIC TASKS

For design organisations that carry out the certification process of products, their planned and systematic tasks should cover the following, and the related procedures should be defined accordingly.

(a) General

(1) Issue or, where applicable, supplement, or amend the documentation of the management system for design (or, if it is used, the declared design organisation exposition (DDOE)) in accordance with point 21L.A.174(d).

(2) Assure that all the procedures are adhered to.

(3) Conduct the certification process.

(4) Nominate staff as 'compliance verification engineers' that are responsible for approving compliance documents as defined in point (c) below.

(5) Nominate staff that belong to the airworthiness function and are responsible as defined in GM1 21L.A.174(b)(1).

(6) In the case of an applicant for an STC, obtain the agreement of the TC holder for the proposed STC to the extent that is defined in point 21L.A.86.

(7) Ensure that there is full and complete liaison between the design organisation and the related organisations that have responsibility for the products and parts that are manufactured according to the type design.

(8) Provide assurance to EASA that any prototype models and test specimens adequately conform to the type design (see points 21L.A.25(c), 21L.A.85(c) and 21L.A.206(c)).

(b) Head of the design organisation (or deputy)

The head of the design organisation (HDO), or an authorised representative, should sign a declaration of compliance (see points 21L.A.25(f), 21.A.85(f) and 21L.A.206(f)) with the applicable type-certification basis and environmental protection requirements after verifying the satisfactory completion of the certification process. The signature of the HDO on the declaration of compliance confirms that the relevant procedures of the management system for design have been followed.

(c) Compliance verification

(1) Approval through the signing of all the compliance documents, including test programmes and data that are necessary for the verification of compliance with the applicable type-certification basis and environmental protection requirements, as defined in the compliance-demonstration plan.

(2) Approval of the technical content (completeness, technical accuracy, etc.), including any subsequent revisions, of the manuals to be approved by EASA (aircraft flight manual (AFM), airworthiness limitations section (ALS) of the instructions for continued airworthiness (ICAs)).

(d) Maintenance and operating instructions

(1) Ensuring the preparation and updating of all the maintenance and operating instructions (including ICAs and SBs) that are needed to maintain airworthiness (i.e. continuing airworthiness) in accordance with the relevant certification specifications (CSs).

(2) In accordance with points 21L.A.8 and 21L.A.9 and, where applicable, point 21.A.609, ensuring that those documents are made available as per point 21.A.9(c).

GM1 21L.A.174(b)(1) Management system for design

ED Decision 2023/013/R

AIRWORTHINESS FUNCTION

The following tasks are normally performed by the airworthiness function:

(a) Liaison between the design organisation and EASA with respect to all aspects of the design certification application.

(b) Preparation of the compliance-demonstration plan and obtaining its approval by EASA.

(c) Coordination internally, in the design organisation, of all compliance-demonstration activities according to the compliance-demonstration plan.

(d) Regular reporting to EASA about the progress of compliance-demonstration activities and coordination of EASA investigations. These include the necessary arrangements for the physical inspection and assessment of the aircraft and the critical design review, in accordance with point 21L.A.241(c)(2), and the first-article inspection, in accordance with point 21L.B.46.

(e) Establishing the compliance checklist and updating it with any changes, as necessary.

(f) Checking that all the compliance documents that are necessary to demonstrate compliance with the applicable type-certification basis and the applicable environmental protection requirements, as well as for completeness, are prepared and signing the documents for release.

(g) Providing verification to the head of the design organisation that all the activities required for a type investigation have been properly completed.

(h) Endorsing the classification of changes and repairs in accordance with point 21L.A.63 and 21L.A.203 respectively.

(i) Ensuring the initiation of activities as a response to an occurrence report and providing information to EASA if the airworthiness is impaired.

(j) Advising EASA on the issuing of airworthiness directives (ADs) in general based on service bulletins (SBs).

(k) Monitoring significant events on other aeronautical products, as far as they are relevant, to determine their effect on the airworthiness of the products designed by the design organisation.

(l) Ensuring that there is cooperation in preparing SBs and any subsequent revisions, with special attention being given to the manner in which the contents affect airworthiness and environmental protection aspects.

GM1 21L.A.174(b)(2) Management system for design

ED Decision 2023/013/R

INDEPENDENT VERIFICATION FUNCTION OF THE DEMONSTRATION OF COMPLIANCE

(a) The independent verification function of the demonstration of compliance is normally carried out by a person that did not create the compliance data. Such a person may work in conjunction with the individuals that prepare compliance data.

(b) The verification is normally shown by signing all compliance documents, including test programmes and data that are necessary for the demonstration of compliance with the applicable type-certification basis and the applicable environmental protection requirements as defined in the compliance-demonstration plan.

(c) For a product, there is normally only one compliance-verification engineer that is nominated for each relevant technical discipline. The relevant procedures would normally describe the way of action in case of non-availability of the nominated persons and their replacement, when necessary.

(d) For STC cases, when compliance statements and associated documentation are produced by the TC holder, and when this data is approved under the system of the authority of the TC holder, then the STC applicant does not need to provide, within its own DDO, the independent verification function that is required by point 21L.A.124(b)(2) for that data.

GM1 21L.A.174(b)(3);(e) Management system for design

ED Decision 2023/013/R

PARTNERS AND SUBCONTRACTORS

Examples of elements that the process to control partners and subcontractors should normally address are:

— the identification of the work to be subcontracted (e.g. design of parts, drafting drawings, stress analysis, laboratory testing);

— the selection of a subcontractor based on its capability to perform the identified work (criteria (e.g. facilities, knowledge and experience) and the selection process);

— the working arrangement (e.g. purchase technical specifications, statement of work); this may cover technical requirements (for parts to be design or tasks to be performed) and process requirements (e.g. procedures to be followed by the subcontractor); and

— the control of the work performed by the subcontractor; this control would not only cover the deliverables provided by the partners and subcontractors but also the monitoring function required under point 21L.A.174(c), and, if relevant, the independent function to verify the demonstration of compliance required under 21L.A.174(b)(2).

If a partner or subcontractor holds a design organisation approval (DOA), then the declared design organisation may take this into account for the effective integration of that partner or subcontractor (e.g. simplifying the selection process when the scope of work of the respective subcontractor's DOA is similar with the scope of the subcontracted work).

The declared design organisation maintains a list of all selected partners and subcontractors, including their respective scope of subcontracted work.

If the independent function to verify the demonstration of compliance required under point 21L.A.174(b)(2) is subcontracted, the declared design organisation should normally identify in its own documentation the authorised staff of the partner or subcontractor performing this function.

GM1 21L.A.174(c) Management system for design

ED Decision 2023/013/R

INDEPENDENT MONITORING FUNCTION

The scope of the independent monitoring function is to ensure that:

— the management system for design remains compliant with the applicable requirements of the Part 21 Light and with any additional requirements as established by the organisation;

— the staff of the design organisation follow the documented procedures of the management system when performing their tasks; and

— the management system for design is adequate and enables the organisation through the use of its procedures to provide assurance that the designed products, changes and repairs are compliant with the applicable type-certification basis and the applicable environmental protection requirements.

An objective review of the complete set of design-management-related activities is provided through independent monitoring activities, such as audits, inspections, reviews. The independence of the monitoring activities is established by always ensuring that those activities are performed by staff that are not involved in the function, procedure or products they monitor, and that are independent from the operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring.

The monitoring is usually performed based on a monitoring plan. This plan is established to show when and how often the activities required by Part 21 Light will be audited. This plan normally includes, in a defined period of time, all the elements of the management system, including all subcontractors. The defined period of time for the audit planning typically does not exceed 24 months.

When a non-compliance is found, the root cause(s) and contributing factor(s) should be identified and corrective actions should be defined and followed up. When providing feedback, the compliance-monitoring function should define who is required to address any non-compliance in each particular case, and the procedure to be followed if the corrective action is not completed within the defined time frame.

Also, as required in point 21L.A.174(c), feedback has to be regularly provided to the head of the design organisation on the overall status of the compliance and adequacy of the management system for design, including main issues identified and cases where corrective actions have not been satisfactorily implemented.

Staff that perform an independent monitoring function should have access to all the parts of the design organisation and, as necessary, to any subcontracted organisations.

GM1 21L.A.174(d) Management system for design

ED Decision 2023/013/R

DOCUMENTATION

Point 21L.A.174(d) requires the declared design organisation to document its processes and procedures.

In order to do so, the declared design organisation may consider to establish a declared design organisation exposition (DDOE). The purpose of a DDOE is to set forth in a concise document format the organisational relationships, responsibilities, terms of reference, and the associated authority, procedures, means and methods of the organisation.

If utilised, the DDOE typically contains the following:

(a) a statement signed by the head of the design organisation confirming that the DDOE and any associated manuals, procedures and instructions that define the organisation's compliance with this Subpart will be complied with at all times;

(b) the title(s) and name(s) of the person(s) nominated in accordance with point 21L.A.175(b);

(c) the duties and responsibilities of the head of the design organisation and the person(s) as specified by point 21L.A.175(b), including matters on which they may deal directly with EASA on behalf of the organisation;

(d) an organisational chart showing the associated chains of responsibility of the managers as required by point 21L.A.175(e);

(e) the list of authorised staff that perform the independent function of verifying the demonstration of compliance as referred to in point 21L.A.174(b)(2);

(f) the nomination procedure for key personnel and authorised staff;

(g) a general description of manpower;

(h) a general description of the facilities located at each address specified in the declaration of design capability;

(i) a general description of the declared design organisation's scope of work as defined in the declaration of design capability (see also point 21L.A.176);

(j) the procedure for the notification of organisational changes to EASA according to point 21L.A.178;

(k) the procedure for the amendment of the DDOE;

(l) the independent system monitoring procedure;

(m) the subcontracting procedure and the list of partners and subcontractors;

(n) the procedure for identification and issuance of type design documentation and configuration control;

(o) the procedure(s) followed and forms used for type certification and supplemental type certification;

(p) the procedures for design changes;

(q) the procedure for design of repairs;

(r) the continued-airworthiness procedures (including reporting system and data in support of the issuance of airworthiness directives);

(s) the procedures for the collaboration between design and production organisations (including transfer of design data and approval of production concessions or non-conformities);

(t) the record-keeping procedure;

(u) the procedure for marking products and parts;

(v) the procedures for the issuance of manuals and instructions for continued airworthiness (ICAs);

(w) the procedures for the interface with EASA (supporting EASA investigations and answering to findings and observations).

The DDOE may be produced and distributed in paper or electronic format. If the above information is documented in separate procedures and instructions, the DDOE may include a summary of the information and an appropriate cross reference.

When changes to the organisation occur, the DDOE should be kept up to date. Changes to the organisation shall be notified to EASA as required by point 21L.A.178.

If the organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof (DOA, POA, etc.), so that the organisation is required to establish another exposition, the organisation may combine the documents by producing a separate manual or supplement that covers the differences between the DDOE and the other exposition. In that case, the manual or supplement should identify where in the other exposition the remaining information on the declared design organisation is covered. That remaining information then formally becomes part of the exposition.

21L.A.175 Resources of the declared design organisation

Regulation (EU) 2022/1358

(a) The declared design organisation shall nominate a head of the design organisation with the authority for ensuring that, within the organisation, all design activities are performed to the required standards and that the declared design organisation is continuously in compliance with the requirements for the management system for design referred to in points (a) to (c) of point 21L.A.174 and the processes and procedures referred to in point (d) of point 21L.A.174.

(b) The head of the design organisation shall nominate and identify key personnel within the organisation that are responsible for:

1. ensuring that the designs of products and the designs of changes and repairs thereto comply with the applicable type-certification basis, applicable detailed technical specifications and applicable environmental protection requirements;
2. the independent monitoring of the compliance and adequacy function; and
3. depending on the size of the organisation, any other person or group of persons who is or are needed to ensure that the organisation is in compliance with the requirements of this Section.

(c) The person or group of persons identified in point (b) shall:

1. be responsible to the head of the design organisation and have direct access to them;
2. have the appropriate knowledge, background and experience to discharge their allocated responsibilities.

(d) The declared design organisation shall ensure that:

1. the staff in all technical departments are of sufficient numbers and experience and have been given the appropriate authority to be able to discharge their allocated responsibilities and that these, together with the accommodation, facilities and equipment, are adequate to enable the staff to ensure that the products designed are airworthy and environmentally compatible;

2. there is full and efficient coordination within the declared design organisation in respect of airworthiness and environmental compatibility matters.

(e) The declared design organisation shall document the organisational structure of their organisation, along with the key personnel who are responsible for ensuring that the organisation is in compliance with this Subpart, keep them updated and make them available to the Agency upon request.

AMC1 21L.A.175(a) Resources of the declared design organisation

ED Decision 2023/013/R

HEAD OF THE DESIGN ORGANISATION

The nominated head of the design organisation should have the direct or functional responsibility for all departments of the organisation that are responsible for the design of products, changes or repairs. If the departments responsible for design are functionally linked, the head of the design organisation still carries the ultimate responsibility for the compliance of the organisation with Subpart J.

The head of the design organisation should:

(a) have sufficient knowledge and authority to be able to respond to EASA regarding major issues of the declared design organisation and the product design approval, and to implement any necessary improvements;

(b) have an understanding of this Annex, sufficient to discharge the relevant responsibilities.

AMC1 21L.A.175(b);(c) Resources of the declared design organisation

ED Decision 2023/013/R

NOMINATED MANAGERS

The person or group of persons nominated in accordance with point 21L.A.175(b) should represent the management structure of the organisation and be responsible for all the functions as specified in Subpart J. Depending on the size of the design organisation, the functions may be subdivided under individual managers (and, in fact, may be further subdivided) or combined.

At least the following key managers should be nominated:

— the manager responsible for the airworthiness function (chief of the airworthiness function); and

— the manager responsible for independent monitoring function (chief of the independent monitoring function).

(a) The responsibilities and tasks of each individual manager should be clearly defined in order to prevent uncertainties about the relations within the organisation. If a manager does not directly report to the head of the design organisation, they should have direct access to the head of the design organisation that is formally established.

(b) The chief of the airworthiness function should be able to demonstrate relevant knowledge, background and appropriate experience that are related to product certification and continued airworthiness, including knowledge of, and experience in, managing the design assurance system.

The tasks for which the chief of the airworthiness function should be responsible are presented in GM1 21L.A.174(b)(1).

(c) The chief of the independent monitoring function should be able to demonstrate relevant knowledge, background and appropriate experience that are related to the activities of the organisation, including knowledge of and experience in compliance monitoring. The chief of the independent monitoring function should not be responsible for other design or airworthiness function aspects.

The role of the chief of the independent monitoring function should be to ensure that:

(1) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21L.A.175(b);

(2) an audit plan is properly implemented, maintained, and continually reviewed and improved; and

(3) corrective actions are requested, as necessary, and their implementation is followed up.

With due regard to the size of the organisation and the nature and complexity of its activities, the compliance-monitoring-manager function may be exercised by the head of the design organisation.

GM1 21L.A.175(d) Resources of the declared design organisation

ED Decision 2023/013/R

PERSONNEL, FACILITIES AND ORGANISATION

(a) Personnel

The declared design organisation should ensure that the personnel that are made available by the organisation to comply with point 21L.A.175(d) are able, based on their special qualifications and numbers, to provide assurance of the design or modification of a product, as well as of the compilation and verification of all the data that is needed to meet the applicable type-certification basis and the applicable environmental protection requirements, as well as the necessary continued-airworthiness activities to support in-service products.

The organisation should have a system in place to plan the availability of staff to ensure that the organisation has sufficient and appropriately qualified staff to plan, perform, supervise, inspect, and monitor the organisation's activities in accordance with the organisation's scope of work.

(b) Facilities

The declared design organisation should have access to:

(1) workshops and production facilities that are suitable for manufacturing prototype models and test specimens;

(2) accommodation and test facilities that are suitable for carrying out tests and measurements needed to demonstrate compliance with the applicable type-certification basis and the applicable environmental protection requirements.

(c) Organisation

The declared design organisation should ensure that:

(1) an airworthiness function has been established and staffed on a permanent basis to act as the focal point for coordinating airworthiness and environmental compatibility matters;

(2) responsibilities for all tasks related to type investigations are assigned in such a way as to exclude gaps in authority; the responsibility for several tasks may be assigned to one person especially in the case of simple projects; and

(3) coordination between the technical departments and the persons in charge of the system monitoring required by point 21L.A.174(c) has been established to:

(i) ensure quick and efficient reporting and resolution of difficulties encountered using the handbook and associated procedures;

(ii) maintain the design assurance system;

(iii) optimise auditing activities.

(d) Competence of staff

The declared design organisation should establish and control the competence of the staff that are involved in the activities of the organisation, as detailed in the organisation's scope of work, in accordance with documented procedures.

Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. This training should be adapted based on experience that is gained within the organisation.

AMC1 21L.A.175(d) Resources of the declared design organisation

ED Decision 2023/013/R

AIRWORTHINESS AND COMPLIANCE-VERIFICATION PERSONNEL

(a) The declared design organisation should maintain a list of the personnel authorised to perform airworthiness and compliance-verification functions.

(b) For these personnel, the organisation should define a system to select, train, maintain and identify them for all the tasks for which they are needed.

(c) The numbers of these personnel that are needed to sustain the design activities should be identified by the organisation.

(d) These personnel should be chosen on the basis of their knowledge, background and experience.

(e) When necessary, complementary training should be established to ensure that personnel have sufficient background and knowledge in the scope of their authorisation. The minimum standards for new personnel to qualify in the functions should be established. The training should lead to a satisfactory level of knowledge of the procedures that are relevant for each particular role. Training policy forms part of the management system for design.

(f) The organisation should maintain a record of the personnel as defined in AMC 21L.A.7(d).

21L.A.176 Scope of work

Regulation (EU) 2022/1358

The declared design organisation shall identify the types of design work, the categories of products for which design activities are conducted, and the functions and duties that the organisation performs in regard to the airworthiness and environmental compatibility of products.

GM1 21L.A.176 Scope of work

ED Decision 2023/013/R

SCOPE OF WORK

The scope of work is stated in the declaration of design capability submitted by the declared design organisation (see AMC1 21L.A.173(c)). This includes the scope of work and the products, changes or repairs to them, with the appropriate limitations for which the design capability is declared. For declared design organisations that cover type-certification activities, the list of product types covered by the design assurance system should be included.

Changes in the scope of work are subject to notification as required by point 21L.A.178.

21L.A.177 Obligations of the declared design organisation

Regulation (EU) 2022/1358

A declared design organisation shall:

(a) work in accordance with clearly defined procedures, practices and processes;

(b) if the declared design organisation intends to conduct flight testing, maintain and keep updated an operations manual that provides a description of the organisation's policies and processes for flight testing and make this manual available to the Agency upon request;

(c) determine whether the designs of products, including changes and repairs, do not have any unsafe features and comply with the applicable type-certification basis, and with the applicable environmental protection requirements, and provide the Agency with statements/documentation confirming this;

(d) provide the Agency with information or instructions relating to continued airworthiness actions;

(e) comply with the requirements in Subpart A of this Annex applicable to declared design organisations.

AMC1 21L.A.127(b) Obligations of the declared production organisation and AMC1 21L.A.177(b) Obligations of the declared design organisation

ED Decision 2023/013/R

FLIGHT TEST OPERATIONS MANUAL (FTOM)

(a) General

(1) Scope: The FTOM covers flight-test operations.

The FTOM complexity should be proportionate to the organisation complexity's as well as to the complexity of a particular aircraft.

(2) Format

The FTOM may:

be included in the declared production organisation's (DPO) / declared design organisation's (DDO) documents; or

be a separate manual.

The FTOM may make reference to other documents to cover the contents listed in point (b) below (e.g. for record-keeping).

(3) Use by subcontractors

When flight tests are performed by subcontractors, they should comply with the FTOM of the declared production or design organisations, unless they have established an FTOM in compliance with Part 21 or Part 21 Light, the use of which has been agreed between the two organisations.

(b) The FTOM should contain the following elements:

(1) Exposition

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the staff in charge of flight-test activities. It should also mention the coordination between all departments affecting flight test, e.g. design office, production and maintenance, in particular the coordination for the establishment and update of flight-test programmes.

(2) Risk and safety management

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation, and associated methodologies.

(e.g. see additional guidance on the EASA webpage at https://www.easa.europa.eu/en/domains/general-aviation/documents-guidance-and-examples)

(3) Crew members

According to the flight-test category, the FTOM should describe the organisation's policy on the composition of the crew and the competence and currency of its flight-test pilots, including procedures for appointing crew members for each specific flight.

Note: For flight tests performed for demonstration-of-compliance activities required by points 21L.A.25 and 21L.A.44, the flight crew conditions or restrictions are part of the flight conditions approved by EASA. As part of the investigations required under point 21L.B.242, EASA will also check the flight crew qualifications to ensure that the flight testing can be conducted safely.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

(4) Carriage of persons other than crew members

According to the flight-test category, the FTOM should describe the organisation's policy in relation to the presence and safety onboard of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests (for the definition of the flight categories, refer to Appendix XII to Annex I (Part 21) to this Regulation).

(5) Instruments and equipment

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

(6) Documents

The FTOM should list the documents to be produced for flight testing, and include (or refer to) the procedures for their issuance, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a flight-test programme:

— flight order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. certification flight, production flight);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew;

— flight crew report;

(ii) documentation and information to be carried on board the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

(7) Permit to fly

The FTOM should describe the involvement of the flight-test organisation or flight-test team (as appropriate) in the process for the approval of flight conditions and the issuance of permits to fly in accordance with Part 21 Light Subpart P (and by reference to Part 21 Subpart P).

(8) Currency and training

The FTOM should describe how training for flight test is organised.

Currency of the flight-test crew may be ensured either through recent experience or refresher training.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight-test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, may be an acceptable means of compliance to demonstrate currency for a pilot that holds a flight-test rating.

GM1 21L.A.177(e) Obligations of the declared design organisation

ED Decision 2023/013/R

APPLICABLE SUBPART A REQUIREMENTS

The following requirements in Subpart A are applicable to declared design organisations:

— points 21L.A.3(a), (c), (d), (e) and (f) Reporting system

— point 21L.A.4 Airworthiness directives

— point 21L.A.5 Collaboration between design and production

— point 21L.A.6(a) Marking

— points 21L.A.7(a), (c) and (d) Record-keeping

— point 21L.A.8 Manuals

— point 21L.A.9 Instructions for continued airworthiness

— point 21L.A.10 Access and investigation

— point 21L.A.11 Findings and observations

— point 21L.A.12 Means of compliance

21L.A.178 Notification of changes and cessation of activities

Regulation (EU) 2022/1358

The declared design organisation shall notify the Agency without undue delay of the following:

(a) any changes to the information that has been declared in accordance with point (c) of point 21L.A.173;

(b) changes to the management system for design that are significant for the demonstration of compliance of the product designed by them;

(c) the cessation of some or all of the activities covered by the declaration.

AMC1 21L.A.178 Notification of changes and cessation of activities

ED Decision 2023/013/R

CHANGES AND THEIR TIMELY NOTIFICATION

The declared design organisation should notify EASA of the following changes:

1. Changes to the information that has been declared in accordance with point (c)

   — change of the registered name of the organisation;

   — change of the registered address of the organisation's principal place of business and, where applicable, change of the operating sites and/or their addresses;

   — change of the head of the design organisation and/or their contact details;

   — change of the scope of work.

   These changes are notified to EASA by submitting a revised declaration of design capability.

2. Significant changes to the management system for design (according to point 21L.A.178(b)):

   — change in the parts of the organisation that contribute directly to the airworthiness or environmental compatibility (independent checking function and airworthiness function);

   — new distribution of responsibilities affecting airworthiness or environmental compatibility aspects;

   — changes in the organisation structure;

   — change to the principles of procedures related to:

   — the type certification (see Subpart B);

   — the approval of changes (see Subpart D);

   — the approval of repair designs (see Subpart M);

   — continued airworthiness (see points 21L.A.3 and 21L.A.4);

   — the configuration control, when airworthiness or environmental compatibility is affected;

   — the acceptability of design tasks undertaken by partners or subcontractors (point 21L.A.174(b)(3));

   These changes are notified without revising the declaration of design capability.

Timely notification: The declared design organisation should notify the change(s) as soon as it has taken the decision to introduce the respective change(s) but no later than 10 working days after the change(s) became effective.

SUBPART K — PARTS

21L.A.191 Scope

Regulation (EU) 2022/1358

This Subpart establishes how the compliance of parts with the airworthiness requirements shall be shown.

21L.A.192 Showing of compliance

Regulation (EU) 2022/1358

(a) The showing of compliance with the airworthiness requirements of parts to be installed in a type-certified product or an aircraft for which design compliance has been declared shall be made:

1. in conjunction with the type-certification procedures of Subpart B, D or E of this Annex for the product in which it is to be installed; or
2. in conjunction with the declaration of design compliance procedures of Subpart C or F of this Annex for the product in which it is to be installed; or
3. under the ETSO authorisation procedure of Subpart O of Section A of Annex I (Part 21) ; or
4. in the case of standard parts, in accordance with officially recognised standards.

(b) In all cases where the approval of a part is explicitly required by Union law or Agency measures, the part shall comply with the applicable ETSO or with the specifications recognised as equivalent by the Agency in the particular case.

AMC1 21L.A.192(a)(4) Showing of compliance

ED Decision 2023/013/R

STANDARD PARTS

(a) In this context, a part is considered as a ‘standard part’ where it is designated as such by the design approval holder or declarant responsible for the product or part in which the part is intended to be used. In order to be considered a ‘standard part’, all design, manufacturing, inspection data and marking requirements necessary to demonstrate conformity of that part should be in the public domain and published or established as part of officially recognised standards; or

(b) For sailplanes and powered sailplanes, where it is a non-required instrument and/or equipment certified under CS 22.1301(b), if that instrument or equipment, when installed, functioning, functioning improperly or not functioning at all, does not in itself, or by its effect upon the sailplane and its operation, constitute a safety hazard.

‘Required’ in the term ‘non-required’ as used in point (b) means required by the applicable certification specifications (CS 22.1303, CS 22.1305 and CS 22.1307) or required by the relevant operating regulations and the applicable rules of the air, or as required by air traffic management (e.g. a transponder in certain controlled airspace).

Examples of equipment which can be considered 'standard parts' are electrical variometers, bank/slip indicators ball type, total energy probes, capacity bottles (for variometers), final glide calculators, navigation computers, data logger / barograph / turnpoint camera, bug wipers and anti-collision systems.

Equipment which must be approved in accordance with the applicable certification specifications shall comply with the applicable ETSO or equivalent, and is not considered a 'standard part' (e.g. oxygen equipment).

GM1 21L.A.192(a)(4) Showing of compliance

ED Decision 2023/013/R

OFFICIALLY RECOGNISED STANDARDS

In this context, 'officially recognised standards' means:

(a) those standards established or published by an official body whether having legal personality or not, which are widely recognised by the air transport sector as constituting good practice;

(b) the standards used by the manufacturer of the equipment as mentioned in point (b) of AMC1 21L.A.192(a)(4).

21L.A.193 Release of parts for installation

Regulation (EU) 2022/1358

(a) A part or product shall only be installed in a product when it is identified by the holder of a type certificate, supplemental type certificate, design change, repair design approval or with a declaration of design compliance as being suitable for installation, and when it is:

1. in a condition for safe operation;
2. marked in accordance with Subpart Q of this Annex; and
3. accompanied by an authorised release certificate (EASA Form 1) certifying that the item was manufactured in conformity with the applicable design data.

(b) By way of derogation from point (a)(3) and provided that the conditions in point (c) are met, the following parts do not require an authorised release certificate (EASA Form 1) in order to be installed in a type-certified product or in an aircraft for which design compliance has been declared:

1. a standard part;
2. a part that is:
   (i) not life limited, nor part of the primary structure, nor part of the flight controls;
   (ii) identified for installation in the specific aircraft by the holder of a type certificate, supplemental type certificate, design change, repair design approval or a declaration of design compliance;
   (iii) to be installed in an aircraft whose owner has verified compliance with the applicable conditions in (i) and (ii), and has accepted responsibility for this compliance;

3. a part for which the consequences of a non-conformity with its approved design data or declared design data has a negligible safety effect on the product and which is identified as such by the holder of the design approval or the declarant of design compliance in the instructions for continued airworthiness. In order to determine the safety effects of a non-conforming part, the design approval holder or declarant of a declaration of design compliance may establish in the instructions for continued airworthiness specific verification activities to be conducted by the installer of the part on the product;

4. in the case of the embodiment of a standard change as per point 21L.A.102 or a standard repair as per point 21L.A.202, a part for which the consequences of a non-conformity with its design data have a negligible safety effect on the product, and the part is identified as such in the certification specifications for standard changes and standard repairs issued in accordance with point 21.B.70 of Annex I (Part 21) . In order to determine the safety effects of a non-conforming part, specific verification activities to be conducted by the person that installs the part in the product may be established in these certification specifications;

5. a part that is exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012[1]; and

6. a part that is an item of a higher assembly identified in points (b)(1) to (b)(5).

(c) Parts listed in point (b) are eligible for installation in a type-certified product or in an aircraft for which design compliance has been declared without being accompanied by an EASA Form 1, provided that the installer holds a document issued by the person or organisation that manufactured the part, which declares the name of the part, the part number, and the conformity of the part with its design data, and which contains the date of issuance.

AMC1 21L.A.193(b)(3);(b)(4) Verification activities to be conducted on the part or appliance or release documentation prior to installation

ED Decision 2023/013/R

To prevent a non-negligible safety effect on the product due to the installation of a part referred to in point 21L.A.193(b)(3) and (b)(4) that could potentially not conform to its design, the design approval holder (DAH), declarant or EASA may identify in the ICAs (in the case of point 21L.A.193(b)(3)) or in CS-STAN (in the case of point 21L.A.193(b)(4)) any specific verification activities to be conducted by the installer on the part or appliance before installing it on the product in accordance with Regulation (EU) No 1321/2014.

When assessing the safety effect of a part identified in point 21L.A.193(b)(3) or (b)(4), the DAH, declarant or EASA should assume that the installer has conducted, in accordance with Regulation (EU) No 1321/2014, any specific verification activities on the part or release documentation, as identified in the ICAs or in CS-STAN.

Example:

Information from the DAH contained in the ICAs: 'Part XXX-YY must comply with flammability requirement JJJ-KKK'.

[1] Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

GM1 21L.A.193(b)(3);(b)(4) Meaning of 'negligible safety effect'

ED Decision 2023/013/R

For the purposes of point 21L.A.193(b)(3) and (b)(4), when 'a part or appliance for which the consequences of non-conformity to its design has a negligible safety effect when installed on the product' is mentioned, it means that any non-conformity of the part not identified by the installer that conducted the specific verification activities referred to in point 21L.A.193(c) at worst:

(a) slightly reduces the operational or functional capabilities of the aircraft or its safety margins;

(b) causes some physical discomfort to its occupants; and

(c) slightly increases the workload of the flight crew.

GM1 21L.A.193(b)(4) Certification specifications referred to in point 21L.A.193(b)(4)

ED Decision 2023/013/R

The corresponding certification specifications issued by EASA and mentioned in point 21L.A.193(b)(4) are the Certification Specifications for Standard Changes and Standard Repairs (CS-STAN)[1].

GM1 21L.A.193(b)(5) Equipment exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012

ED Decision 2023/013/R

The equipment exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012[2] that can be installed during maintenance as new equipment on an aircraft under point 21L.A.193(b)(5) is the equipment identified in the following points:

— CAT.IDE.A.100(a),

— CAT.IDE.H.100(a),

— NCC.IDE.A.100(b) and (c),

— NCC.IDE.H.100(b) and (c),

— NCO.IDE.A.100(b) and (c),

— NCO.IDE.H.100(b) and (c),

— NCO.IDE.S.100(b) and (c),

— NCO.IDE.B.100(b) and (c),

— SPO.IDE.A.100(b) and (c),

[1] https://www.easa.europa.eu/en/certification-specifications/cs-stan-standard-changes-and-standard-repairs

[2] Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0965&qid=1680007544570).

— SPO.IDE.H.100(b) and (c),

— SPO.IDE.S.100(b) and (c), and

— SPO.IDE.B.100(b) and (c)

of Commission Regulation (EU) No 965/2012.

GM1 21L.A.193(b)(6) Part that is part of a higher-level assembly

ED Decision 2023/013/R

An EASA Form 1 is not required for a part when that part is an element of a higher-level assembly for which an EASA Form 1 is not required.

SUBPART M — DESIGN OF REPAIRS TO TYPE-CERTIFIED PRODUCTS

21L.A.201 Scope

Regulation (EU) 2022/1358

This Subpart establishes:

(a) the procedure for applying for the approvals of repair designs to type-certified products;

(b) the rights and obligations of the applicants for, and holders of, those approvals referred to in point (a);

(c) provisions for standard repairs that do not require an approval.

GM1 21L.A.201 Scope

ED Decision 2023/013/R

Manuals and other instructions for continued airworthiness (such as the manufacturer's structural repair manual, maintenance manuals and engine manuals provided by the type-certificate holder or the supplemental type-certificate holder, as applicable) for operators contain useful information for the development and approval of repairs.

When that data is explicitly identified as approved, it may be used by operators without further approval to cope with anticipated in-service problems arising from normal usage provided that it is used strictly for the purpose for which it has been developed.

Approved data is data which is approved either by EASA or by an appropriately approved design organisation.

21L.A.202 Standard repairs

Regulation (EU) 2022/1358

(a) Standard repairs are repair designs to a type-certified product approved in accordance with Subpart B of Section B of this Annex and which:

1. follow the design data included in the certification specifications issued by the Agency, containing the acceptable methods, techniques and practices for carrying out and identifying standard repairs, including the associated instructions for continued airworthiness; and

2. are not in conflict with the data of the holder of that type certificate.

(b) Points 21L.A.203 to 21L.A.211 are not applicable to standard repairs.

GM1 21L.A.202 Standard repairs

ED Decision 2023/013/R

CS-STAN[1] contains the certification specifications referred to in point 21L.A.202(a)(1). Guidance on the implementation of Standard Changes and Standard Repairs may be found in AMC M.A.801 of the AMC to Part-M.

[1] https://www.easa.europa.eu/en/certification-specifications/cs-stan-standard-changes-and-standard-repairs

21L.A.203 Classification of repair designs to a type-certified product

Regulation (EU) 2022/1358

(a) Repair designs to a type-certified product shall be classified as minor or major.

(b) A 'minor repair' is a repair design that has no appreciable effect on the mass, balance, structural strength, reliability, certified noise or emissions level, operational characteristics, or other characteristics affecting the airworthiness or the environmental compatibility of the product.

(c) All other repair designs are 'major repairs'.

(d) The requirements for the approval of minor repair designs are those established in point 21L.A.207.

(e) The requirements for the approval of major repair designs are those established in point 21L.A.208.

GM1 21L.A.203(a) Classification of repair designs to a type-certified product

ED Decision 2023/013/R

(a) Clarification of the terms 'Major/Minor'

In line with the definitions given in point 21L.A.203, a new repair is classified as 'major' if the result on the approved type design has an appreciable effect on structural performance, weight, balance, systems, operational characteristics, certified noise or emissions levels, or other characteristics affecting the airworthiness or the environmental compatibility of the product or part. In particular, a repair is classified as 'major' if it requires extensive static, fatigue and damage tolerance strength justification and/or testing in its own right, or if it requires methods, techniques or practices that are unusual (i.e. unusual material selection, heat treatment, material processes, jigging diagrams, etc.).

Repairs that require a reassessment and re-evaluation of the original certification substantiation data to ensure that the aircraft continues to comply with all the relevant requirements should be considered 'major' repairs.

Repairs whose effects are considered minor and require minimal or no assessment of the original certification substantiation data to ensure that the aircraft continues to comply with all the relevant requirements should be considered 'minor'.

It is understood that not all the certification substantiation data will be available to those persons/organisations classifying repairs. A qualitative judgement of the effects of the repair will, therefore, be acceptable for the initial classification. The subsequent review of the design of the repair may lead to it being reclassified, owing to early judgements being no longer valid.

(b) Airworthiness and environmental protection concerns for 'Major/Minor' classification

The following should be considered for the magnitude of their effect when classifying repairs. Should the effect be considered significant, then the repair should be classified as 'major'. The repair may be classified as 'minor' where the effect is known to be without appreciable consequence.

(1) Structural performance

The structural performance of the product includes static strength, fatigue, damage tolerance, flutter and stiffness characteristics. Repairs to any element of the structure should be assessed for their effect upon the structural performance.

(2) Weight and balance

The weight of the repair may have a greater effect upon smaller aircraft as opposed to larger aircraft. The effects to be considered are related to overall aircraft centre of gravity and aircraft load distribution. Control surfaces are particularly sensitive to the changes due to the effect upon the stiffness, mass distribution and surface profile which may have an effect upon flutter characteristics and controllability.

(3) Systems

Repairs to any elements of a system should be assessed for the effect intended on the operation of the complete system and for the effect on system redundancy. The consequence of a structural repair on an adjacent or remote system should also be considered as above (for example, airframe repair in the area of a static port).

(4) Operational characteristics

Changes may include:

— stall characteristics,

— handling,

— performance and drag,

— vibration.

(5) Other characteristics:

— changes to load path and load sharing,

— fire protection/resistance,

— characteristics affecting the environmental compatibility of the product are characteristics affecting the compliance of the product with the applicable environmental protection requirements

Note: Considerations for classifying repairs as ‘Major/Minor’ should not be limited to those listed above.

(c) Examples of ‘major’ repairs

(1) A repair that requires a permanent additional inspection to the approved maintenance programme, necessary to ensure the continued airworthiness of the product. Temporary repairs for which specific inspections are required prior to installation of a permanent repair do not necessarily need to be classified as ‘major’. Also, inspections and changes to inspection frequencies not required as part of the approval to ensure continued airworthiness do not cause the classification of the associated repair as ‘major’.

(2) A repair to life-limited or critical parts.

(3) A repair that introduces a change to the aircraft flight manual (AFM).

21L.A.204 Eligibility

Regulation (EU) 2022/1358

(a) Any natural or legal person who has demonstrated, or is in the process of demonstrating, their design capability in accordance with point 21L.A.23, may apply for the approval of a major repair design to a type-certified product under the conditions laid down in this Subpart.

(b) Any natural or legal person may apply for the approval of a minor repair design to a type-certified product under the conditions laid down in this Subpart.

21L.A.205 Application for the approval of a repair design to a type-certified product

Regulation (EU) 2022/1358

(a) An application for an approval of a repair design to a type-certified product shall be made in a form and manner established by the Agency.

(b) For the approval of a major repair design, the applicant shall include in the application, or submit after the initial application, a compliance demonstration plan:

1. containing a description of the damage and the repair design, identifying the configuration of the type design upon which the repair design is made;
2. identifying all the areas of the type design and the approved manuals that are changed or affected by the repair design;
3. identifying any reinvestigations necessary to demonstrate the compliance of the repair design and the areas affected by the repair design with the type-certification basis and the applicable environmental protection requirements, incorporated by reference in, as applicable, either the type certificate or the supplemental type certificate;
4. identifying any proposed amendments to the type-certification basis incorporated by reference in, as applicable, either the type certificate or supplemental type certificate;
5. specifying whether the certification data has been or will be prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.

AMC1 21L.A.205(a) Application for the approval of a repair design to a type-certificated product

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FORM AND MANNER

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application forms for the approval of major changes/major repair designs or for the approval of minor changes/minor repair designs, which may be downloaded from the EASA website.

The forms should be completed in accordance with the instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[2].

[1] https://ap.easa.europa.eu (accessed: 20 October 2023)

[2] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals https://ap.easa.europa.eu (accessed: 20 October 2023)

AMC1 21L.A.205(b) Application for the approval of a repair design to a type-certificated product

ED Decision 2023/013/R

RECORD-KEEPING

(a) Relevant substantiation data associated with a new major repair design and record-keeping should include:

(1) the identification of the damage and the reporting source;

(2) the major repair design approval sheet identifying the applicable specifications and references of justifications;

(3) the repair drawing and/or instructions and scheme identifier;

(4) the correspondence with the type-certificate (TC) holder or the supplemental type-certificate (STC) holder if its advice on the design has been sought;

(5) the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to this data;

(6) if applicable, the effect on the certified noise and emissions levels and the characteristics that may affect the environmental compatibility of the product;

(7) the effect on the aircraft, engines and/or systems (performance, flight handling, etc., as appropriate);

(8) the effect on the maintenance programme;

(9) the effect on airworthiness limitations, the flight manual and the operating manual;

(10) any weight and moment changes; and

(11) special test requirements.

(b) Special consideration should be given to repairs that impose subsequent limitations on the part, product or appliance (e.g. engine turbine segments that may only be repaired a finite number of times, the number of repaired turbine blades per set, oversizing of fastener holes, etc.).

(c) Special consideration should also be given to life-limited parts and critical parts, notably with the involvement of the TC or STC holder, when deemed necessary under point 21L.A.208.

(d) Repairs to engines would normally only be accepted with the involvement of the TC holder.

21L.A.206 Demonstration of compliance

Regulation (EU) 2022/1358

(a) The applicant for the approval of a major repair design shall demonstrate compliance with the applicable type-certification basis and applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with point 21L.B.201 and shall provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant for the approval of a major repair design shall provide the Agency with a recorded justification of the means of compliance within compliance documents according to the compliance demonstration plan.

(c) When carrying out testing and inspections to demonstrate compliance in accordance with point (a), the applicant shall have verified and documented this verification prior to carrying out any test:

1. for the test specimen, that:

(i) the materials and processes adequately conform to the specifications for the proposed type design;

(ii) the constituent parts of the products adequately conform to the drawings in the proposed type design;

(iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and

2. that the test and measuring equipment used for the test were adequate for the test and appropriately calibrated.

(d) The flight testing for the purpose of obtaining an approval of a major repair design shall be conducted in accordance with methods for such flight testing specified by the Agency. The applicant shall make all the flight tests necessary to determine compliance with the applicable type-certification basis and the applicable environmental protection requirements.

(e) An applicant for the approval of a major repair design shall allow the Agency to:

1. review any data and information related to the demonstration of compliance;

2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance; and

3. if it is considered necessary, conduct a physical inspection of the repaired product to verify the compliance of the design with the type-certification basis and the applicable environmental protection requirements.

(f) Upon completion of the compliance demonstration, the applicant shall declare to the Agency that:

1. they have demonstrated compliance with the type-certification basis and the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with points 21L.B.201, according to the compliance demonstration plan; and

2. no feature or characteristic has been identified that may make the product with the repair design unsafe or environmentally incompatible for the uses for which certification is requested.

AMC1 21L.A.206 Demonstration of compliance

ED Decision 2023/013/R

The description of the repair should include an explanation of the purpose of the repair, the pre-repair and post-repair configuration(s) of the product, schematics/pictures, and any other detailed features and boundaries of the repair (this may be supplemented by drawings or outlines of the design, if this helps to understand the repair), as well as the identification of the affected areas of the product that are functionally affected by the repair, and the identification of any changes to the approved manuals.

The applicant should identify any reinvestigations that are necessary to demonstrate compliance. This is a list of affected items of the applicable certification basis for which a new demonstration is

necessary, together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

For a major repair, AMC1 21L.A.24(b)(4) should be used as applicable to the change for the development of the compliance-demonstration plan.

Compliance documentation for the demonstration of compliance in point 21L.A.206(a) comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable type-certification basis and environmental protection requirements is demonstrated.

Each compliance document should typically contain:

— the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;

— substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

— the appropriate authorised signature.

Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7.

The level of detail of the compliance documentation that is referred to in point 21L.A.206(a) should be the same regardless of whether the repair is approved by EASA or under a design organisation approval (DOA) privilege, to allow the repair to be assessed in the frame of the DOA surveillance.

The compliance-demonstration process always takes into account the specific configuration(s) in the type certificate (TC) to which the major repair under approval is applied. This (these) configuration(s) may be defined by product models/variants or by repairs to the type design. The demonstration of compliance covers this (these) applicable specific configuration(s). Consequently, the approval of the major repair excludes any other configurations, in particular those that already exist but are not considered in the compliance-demonstration process, as well as those that may be certified in the future.

For major repairs approved by a design organisation approval (DOA) holder on the basis of its privilege as per point 21.A.263(c)(5) of Annex I (Part 21), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

AMC1 21L.A.206(c) Demonstration of compliance

ED Decision 2023/013/R

INSPECTIONS AND TESTS

Proposed type design: this term defines the type design (or the portion of the type design) as it is determined at the time when the testing and inspections are performed.

Verification document (also known as ‘statement of conformity’): before each testing and inspection, the verification document must confirm that the test specimen conforms with the proposed design, the test and measuring equipment is adequate for the test, and the sensors and measuring system are appropriately calibrated.

Conformity of the test specimen: the documented verification is intended to ensure that the manufactured test specimen, even in the presence of non-conformities, adequately represents the proposed type design. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the proposed type design at the time of the test. These are typically identified in the early stage of the testing and inspections planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity as early as possible, the applicant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed, justified in the verification document or by cross reference to the test plan or other documents. However, testing for the demonstration of compliance with the applicable environmental protection requirements may be conducted in the final design of the product having incorporated the repair design.

Type certification is typically an iterative process in which the design is under continuous evolution. If the type design evolves after the time of the testing and inspections, then the final type design should be checked against the proposed type design (as it was at the time of the testing and inspections), and the differences (if any) should be analysed to ensure that the testing and inspection results are representative of the final configuration. However, such changes made to the type design may lead to the invalidation of the testing and inspection results, and the need to repeat the testing and inspections. It is recommended that the design organisation should have a thorough configuration management process to track the evolving type design.

Conformity of the test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

— type/model of sensors, together with their technical characteristics;

— position and orientation of exciters and sensors; and

— electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through certification test plans and supporting documentation, according to the design assurance system, if applicable. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The verification document should confirm that the test and measuring equipment conforms to its purpose, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This may be done either in the verification document or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term ‘adequate’: the test specimen, as well as the test and measuring equipment, is considered ‘adequate’ as long as the test execution on the manufactured test specimen (including any

non-conformity) and the use of the installed test set-up do not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or masking any potential failure mode or behaviour).

Changes that affect the validity of the verification document: if changes need to be introduced to the test specimen or to the test and measurement equipment after the verification is documented (and before the test is undertaken), then the verification document must be updated. The updated verification document must be made available to EASA before the test if EASA has informed the applicant that it will witness or carry out the tests or inspections.

Development versus certification tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for certification (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21L.A.206(c).

Any planned test event should be classified in advance as either a development test or a certification test. Tests that support the compliance demonstration should be classified as certification tests.

It is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a certification test as long as it meets the requirements of point 21L.A.206(c). For this reason, it is important to keep the configuration of such tests under control.

If the test specimen used for a certification test has already undergone a series of previous tests that may affect or ultimately invalidate its acceptance as required by point 21L.A.206(c), this aspect should be considered when documenting the verification, and specific analyses or inspections may be required.

Because of the above aspects, EASA advises applicants to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as certification tests to establish whether EASA would wish to witness the tests.

AMC1 21L.A.206(e)(1) Demonstration of compliance

ED Decision 2023/013/R

REVIEW OF DATA AND INFORMATION RELATED TO THE DEMONSTRATION OF COMPLIANCE

Availability of compliance data (see point 21L.A.206(e)): data and information required to be provided by the applicant should be made available to EASA in a reliable and efficient way as agreed with EASA.

AMC1 21L.A.206(e)(2) Demonstration of compliance

ED Decision 2023/013/R

TESTS AND INSPECTIONS

The applicant should inform EASA sufficiently in advance about the execution of tests and inspections that:

— are used for compliance-demonstration purposes; and

— have been identified as being of particular interest to EASA during the review and approval of the compliance-demonstration plan

in order to permit EASA the opportunity to witness or carry out these inspections or tests.

The applicant may propose to EASA to witness or carry out flight or other tests of particular aspects of the product during its development and before the type design is fully defined.

However, in case of flight tests, the applicant should perform the tests before EASA witnesses or performs them to ensure that no features of the product preclude the safe conduct of the evaluation requested. EASA may require any such tests to be repeated once the type design is fully defined to ensure that subsequent changes have not adversely affected the conclusions from any earlier evaluation.

A verification document as per point 21L.A.206(c) is required for the above tests.

AMC1 21L.A.206(e)(3) Demonstration of compliance

ED Decision 2023/013/R

PHYSICAL INSPECTION OF THE FIRST ARTICLE

The applicant should be prepared for any additional investigations as notified by EASA according to point 21L.B.203(c).

Refer to AMC1 21L.A.25(e)(3) for an explanation of the activities performed under the first-article inspection.

GM1 21L.A.206(f) Demonstration of compliance

ED Decision 2023/013/R

DECLARATION OF COMPLIANCE

All compliance-demonstration activities in accordance with the compliance-demonstration plan, including all the testing and inspections in accordance with point 21L.A.206(c) and all flight testing in accordance with point 21L.A.206(d), should be completed before the issuance of the final declaration of compliance.

'No feature or characteristic' that may make the product with the repair design unsafe in point 21L.A.206(f)(2) means the following: while every effort is made to address in the applicable certification basis all the risks to product safety that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant should declare that it has not identified any such feature or characteristic.

'No feature or characteristic' that may make the product with the repair design environmentally incompatible (point 21L.A.206(f)(2):

It is assumed that environmental compatibility is demonstrated when the product with the repair design complies with the applicable environmental protection requirements. Therefore, the applicant, when declaring that the product with the repair design complies with the applicable environmental protection requirements under point 21L.A.206(f)(1), should also declare that it has not identified any such feature or characteristic.

21L.A.207 Requirements for the approval of a minor repair design

Regulation (EU) 2022/1358

In order to be issued with an approval of a minor repair design to a type-certified product, the applicant shall:

(a) demonstrate that the repair design and the areas affected by the repair design comply:

1. with the type-certification basis and the applicable environmental protection requirements incorporated by reference in the type certificate; or

2. if the applicant chooses to, with the certification specifications that are applicable to the product on the date of the application for the approval of the repair design;

(b) declare compliance with the type-certification basis and the applicable environmental protection requirements that apply in accordance with point (a)(1), or with the certification specifications chosen in accordance with point (a)(2), record the justifications of compliance in the compliance documents, and record that no feature or characteristic has been identified that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested;

(c) submit to the Agency the justification of compliance for the repair and the declaration of compliance.

AMC1 21L.A.207 Requirements for the approval of a minor repair design

ED Decision 2023/013/R

(a) Applicability of point 21L.A.207

Point 21L.A.207 should be complied with by applicants for the approval of a minor repair to a type certificate (TC), and by design organisation approval (DOA) holders that approve minor changes under their privileges.

Point 21L.A.207(c), however, only applies to projects for which an application is submitted to EASA. For DOA holders that approve minor repairs under their privileges, the justification of compliance and the declaration of compliance required by point 21L.A.207(b) should be produced but do not need to be submitted to EASA. They should be, however, kept on record and submitted to EASA upon request during its DOA continued surveillance process.

(b) The approval process

The approval process comprises the following steps:

Note: Steps 1, 2 and 4 should be followed only by applicants for minor repairs approved by EASA. DOA holders that approve minor repairs under their privileges should refer to AMC No 1 to 21.A.263(c)(2) or AMC No 2 to 21.A.263(c)(2), as applicable to their approval process.

(1) Application

When the minor repair is approved by EASA, an application should be submitted to EASA as described in point 21L.A.205 and in AMC1 21L.A.205(a).

(2) Certification basis

(3) Justification of compliance

(4) Declaration of compliance

(c) Certification basis

The certification basis for a minor repair consists of a subset of the elements of the product's certification basis 'incorporated by reference in the type certificate'.

The certification basis 'incorporated by reference in the type certificate' is the certification basis for the product as recorded in the type certificate data sheet (TCDS) for the product type/model in the applicable configuration(s).

The certification basis contains the applicable airworthiness and environmental protection requirements specified by reference to their amendment level, as complemented by special conditions, equivalent safety findings, deviations, a proposed 'elect to comply', etc., as applicable.

By way of derogation from the above, CSs that became applicable after those incorporated by reference in the TC may be used for the approval of a minor repair (see the guidance below on certification specifications that became applicable after those 'incorporated by reference in the type certificate').

If other changes are required for the embodiment of the minor repair, the certification basis corresponding to the product modified by these other changes should also be considered when determining the certification basis for the minor repair.

(d) Justification of compliance required by point 21L.A.207(c)

The applicant should justify compliance with the certification basis established for the minor repair for all areas that are either physically changed or functionally affected by the minor repair.

(1) Means of compliance: the applicant should define and record the means (calculation, test or analysis, etc.) by which compliance is demonstrated. Appendix A to AMC1 21L.A.24(b) may be used to describe how compliance is demonstrated.

(2) Compliance documents: the compliance demonstration should be recorded in compliance documents. For minor repairs, one comprehensive compliance document may be sufficient, provided that it contains evidence of all aspects of the compliance demonstration.

See also the additional guidance in point (e).

(3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

See also additional guidance below in point (f) on embodiment/installation instructions.

(e) Definition of the repair design to the type certificate

The repair design to the type certificate should be defined in accordance with the aspects in GM 21L.A.61.

(f) Embodiment/installation instructions

The instructions for the embodiment/installation of the repair (e.g. service bulletin, modification bulletin, production work order, etc.) should be defined. This may include the installation procedure, the required materials, etc.

(g) Certification specifications that are applicable to the product on the date of the application for the change

(1) Minor repairs are those changes to the design that do not affect the airworthiness and the environmental compatibility of the product or the certified noise and emissions levels. This means that the certification basis for the minor repair may consist of the items of the certification basis incorporated by reference in the TCDS of the product type/model, and normally it should not be necessary for a minor repair to use certification specifications that became applicable after those that are incorporated by reference in the type certificate.

(2) On the other hand, the applicant may elect to use the certification specifications that are applicable to the product on the date of the application for the change for the compliance demonstration. This does not affect the classification of the repair.

(h) Feature or characteristic affecting the airworthiness or environmental compatibility of the product with the repair design

The term 'no feature or characteristic' applies to a minor repair design to a product, in which case the effect of the repair on the product's safety or environmental compatibility is quite low. Minor repair designs should not be approved if either the design organisation approval (DOA) holder approving minor repairs under its privileges or EASA is aware of a feature or characteristic that may make the product with the repair design unsafe or environmentally incompatible for the uses for which approval is requested.

GM1 21L.A.207(c) Requirements for the approval of a minor repair design

ED Decision 2023/013/R

The level of detail of the justification that is referred to in point 21L.A.207(c) should be the same regardless of whether the repair is approved by EASA or under a design organisation approval (DOA) privilege, to allow the repair to be assessed in the frame of the DOA surveillance.

21L.A.208 Requirements for the approval of a major repair design

Regulation (EU) 2022/1358

In order to be issued with an approval of a major repair design to a type-certified product, the applicant shall:

(a) demonstrate that the repair design and the areas affected by the repair design comply with the type-certification basis and the applicable environmental protection requirements as established and notified to the applicant by the Agency in accordance with point 21L.B.201;

(b) demonstrate compliance in accordance with point 21L.A.206;

(c) if the applicant has specified that they provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21L.A.205(b)(5), demonstrate that the type-certificate holder:

1. has no technical objection to the information submitted under point 21L.A.205; and

2. has agreed to collaborate with the applicant to ensure the discharge of all the obligations for continued airworthiness of the repaired product through compliance with points 21L.A.28 and 21L.A.88;

(d) demonstrate that there are no unresolved issues from the physical inspection of the first article of that product with the repair design in the final changed configuration carried out by the Agency in accordance with point 21L.A.206(e)(3).

AMC1 21L.A.208 Requirements for the approval of a major repair design

ED Decision 2023/013/R

(a) For major repairs approved by EASA, the applicant should use all the AMC and GM to point 21L.A.25.

(b) For major repairs approved by the design organisation approval (DOA) holder on the basis of its privilege as per point 21.A.263(c)(5) of Annex I (Part 21), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

AMC1 21L.A.208(c) Requirements for the approval of a major repair design

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For the demonstration by the applicant that there are no unresolved issues, see AMC1 21L.A.27(d).

GM1 21L.A.208 Requirements for the approval of a major repair design

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REPAIR DESIGN APPROVAL BY EASA

EASA's approval is required in cases of major repair designs proposed by design organisation approval (DOA) holders that do not hold the necessary privilege as per point 21.A.263(c)(5) of Annex I (Part 21) to Regulation (EU) No 748/2012 to approve certain major repair designs, as well as in cases of minor repair designs proposed by persons or organisations that have submitted a declaration of design capability (declared design organisation) in accordance with Subpart J of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012.

21L.A.209 Approval of a repair design under a privilege

Regulation (EU) 2022/1358

(a) The approval of a repair design that it has designed may be issued by an approved design organisation without an application according to point 21L.A.205 in accordance with the scope of its privileges provided for in points (2) and (5) of point 21.A.263(c) of Annex I (Part 21) instead of the Agency, as recorded in the terms of approval.

(b) When issuing a repair approval in accordance with point (a), the design organisation shall:

1. ensure that all the substantiation data and justifications are available;
2. ensure that the compliance of the change with the type-certification basis and the applicable environmental protection requirements according to point (a)of point 21L.A.207 or point (a) of point 21L.A.208 has been demonstrated and declared in accordance with point 21L.A.206;

3. confirm that it has not found:

   (i) any non-compliances with the type-certification basis or, where applicable, with the applicable environmental protection requirements, or with the certification specifications chosen;

   (ii) any feature or characteristic of the repair that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested;

4. limit the approval of a repair to a type certificate to the specific configuration(s) in the type certificate to which the repair relates.

GM1 21L.A.209(b) Approval of a repair design under a privilege

ED Decision 2023/013/R

REPAIR DESIGN APPROVAL BY A DESIGN ORGANISATION APPROVAL (DOA) HOLDER

(a) Approval by a DOA holder

The approval of repairs through the use of procedures agreed with EASA implies that the DOA holder issues the approval without EASA's involvement. EASA will monitor the application of this procedure within the surveillance plan for the relevant organisation. When the organisation exercises this privilege, the repair release documentation should clearly show that the approval is issued on the basis of its privilege.

(b) Previously approved data for other applications

When it is intended to use previously approved data for other applications, it is expected that an appropriately approved design organisation has checked the applicability and effectiveness of this data. After damage identification, if a repair solution exists in the available approved data, and if the application of this solution to the identified damage remains justified by the previously approved repair design (structural justifications still valid, possible airworthiness limitations unchanged), the solution may be considered approved and may be used again.

(c) Temporary repairs

These are life-limited repairs to be removed and replaced by permanent repairs after a limited service period. These repairs should be classified under point 21L.A.203, and the service period should be defined when the temporary repair is approved.

(d) Fatigue and damage tolerance

An approved design issued before the fatigue- and damage-tolerance evaluation has been completed should specify the limited service period.

21L.A.210 Obligations of a holder of a repair design approval

Regulation (EU) 2022/1358

The holder of a repair design approval shall:

(a) if they are not the type-certificate or supplemental type-certificate holder, and certification data has been supplied in accordance with 21L.A.205 (b)(5), establish an arrangement with the relevant holder;

(b) provide to the organisation performing the repair all the necessary instructions to install or embody the repair design;

(c) support any production organisation producing parts for the repair design, and ensure that those parts are produced using production data that is based upon the design data that is provided by the repair design approval holder;

(d) ensure that the repair design includes all the necessary instructions and limitations, if a repair design is approved subject to limitations. These instructions and limitations shall be transmitted to the operator by the holder of the repair design approval in accordance with a procedure agreed with the Agency;

(e) undertake the obligations of a repair design approval holder of Subpart A of this Annex.

21L.A.211 Unrepaired damage

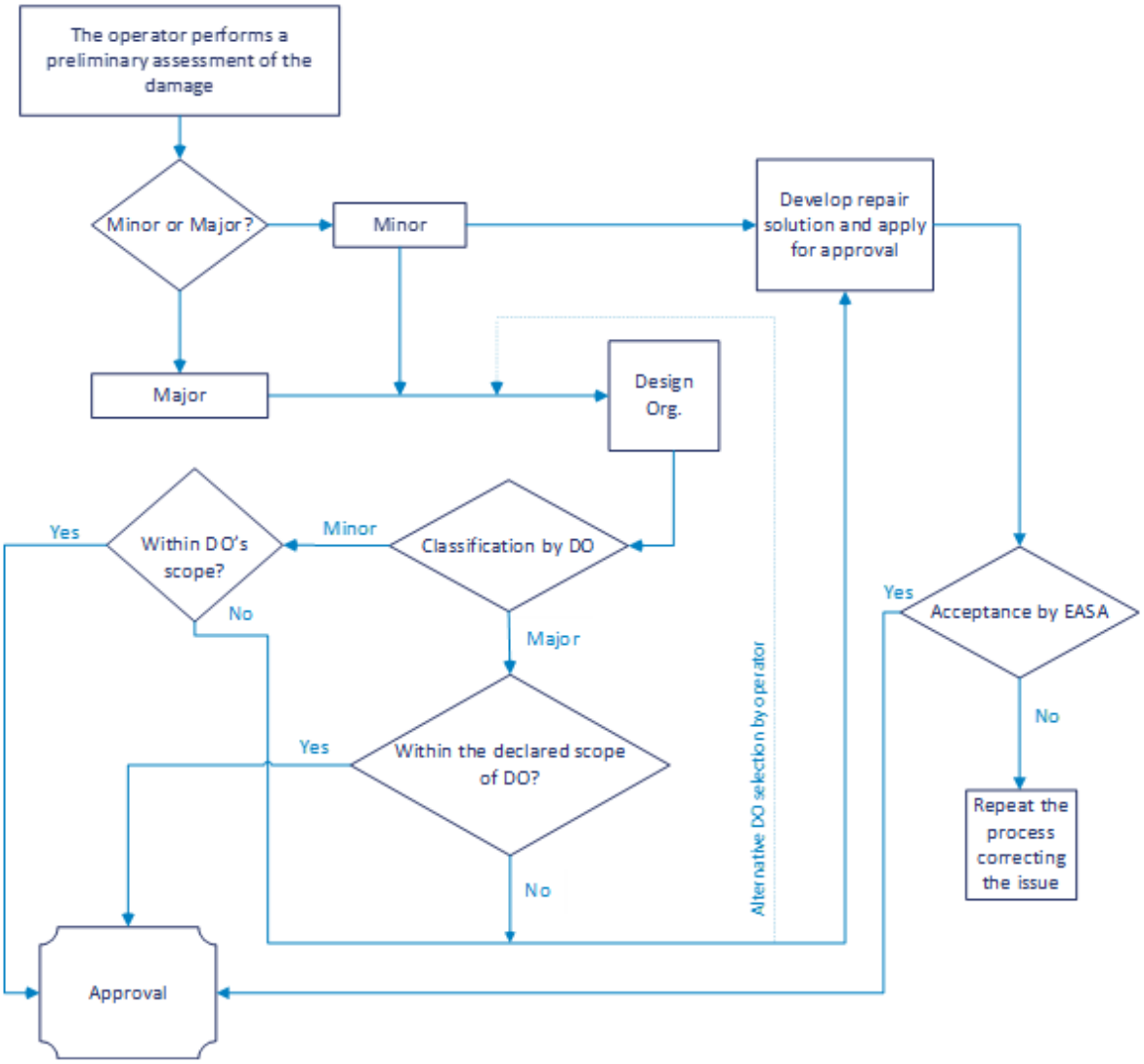
Regulation (EU) 2022/1358

Damage to a product, the design of which has been approved in accordance with Section B, may not require a repair design if an evaluation of the airworthiness consequences justifies it. Such an evaluation is to be made by either the Agency or by a design organisation which is appropriately approved in accordance with Subpart J of Section A of Annex I (Part 21), under a procedure accepted by the Agency. If the evaluation concludes that the unrepaired damage requires limitations, those shall be processed in accordance with point (d) of point 21L.A.210.

GM1 21L.A.211 Unrepaired damage

ED Decision 2023/013/R

This process is not intended to supersede the normal maintenance practices defined by the type-certificate holder (e.g. blending out corrosion and re-protection, stop drilling cracks, etc.), but addresses specific cases not covered in the manufacturer's documentation.


The operator performs a preliminary assessment of the damage
Minor or Major?
Minor
Major
Develop repair solution and apply for approval
Design Org.
Classification by DO
Minor
Within DO's scope?
Yes
No
Major
Within the declared scope of DO?
Yes
No
Alternative DO selection by operator
Acceptance by EASA
Yes
No
Repeat the process correcting the issue
Approval

SUBPART N — DESIGN OF REPAIRS TO AIRCRAFT FOR WHICH DESIGN COMPLIANCE HAS BEEN DECLARED

21L.A.221 Scope

Regulation (EU) 2022/1358

This Subpart establishes:

(a) the procedure for declaring the compliance of repair designs to an aircraft which was subject to a declaration made in accordance with Subpart C of this Annex;

(b) the rights and obligations of the declarant making a declaration of compliance of the change referred to in point (a);

(c) provisions regarding the standard repairs that do not require a declaration of design compliance.

GM1 21L.A.221 Scope

ED Decision 2023/013/R

Manuals and other instructions for continued airworthiness (such as the manufacturer's structural repair manual, maintenance manuals and engine manuals provided by the declarant for a declaration of design compliance) for operators contain useful information for the development and approval of repairs.

When that data is explicitly identified as being declared applicable for use, it may be used by operators without further actions to cope with anticipated in-service problems arising from normal usage provided that it is used strictly for the purpose for which it has been developed.

Declared design data is data which is declared as being applicable for use by the declarant of a declaration of design compliance.

Approved data is data which is approved by an appropriately approved design organisation.

21L.A.222 Standard repairs

Regulation (EU) 2022/1358

(a) Standard repairs are repair designs to an aircraft which was subject to a declaration made in accordance with Subpart C of this Annex and which:

1. follow the design data included in the certification specifications issued by the Agency, containing the acceptable methods, techniques and practices for carrying out and identifying standard repairs, including the associated instructions for continued airworthiness; and

2. are not in conflict with the design data covered by the declaration of aircraft design compliance made in accordance with Subpart C of this Annex.

(b) Points 21L.A.223 to 21L.A.229 are not applicable to standard repairs.

GM1 21L.A.222 Standard repairs

ED Decision 2023/013/R

CERTIFICATION SPECIFICATIONS

CS-STAN[1] contains the certification specifications referred to in point 21L.A.222(a)(1). Guidance on the implementation of Standard Changes and Standard Repairs may be found in AMC M.A.801 of the AMC to Part-M.

21L.A.223 Classification of repair designs to an aircraft for which design compliance has been declared

Regulation (EU) 2022/1358

(a) Repair designs to an aircraft which was subject to a declaration made in accordance with Subpart C of this Annex shall be classified as either a major or minor, using the criteria laid down in points (b) and (c) of 21L.A.203.

(b) The design compliance of a minor repair design shall be declared in accordance with point 21L.A.225.

(c) The design compliance of a major repair design shall be declared in accordance with point 21L.A.226.

GM1 21L.A.223(a) Classification of repairs designs to an aircraft for which design compliance has been declared

ED Decision 2023/013/R

(a) Clarification of the terms 'Major/Minor'

In line with the definitions given in point 21L.A.203, a new repair is classified as 'major' if the result on the aircraft, engine or propeller design has an appreciable effect on structural performance, weight, balance, systems, operational characteristics, declared noise or emissions levels or other characteristics affecting the airworthiness or the environmental compatibility of the product or part. In particular, a repair is classified as 'major' if it requires extensive static, fatigue and damage tolerance strength justification and/or testing in its own right, or if it requires methods, techniques or practices that are unusual (i.e. unusual material selection, heat treatment, material processes, jigging diagrams, etc.).

Repairs that require a reassessment and re-evaluation of the original substantiation data to ensure that the aircraft continues to comply with all the relevant requirements should be considered 'major' repairs.

Repairs whose effects are considered minor and require minimal or no assessment of the original substantiation data to ensure that the aircraft continues to comply with all the relevant requirements should be considered 'minor'.

It is understood that not all the substantiation data will be available to those persons/organisations classifying repairs. A qualitative judgement of the effects of the repair will, therefore, be acceptable for the initial classification. A subsequent review of the design of the repair may lead to it being reclassified, owing to early judgements being no longer valid.

[1] https://www.easa.europa.eu/en/certification-specifications/cs-stan-standard-changes-and-standard-repairs

(b) Airworthiness and environmental protection concerns for 'Major/Minor' classification

The following should be considered for the magnitude of their effect when classifying repairs. Should the effect be considered significant, then the repair should be classified as 'major'. The repair may be classified as 'minor' where the effect is known to be without appreciable consequence.

(1) Structural performance

The structural performance of the product includes static strength, fatigue, damage tolerance, flutter and stiffness characteristics. Repairs to any element of the structure should be assessed for their effect upon the structural performance.

(2) Weight and balance

The weight of the repair may have a greater effect upon smaller aircraft as opposed to larger aircraft. The effects to be considered are related to overall aircraft centre of gravity and aircraft load distribution. Control surfaces are particularly sensitive to the changes due to the effect upon the stiffness, mass distribution and surface profile which may have an effect upon flutter characteristics and controllability.

(3) Systems

Repairs to any elements of a system should be assessed for the effect intended on the operation of the complete system and for the effect on system redundancy. The consequence of a structural repair on an adjacent or remote system should also be considered as above (for example, airframe repair in the area of a static port).

(4) Operational characteristics

Changes may include:

— stall characteristics,

— handling,

— performance and drag,

— vibration.

(5) Other characteristics:

— changes to load path and load sharing,

— fire protection/resistance,

— characteristics affecting the environmental compatibility of the product are characteristics affecting the compliance of the product with the applicable environmental protection requirements

Note: Considerations for classifying repairs as 'Major/Minor' should not be limited to those listed above.

(c) Examples of 'major' repairs

(1) A repair that requires a permanent additional inspection to the maintenance programme, necessary to ensure the continued airworthiness of the product. Temporary repairs for which specific inspections are required prior to installation of a permanent repair do not necessarily need to be classified as 'major'. Also, inspections and changes to inspection frequencies not required to ensure continued airworthiness do not cause the classification of the associated repair as 'major'.

(2) A repair to life-limited or critical parts.

(3) A repair that introduces a change to the aircraft flight manual (AFM).

21L.A.224 Eligibility

Regulation (EU) 2022/1358

(a) A declarant who made a declaration of aircraft design compliance in accordance with Subpart C of this Annex may declare compliance of a minor repair design of that aircraft under the conditions laid down in this Subpart. In addition, such a declaration of compliance may be also made, under the conditions laid down in this Subpart, by a design organisation approved in accordance with point (c)(3) of point 21.A.263 of Annex I (Part 21).

(b) Only the declarant who made a declaration of aircraft design compliance in accordance with Subpart C of this Annex may declare the compliance of a major repair design to an aircraft for which design compliance has been declared in accordance with Subpart C of this Annex, under the conditions laid down in this Subpart.

(c) By derogation from point (b), if the declarant who made a declaration of aircraft design compliance in accordance with Subpart C of this Annex is no longer active or is unresponsive to requests for repair designs, the compliance of a changed aircraft design may also be declared in accordance with Subpart C of this Annex by a design organisation approved in accordance with point (c)(2) of point 21.A.263 of Annex I (Part 21) within the scope of their terms of approval, or by any other natural or legal person who is able to undertake the obligations laid down in point 21L.A.47 with respect to that changed aircraft.

21L.A.225 Declaration of design compliance for minor repair designs

Regulation (EU) 2022/1358

(a) Prior to incorporating or embodying or agreeing with a production organisation to incorporate or embody a minor repair design to an aircraft for which design compliance has been declared in accordance with Subpart C of this Annex, the declarant or the organisation that has designed the minor repair shall declare that the minor repair design complies with the detailed technical specifications and the applicable environmental protection requirements with which compliance had been declared according to point 21L.A.43.

(b) The declaration of design compliance shall be made in a form and manner established by the Agency.

(c) The declarant or the organisation that has designed the minor change shall maintain a register of minor repair designs to aircraft for which design compliance has been declared, and make any declaration made in accordance with point (a) available to the Agency upon request.

AMC1 21L.A.225(a) Declaration of design compliance for minor repair designs

ED Decision 2023/013/R

REQUIREMENTS FOR THE DECLARATION OF A MINOR REPAIR

(a) Applicability of point 21L.A.225

Point 21L.A.225 should be complied with by declarants for the declaration of compliance of a minor repair, including design organisation approval (DOA) holders that declare compliance of minor changes under their privileges as per point (c)(3) of point 21.A.263 of Annex I (Part 21).

In accordance with point 21L.A.225(c) for declarations of compliance for minor repairs, the substantiating data and the declaration of compliance required by point 21L.A.225(a) should be produced but do not need to be submitted to EASA. They should be, however, kept on record and made available to EASA upon request during any oversight visit.

(b) The declaration process

The declaration process comprises the following steps:

(1) classification of the repair;

(2) applicable detailed technical specifications;

(3) determination of compliance;

(4) declaration of design compliance.

(c) Detailed technical specifications

The detailed technical specifications for a minor repair consist of the detailed technical specifications that were incorporated by reference in the declaration of design compliance that was submitted for the particular aircraft under Subpart C unless EASA has determined that these are no longer appropriate and the latest detailed technical specifications should be complied with or the declarant elects to comply with these detailed technical specifications.

(d) Determination of compliance required by point 21L.A.103(a)

The declarant should determine compliance with the applicable detailed technical specifications established for the minor change for all areas that are either physically changed or functionally affected by the minor change.

(1) Means of compliance: the declarant should define and record the means (calculation, test or analysis, etc.) by which compliance is determined. Appendix A to AMC1 21L.A.44(a) may be used for this purpose.

(2) Compliance documents: the compliance determination should be recorded in compliance documents. For minor changes, one comprehensive compliance document may be sufficient, provided that it contains evidence of all aspects for compliance. AMC1 21L.A.227(b) may also be used, where applicable.

(3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

See also additional guidance below in point (e) on embodiment/installation instructions.

(e) Embodiment/installation instructions

The instructions for the embodiment/installation of the repair (e.g. service bulletin, modification bulletin, production work order, etc.) should be defined. This may include the installation procedure, the required materials, etc.

AMC1 21L.A.225(b) Declaration of design compliance for minor repair designs

ED Decision 2023/013/R

FORM AND MANNER

The declarant should complete and file a declaration of compliance for the minor repair using the applicable form below (which can also be downloaded from the EASA website) for the declaration of minor changes/minor repair designs.

If there are any changes to the data (e.g. propeller or engine designation) that was provided in the EASA Part 21 Light database of declared noise levels as a result of the minor repair design, then this data should be added by the declarant.

The justification of the classification of the change should also be recorded.

EASA Form 201

Declaration of design compliance for a Minor Change / Minor Repair Design

1. Designation	
Minor Change ☐	Minor Repair ☐

2. Product Identification	
☐ Small Aeroplane with a MTOM of 1200Kg or less and a max seating configuration of 2 persons.	☐ Sailplane with a MTOM of 1200kg or less ☐ Powered Sailplane with a MTOM of 1200kg or less ☐ Balloon designed for no more than 4 persons ☐ Hot Airship designed for no more than 4 persons.

2.2 Applicability		
2.2.1 Design details	Registered Declaration Number for the original product	
	Original Declarant	
	Type Name	

	Model(s)	
2.3 Applicable technical specifications	Please specify the applicable airworthiness code, e.g. CS-23 (if these are not the original technical specifications against which compliance was originally declared in accordance with Part 21 Light Subpart C due to the reasons stated in 21L.A.105 (a)(1) or (2) then this should be indicated here).	

3. Description	
3.1 Title	Please limit to 40 characters
3.2 Description	
3.3 Affected Areas (including manuals)	
3.4 Re-Investigations	

4. Declarants' declaration and acceptance of the General Conditions		
I declare that I have the legal capacity to make this declaration and that all information provided in this declaration is correct and complete. I hereby declare that the design of the minor change/repair described in Section 3 is in compliance with the applicable detailed technical specifications detailed in Section 2.3 and the applicable environmental protection requirements. I hereby declare that no features or characteristics have been identified that may make the aircraft after the minor change or repair has been incorporated unsafe or environmentally incompatible for the intended use. I hereby commit to undertake the obligations of a declarant of a declaration of design compliance as detailed in point 21L.A.106 of Annex Ib to Regulation (EU) 748/2012. I declare that I have provided the required information and that it is accurate and complete and indicated where it is not applicable.		
Date/Location	Name	Signature

This Declaration should be retained by the declarant and made available upon request by EASA

AMC1 21L.A.225(c) Declaration of design compliance for minor repair designs

ED Decision 2023/013/R

REGISTER OF DECLARATIONS FOR MINOR REPAIRS

The register that is used by the declarant to record the declarations of design compliance for minor repairs should also comply with point 21L.A.7 and be easily accessible in case EASA requests the details of a specific minor change during oversight.

21L.A.226 Declaration of design compliance of major repair designs

Regulation (EU) 2022/1358

(a) Prior to incorporating or embodying or agreeing with a production organisation to incorporate or embody a major repair design to an aircraft for which design compliance has been declared in accordance with Subpart C of this Annex, the declarant shall declare that the design of the major repair complies with the detailed technical specifications and the applicable environmental protection requirements with which compliance had been declared according to point 21L.A.43.

(b) The declaration of design compliance shall be made in a form and manner established by the Agency.

(c) The declaration shall contain at least the following information:

1. the name of the person submitting the declaration, and their address/place of business;
2. the declaration reference number of the aircraft to which the major repair design relates;
3. a unique reference for identifying the major repair design;
4. indication of the detailed technical specifications and the applicable environmental protection requirements with which the compliance of the aircraft had been declared by the declarant according to point 21L.A.43;
5. a signed statement made under the sole responsibility of the person making the declaration that the design of the major repair is in compliance with the detailed technical specifications and the applicable environmental protection requirements referred to in point (4), according to the compliance demonstration plan referred to in point (d)(3);
6. a signed statement made under the sole responsibility of the person making the declaration that no features or characteristics have been identified by that person that may make the aircraft unsafe or environmentally incompatible for the intended use;

7. a description of the damage and the repair design identifying the configuration of the type design upon which the repair is made;

8. identification of all the areas of the type design and the approved manuals that are changed or affected by the repair design.

(d) The declarant that designs a major repair shall submit the declaration referred to in point (c) to the Agency. Together with this declaration, the declarant shall provide to the Agency:

1. a description of the major repair;

2. basic data about the major repair, including the operating characteristics, design features and any limitations;

3. a compliance demonstration plan detailing the means for compliance demonstration that was followed during the compliance demonstration;

4. recorded justifications of compliance within compliance data obtained from the compliance activities that have been conducted according to the compliance demonstration plan;

5. the means by which compliance with the detailed technical specifications and the applicable environmental protection requirements with which the declarant had declared that aircraft compliance according to point 21L.A.43 has been demonstrated;

6. where compliance is demonstrated by carrying out tests, a recorded justification of the conformity of the test articles and equipment, demonstrating:

(i) for the test specimen, that:

(A) the materials and processes adequately conformed to the specifications for the design;

(B) the constituent parts of the products adequately conformed to the drawings in the design; and

(C) the manufacturing processes, construction and assembly adequately conformed to those specified in the design;

(ii) that the test and measuring equipment used for the tests were adequate for the tests and appropriately calibrated;

7. reports, results of inspections or tests that the declarant found necessary to determine that the aircraft complies with the detailed technical specifications and the applicable environmental protection requirements.

(e) The declaration of a major repair to a declaration of design compliance shall be limited to the specific configuration(s) in the declaration of design compliance to which the change relates.

AMC1 21L.A.226(b) Declaration of design compliance of major repair designs

ED Decision 2023/013/R

FORM AND MANNER

The request for registration should be completed along with the declaration of design compliance and sent to EASA by email or regular mail following the information provided on the EASA website[1].

If the data sheet for airworthiness needs to be adapted, then an amended version should also be provided.

If there are any changes to the data that was provided in the EASA Part 21 Light database of declared noise levels as a result of the major repair, then this data should be added by the declarant as a new record within the EASA Part 21 Light database identifying that it is applicable after the major repair.

EASA Form 202

PART 1 – REQUEST FOR REGISTRATION AND DECLARATION OF DESIGN COMPLIANCE FOR A MAJOR CHANGE/ MAJOR REPAIR

1. Identification of Activity		
Major Change ☐	**Major Repair** ☐	

2. Product Identification		
2.1 Applicability	Declared Type Name (this must be a unique means to identify the aircraft)	
	Declared Model Name(s)	
	Original Declarant	
	Registered Declaration No	
2.2 Product Category	☐ Small Aeroplane with a MTOW of 1 200 kg or less and a max. seating configuration of 2 persons ☐ Sailplane with a MTOW of 1 200 kg or less ☐ Powered Sailplane with a MTOW of 1 200 kg or less ☐ Balloon designed for no more than 4 persons ☐ Hot Air Airship designed for no more than 4 persons	
2.3 Technical Specifications	Please specify the applicable technical specifications, e.g. CS-23 (if these are not the original technical specifications against which compliance was originally declared in accordance with Part 21 Light Subpart C due to the reasons stated in 21L.A.107 (a)(1) or (2) then this should be indicated here).	

[1] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals https://ap.easa.europa.eu (accessed: 20 October 2023).

2.4 Environmental Protection Requirements (if applicable)	Please specify the environmental protection requirements with which compliance has been determined

3. Description	
3.1 Title	Please limit to 40 characters
3.2 Description	
3.3 Affected Areas including manuals	
3.4 Re-Investigations	Compliance Demonstration Plan – doc. Ref.: (Please provide the reference of the Compliance Demonstration Plan required by 21L.A.107(d)(3) or 21L.A.226(d)(3), respectively) Documentation, if changed, to submit with the Declaration in accordance 21L.A.107 (c): • Airworthiness Data Sheet • Aircraft Flight Manual including any limitations • Instructions for Continued Airworthiness • Any other conditions/limitations which the declarant wishes to declare • EASA Noise Record Number

4. Declarant's Statement
4.1. Declaration of Compliance
I declare that I have the legal capacity to submit this Declaration to EASA and that all information provided in this Declaration form is correct and complete. I hereby declare that the design of the major change/repair described in Section 3 is in compliance with the applicable detailed technical specifications detailed in Section 2.3 and the applicable environmental protection requirements (if applicable) in Section 2.4 in accordance with the compliance demonstration plan detailed in Section 3.4.

I hereby declare that no features or characteristics have been identified that, after the major change or repair has been incorporated, may make the aircraft unsafe or environmentally incompatible for the intended use. I hereby commit to undertake the obligations of a Declarant of a Declaration of Design Compliance as detailed in point 21L.A.47 and for major repairs (if applicable) point 21L.A.228 of Annex Ib to Regulation (EU) 748/2012.		
Date/Location	Name	Signature
Important Note: EASA cannot accept Declarations without signature. Please make sure that you sign the Declaration.		
This declaration should be sent by email to: applicant.services@easa.europa.eu		

GM1 21L.A.226(c) Declaration of design compliance of major repair designs

ED Decision 2023/013/R

INFORMATION TO BE PROVIDED TO EASA

The documents and information that are required to be provided to EASA in point 21L.A.226(c) may be provided to EASA by the declarant in advance of the submission of the declaration of design compliance for the 'major' change. This would be advantageous for the declarant to facilitate EASA's investigations and to determine the need for the first-article inspection under point 21L.B.221(b).

AMC1 21L.A.226(e) Declaration of design compliance of major repair designs

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SPECIFIC CONFIGURATION(S)

The compliance-demonstration process always takes into account the specific configuration(s) in the declaration of design compliance to which the major repair relates. This (these) configuration(s) may be defined by product models/variants or by design changes to the declaration. The demonstration of compliance applies to this (these) applicable specific configuration(s). Consequently, the declaration of the major change excludes any other configurations, in particular those that already exist but are not considered in the compliance-demonstration process, as well as those that may be declared in the future.

21L.A.227 Compliance activities for declaring compliance of a major repair design

Regulation (EU) 2022/1358

Prior to making a declaration of compliance in accordance with point 21L.A.226, the declarant shall, for that specific design:

(a) establish a compliance demonstration plan detailing the means for compliance demonstration that shall be followed during the compliance demonstration. This document shall be updated as necessary;

(b) record the justification of compliance within compliance documents according to the compliance demonstration plan;

(c) perform testing and inspections as necessary in accordance with the compliance demonstration plan;

(d) ensure and record the conformity of the test articles and equipment and ensure that the test specimen conforms to the specifications, drawings, manufacturing processes, construction and assembly means in the design;

(e) ensure that the test and measuring equipment to be used for testing are adequate for testing and appropriately calibrated;

(f) allow the Agency to conduct or participate in any inspections or tests of aircraft in the final or suitably mature design and production configuration that are necessary to determine that the product with the repair design has no feature or characteristic that makes the aircraft unsafe or environmentally incompatible for the intended use;

(g) carry out flight testing, in accordance with the flight conditions for such flight testing specified by the Agency, as necessary in order to determine that the aircraft complies with the applicable detailed technical specifications and the applicable environmental protection requirements.

GM1 21L.A.227 Compliance activities for declaring compliance of a major repair design

ED Decision 2023/013/R

VOLUNTARY INVOLVEMENT OF EASA PRIOR TO THE SUBMISSION OF DECLARATION

The declarant may choose to involve EASA prior to submitting the declaration of design compliance for a major repair design. This would allow EASA to:

(a) check the scope of the product is still within the scope of Subpart C;

(b) provide guidance on the completeness of the compliance-demonstration plan and the selection of means of compliance;

(c) advise on the selection of the applicable detailed technical specifications and applicable noise requirements;

(d) provide guidance about noise tests (if applicable) and witness them;

(e) avoid any issues or delays during the first-article inspection (after submission of the declaration of design compliance and if considered necessary under point 21L.B.221(b)).

The initiation of the project may occur before starting the compliance activities or during those activities. The assignment of a dedicated project number would facilitate any subsequent communication with EASA. This will facilitate the provision of compliance documentation required by point 21L.A.226(d) which may be provided by the declarant to EASA at key stages in the compliance demonstration prior to the submission of the declaration of design compliance for the major repair design.

AMC1 21L.A.227(a) Compliance activities for declaring compliance of a major repair design

ED Decision 2023/013/R

COMPLIANCE-DEMONSTRATION PLAN FOR A MAJOR REPAIR

The compliance-demonstration plan for a major repair is a document that allows the declarant to manage and control the design of the major repair, as well as the process of compliance demonstration, and that enables EASA to investigate the root cause(s) in the event of a safety issue being discovered.

The description of the repair should include an explanation of the purpose of the repair, the pre-repair and post-repair configuration(s) of the aircraft, schematics/pictures, and any other detailed features and boundaries of the physical change (this may be supplemented by drawings or outlines of the design, if this helps to understand the design change), as well as the identification of the areas of the aircraft that are affected by the repair, and the identification of any changes to the approved manuals.

The items of the declaration of aircraft design compliance made in accordance with Subpart C that are affected by the repair and for which a new demonstration of compliance is necessary should be identified together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

The compliance demonstration should include the analysis for the classification of the change in accordance with GM1 21L.A.223.

In particular, the following information should typically be expected:

— identification of the relevant personnel that make decisions affecting airworthiness and environmental compatibility, and that will interface with EASA during any physical inspection and assessment of the repaired aircraft if required under point 21L.B.221(b);

— subcontracting arrangements for design, environmental compatibility and/or production (if applicable).

Point 21L.A.226(d)(1) ‘Description of the major repair’

An overview of the nature and type of repair that is required should be provided that describes the changes to the previously declared design.

Point 21L.A.226(d)(2) ‘Operating characteristics, design features and limitations’

The declarant should consider whether there are any affects to the operating characteristics and limitations as a result of the repair, including:

— operating speed limitations;

— service ceiling, maximum airfield elevation;

— cabin pressure;

— limit load factors;

— number of passengers, minimum crew, payload, range;

— weight and centre-of-gravity (CG) envelope and fuel loading;

— performance;

— environmental envelope;

— runway surface conditions;

— other items, if considered to be more appropriate, which address the specific aeronautical product.

The declarant should provide detailed information about the means of compliance with the applicable requirements identified under point 21L.A.226(a). This should include the following:

— a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC1 21L.A.227(a) below for the relevant codes), and the related compliance document(s);

— identification of industry standards, methodology documents, handbooks and any other acceptable means of compliance, specified in the airworthiness or noise data sheet, which have been followed in the demonstration of compliance;

— when the compliance demonstration involves testing, a description of the ground- and flight-test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and

— when the compliance demonstration involves analyses/calculations, a description/ identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose.

For every aspect mentioned above, the declarant should clearly identify whether the demonstration of compliance involves different means than those contained in the published AMC to the relevant CSs and any method (analysis or test) which is novel or unusual for the declarant.

For every aspect related to compliance with the applicable environmental protection requirements mentioned above, the declarant should clearly identify whether the demonstration of compliance involves means that are described in ICAO Doc 9501 ‘Environmental Technical Manual’.

Appendix A to AMC1 21L.A.227(a) Compliance activities for declaring compliance of a major repair design

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MEANS-OF-COMPLIANCE CODES

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analyses
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	*Note*: Equipment qualification is a process that may include all previous means of compliance at equipment level.

AMC1 21L.A.227(b) Compliance activities for declaring compliance of a major repair design

ED Decision 2023/013/R

COMPLIANCE DOCUMENTATION

(a) Compliance documentation comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable detailed technical specifications and environmental protection requirements has been demonstrated.

(b) Each compliance document should typically contain:

— the reference of the detailed technical specifications or environmental protection requirements addressed by the document;

— substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the declarant declaring that the document provides the proof of compliance for which it has been created; and

— the declarant's signature.

(c) Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21L.A.7.

AMC1 21L.A.227(c);(d);(e) Compliance activities for declaring compliance of a major repair design

ED Decision 2023/013/R

INSPECTIONS AND TESTS

In accordance with point 21L.A.227(d), the declarant must address the conformity of the test specimen, as well as of the test and measuring equipment.

Conformity of the test specimen

The recorded justification of the conformity of the test articles is intended to ensure that the manufactured test specimen adequately represents the declared applicable design data. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the originally intended design data at the time of the test. These are typically identified in the early stage of the test planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity as early as possible, the declarant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed and justified by cross reference to the test plan or other documents. However, testing for the demonstration compliance with the applicable environmental protection requirements may be conducted in the final design of the product having incorporated the repair design.

Compliance demonstration is typically an iterative process in which the design is under continuous evolution. If the aircraft design evolves after the time of the inspection or test, then the final major change design should be checked against the originally intended design (as it was at the time of the inspection or test), and the differences (if any) should be analysed to ensure that the inspection or test results are representative of the final configuration. However, such changes made to the design may lead to the invalidation of the inspection or test results and the need to repeat the inspection or test. It is recommended that the declarant should have a thorough configuration management process to track the evolving design of the major repair.

Conformity of the test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

— type/model of sensors, together with their technical characteristics;

— position and orientation of exciters and sensors; and

— electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through test plans and supporting documentation. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The declarant should confirm that the test and measuring equipment conform to its definition in the test plan, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This may be done either in the recorded justification of the conformity of the test articles and equipment or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test and measuring equipment is considered 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up do not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or by masking any potential failure mode or behaviour).

Changes that affect the validity of the recorded justification of the conformity of the test articles and equipment: if changes need to be introduced to the test specimen or to the test and measurement equipment after the justification has been recorded (and before the test is undertaken), then it must be updated.

Development versus compliance demonstration tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for demonstration of compliance (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21L.A.227(d) and (e).

Any planned test event should be classified in advance as either a development test or a compliance demonstration test.

It is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a compliance demonstration test as long as it meets the requirements of point 21L.A.227(d) and (e). For this reason, it is important to keep the configuration of such tests under control.

If the test specimen used for a compliance-demonstration test has already undergone a series of previous tests that may affect or ultimately invalidate its validity due to potential non-conformity to point 21L.A.227(d) as required by point 21L.A.226(d)(6), this aspect should be considered when justifying the conformity, and specific analyses or inspections may be required to support such a statement.

Because of the above aspects, declarants may wish to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as demonstration-of-compliance tests to establish whether EASA would wish to witness the tests.

AMC1 21L.A.227(f) Compliance activities for declaring compliance of a major repair design

ED Decision 2023/013/R

PHYSICAL INSPECTION OF THE FIRST ARTICLE

The declarant should be prepared for any additional investigations as notified by EASA according to point 21L.B.222(b).

Refer to AMC 21L.A.47(a) for an explanation of the activities performed under the first-article inspection.

GM1 21L.A.227(f) Compliance activities for declaring compliance of a major repair design

ED Decision 2023/013/R

TESTS AND INSPECTIONS PERFORMED BY THE AGENCY

The declarant should inform EASA sufficiently in advance about the execution of significant inspections and tests that are used for compliance-demonstration purposes in order to permit EASA the opportunity to perform or witness these inspections or tests in advance of any physical inspection and assessment of the repaired aircraft if required by point 21L.B.221(b).

This would be advantageous for the declarant to avoid any issues or delays if a physical inspection and assessment of the repaired product is required.

Additionally, the declarant may propose to EASA to perform or witness flight or other tests of particular aspects of the product during its development and before the design of the major repair is fully defined. However, before EASA performs or witnesses any flight test, the declarant should perform these tests and should ensure that no features of the product preclude the safe conduct of the evaluation requested.

A recorded justification of the conformity of the test articles and equipment as per point 21L.A.226(d)(6) is required for the above tests.

21L.A.228 Obligations of the declarant of a declaration of design compliance of a repair design

Regulation (EU) 2022/1358

The declarant of a declaration of design compliance shall:

(a) for minor repair designs maintain a register of those declarations and shall make those declarations available to the Agency upon request;

(b) provide to the organisation performing the repair all the necessary instructions to install or embody the repair design;

(c) support any production organisation producing parts for the repair design, and ensure that those parts are produced using production data that is based upon the design data that is provided by the declarant;

(d) if a repair design is declared subject to limitations, transmit these limitations to the operator using a documented procedure that is made available to the Agency upon request;

(e) undertake the obligations of a declarant of design compliance of a repair design of Subpart A of this Annex.

21L.A.229 Unrepaired damage

Regulation (EU) 2022/1358

The declarant of design compliance of an aircraft in accordance with Subpart C of this Annex or an approved design organisation with privileges provided in accordance with point (c)(3) of point 21.A.263 of Annex I (Part 21) and with the appropriate scope of approval shall conduct an evaluation of the airworthiness and environmental compatibility consequences of any damage to such aircraft that is left unrepaired and that is not covered by previously declared data. Any necessary limitations shall be processed in accordance with point (d) of point 21L.A.228.

GM1 21L.A.229 Unrepaired damage

ED Decision 2023/013/R

This process is not intended to supersede the normal maintenance practices defined by the declarant (e.g. blending out corrosion and re-protection, stop drilling cracks, etc.), but addresses specific cases not covered in the manufacturer's documentation.

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS (RESERVED)

SUBPART P — PERMIT TO FLY

21L.A.241 Permit to fly and flight conditions

Regulation (EU) 2022/1358

(a) The procedures for applying for the issuance of permits to fly and related flight conditions for aircraft within the scope of this Annex shall be those established in Subpart P of Section A of Annex I (Part 21) and those established in points (b) and (c) of point 21L.A.241.

(b) When applying for a permit to fly in accordance with point 21.A.707 of Annex I (Part 21) , the applicant shall arrange for the competent authority to conduct a conformity inspection of the aircraft when the application for a permit to fly relates to:

1. the demonstration of compliance activities in point 21L.A.25 for an aircraft which is, or is intended to be, type-certified;

2. the demonstration of compliance activities in point 21L.A.44 for an aircraft for which design compliance is, or is intended to be, declared.

(c) When applying for flight conditions in accordance with point 21.A.709 of Annex I (Part 21), the applicant shall arrange for the Agency:

1. to physically inspect and assess the aircraft if the flight conditions are related to the demonstration of compliance to support a declaration of design compliance in point 21L.A.44 and if requested by the Agency during the demonstration of compliance activities as referred to in point (b) of point 21L.B.121 and point (c) of point 21L.B.203; or

2. to physically inspect and assess the aircraft and to conduct a critical design review if the flight conditions are related to the demonstration of compliance associated with the certification of the design in point 21L.A.25 and if requested by the Agency in point 21L.B.83, point 21L.B.102 and point 21L.B.203.

AMC1 21L.A.241(b)(1);(c)(2) Physical inspection and critical design review

ED Decision 2023/013/R

PHYSICAL INSPECTION AND CRITICAL DESIGN REVIEW OF PRODUCTS TO BE CERTIFIED

1. Introduction

For the purposes of this AMC, 'physical inspection and critical design review' includes:

a. the investigation prior to the issuance of the permit to fly, which consists of a physical conformity inspection of the aircraft by the competent authority; and

b. the investigation prior to the approval of the flight conditions, which consists of a critical design review of the design at this stage supported by a physical inspection and assessment of the aircraft design by EASA.

Note: It is possible that an oversight visit to the applicant may be found to be necessary prior to the submission of the application for the approval of the flight conditions and the issuance of a permit to fly to ensure the conformity of the aircraft for which a permit to fly has been requested. This could be due to difficulties the competent authority could have in establishing the conformity of major subassemblies after final assembly or due to the fact that the competent authority may wish to check the conformity of lower assemblies. The applicant should approach its competent authority to identify this need early on in the production of the prototype.

2. Purpose

The purposes of the physical inspection and the critical design review prior to the approval of the flight conditions and the issuance of a permit to fly for a particular aircraft design for which an application for a type certificate has been submitted are:

a. for EASA to verify[1] that the demonstration-of-compliance activities conducted by the applicant under point 21L.A.25 have reached a sufficient level of maturity to progress to flight testing in order to conclude the demonstration of compliance;

b. for EASA to ensure that the design configuration for which the flight conditions have been requested is capable of conducting safe flight during flight testing;

c. in case the applicant is a declared design organisation, for EASA to conduct the first oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the applicant is able to discharge its obligations;

d. for the competent authority to ensure the conformity of the aircraft with the configuration for which the issuance of a permit to fly has been requested;

e. in case the applicant is a declared production organisation, for the competent authority to conduct the first oversight visit in accordance with point 21L.B.143(b) of Subpart G and point 21L.B.241 of Subpart P in order to ensure that the applicant is able to discharge its obligations and is capable of producing or controlling the production of aircraft, products and parts that conform with the design data.

3. Methodology and evidence

The applicant should arrange for the physical inspection and the critical design review to be conducted by EASA and the competent authority at an appropriate location(s) where effective design review and inspection activities can take place.

This (these) location(s) should:

— include the physical location of the aircraft for which the approval of the flight conditions and the issuance of a permit to fly have been requested;

— be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State); and

— in case the applicant is a declared production organisation, be in a location that enables the competent authority to conduct the oversight visit stated in point 2(e) above; this (these) location(s) should include the actual production and manufacture of significant elements of the aircraft to enable the competent authority to determine that the declared production organisation is in compliance with the declaration of production capability that was submitted.

[1] The verification is limited to the scope of the activities that can be conducted under point 3 and the elements of the design that are selected for review based upon a risk-based approach to compliance.

Note: The principal place of business is defined as follows: 'The head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised.'

The Agency and the competent authority will conduct a physical inspection of the aircraft, engine or propeller for which the approval of the flight conditions and the issuance of a permit to fly have been requested. This inspection, along with any other activity that EASA deems necessary (see point 21L.A.25(e)), should ensure that the objectives mentioned in point 2 are met.

The applicant for the approval of the flight conditions and for the issuance of a permit to fly should make the following arrangements to support the physical inspection and critical design review:

a. prepare the aircraft, engine, propeller, systems or components for live testing upon the request of EASA or the competent authority;

b. make available the latest compliance-demonstration plan;

c. make available the latest versions of supporting compliance documentation and test reports;

d. provide access to key design and production personnel;

e. make available any relevant conformity documentation;

f. make available the relevant design or production processes and procedures used.

4. Aircraft condition and configuration

The applicant should ensure that the aircraft presented to EASA and the competent authority is in a condition for first flight and is in the configuration for which the approval of the flight conditions and the issuance of a permit to fly have been requested.

5. Findings and resolution

In the process of the activities mentioned in point 3, EASA or the competent authority may raise an appropriate finding against the aircraft or declared design organisation or declared production organisation if a non-compliance is discovered. Depending upon their nature, these findings may need to be resolved by the applicant before the flight conditions are approved or the permit to fly is issued.

AMC1 21L.A.241(b)(2);(c)(1) physical inspection and safety review

ED Decision 2023/013/R

PHYSICAL INSPECTION AND SAFETY REVIEW OF AIRCRAFT TO BE DECLARED

1. Introduction

For the purposes of this AMC, 'physical inspection and safety review' includes:

a. the investigation prior to the issuance of the permit to fly, which consists of a physical conformity inspection of the aircraft by the competent authority; and

b. the investigation prior to the approval of the flight conditions, which consists of a safety review by conducting a physical inspection and assessment of the aircraft by EASA.

Note: It is possible that an oversight visit to the declarant may be found to be necessary prior to the submission of the application for the approval of the flight conditions and the issuance of a permit to fly to ensure the conformity of the aircraft for which a permit to fly has been requested. This could be due to difficulties the competent authority could have in establishing the conformity of major subassemblies after final assembly or the fact that the competent authority would wish to check the conformity of lower assemblies. The declarant should approach its competent authority to identify this need early on in the production of the prototype.

2. Purpose

The purposes of the physical inspection and the safety review prior to the approval of the flight conditions and the issuance of a permit to fly for a particular aircraft design for which the declarant intends to submit a declaration of design compliance are:

a. for EASA to ensure[1] that the design configuration, for which the flight conditions have been requested for the compliance activities under point 21L.A.44, is capable of conducting safe flight during flight testing and that the design and the related compliance are sufficiently mature so as not to pose an unacceptable level of risk;

b. in case the declarant is a declared design organisation, for EASA to conduct the first oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the declarant is able to discharge its obligations;

Note: Under Subpart C of Section A there is no obligation for a declarant to submit a declaration of design capability and become a declared design organisation.

c. for the competent authority to ensure the conformity of the aircraft with the configuration for which the issuance of a permit to fly has been requested;

d. for the competent authority to:

i. either, in case the declarant is a declared production organisation, conduct the first oversight visit in accordance with point 21L.B.143(b) of Subpart G and point 21L.B.241 of Subpart P in order to ensure that the declarant is able to discharge its obligations and is capable of producing or controlling the production of aircraft, products and parts that conform with the design data; or

ii. conduct a first oversight visit of the production organisation that intends to issue statements of conformity for aircraft, which conform to a declaration of design compliance, to ensure that the production organisation is capable of fulfilling its obligations under Subpart R.

3. Methodology and evidence

The declarant should arrange for the physical inspection and the safety review to be conducted by EASA and the competent authority at an appropriate location(s) where an effective review and inspection activities can take place.

This (these) location(s) should:

— include the physical location of the aircraft for which the approval of the flight conditions and the issuance of a permit to fly have been requested;

— be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State); and

— in case the declarant is a declared production organisation or uses Subpart R, be in a location that enables the competent authority to conduct the oversight stated in point (2)(d) above; this location should include the actual production and manufacture of significant elements of the aircraft to enable the competent authority to determine that the declared production organisation or natural or legal person is in compliance with either the declaration of production capability that was submitted or with Subpart R.

[1] This is limited to the scope of the activities that can be conducted under point 3 and the elements of the product that are selected for inspection based upon a risk-based approach to safety and environmental incompatibility.

Note: The principal place of business is defined as follows: 'The head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised.'

The Agency and the competent authority will conduct a physical inspection of the aircraft, engine or propeller for which the approval of the flight conditions and the issuance of a permit to fly have been requested. This inspection, along with any other activity that EASA or the competent authority deems necessary (for example, see point 21L.A.44(f)), should ensure that the objectives mentioned in point 2 are met.

The declarant that applies for the approval of the flight conditions and the issuance of a permit to fly should make the following arrangements to support the physical inspection and safety review:

a. prepare the aircraft, engine, propeller, systems or components for live testing upon the request of EASA or the competent authority;

b. make available the compliance-demonstration plan for a particular aircraft;

c. make available relevant supporting compliance documentation and test reports;

d. provide access to key design and production personnel;

e. make available relevant conformity documentation;

f. make available the relevant design or production processes and procedures used.

4. Aircraft condition and configuration

The declarant should ensure that the aircraft presented to EASA and the competent authority is in a condition for first flight and is in the configuration for which the approval of the flight conditions and the issuance of a permit to fly have been requested.

5. Findings and resolution

In the process of the activities mentioned in point 3, EASA or the competent authority may raise an appropriate finding against the aircraft or the production organisation if a non-compliance is discovered. These findings may need to be resolved by the declarant before the flight conditions are approved or the permit to fly is issued.

SUBPART Q — IDENTIFICATION OF PRODUCTS AND PARTS

21L.A.251 Scope

Regulation (EU) 2022/1358

This Subpart establishes the requirements for the identification of products and parts designed and produced under this Annex.

21L.A.252 Design of markings

Regulation (EU) 2022/1358

(a) The holder of a type certificate, supplemental type certificate, approval of a change to type certificate or approval of a repair design, or the declarant of a declaration of design compliance shall specify in the design data the marking of products and parts designed in accordance with this Annex.

(b) The specifications of the marking shall include the following information:

1. for products:
   - (i) the name of the production organisation;
   - (ii) the product designation;
   - (iii) the serial number of the product;
   - (iv) any other information appropriate to identify the product;
2. for parts:
   - (i) a name, trademark, or symbol identifying the production organisation;
   - (ii) the part number;
   - (iii) the serial number, in cases where a part to be fitted on a product has been identified as a critical part.

(c) The specification of parts in accordance with point (ii) of point (b)(2) shall include the letter '(R)' at the end of the part number when:

1. the part is from a design subject to a declaration of design compliance in accordance with Subpart C of this Annex;
2. the part is to be released on an EASA Form 1 in accordance with point (a)
3. the part has been produced in accordance with Subpart R of this Annex.

GM1 21L.A.252(b)(2) Identification of parts

ED Decision 2023/013/R

It is not the intent of point 21L.A.252(b)(2) to introduce an obligation for an approved production organisation, declared production organisation or a natural or legal person who produce under subpart R to mark new parts with information which is not identified by the design approval holder or declarant. Therefore, the physical marking of parts is only required when established by the design approval (TC, STC, repair, change) holder or declarant.

GM1 21L.A.252(b)(2)(iii) Identification of critical parts

ED Decision 2023/013/R

PARTS TO BE MARKED

For the purposes of point 21L.A.252(b)(2)(iii), a part that requires individual traceability for the management of its continued airworthiness, as identified by the design approval holder or declarant, should be permanently marked with a part number and a serial number.

The need for the design approval holder or declarant to identify and mark parts may be related to specific requirements for critical parts included in a certification specification. For instance, according to point (c) of CS-E 110 *Drawings and Marking of Parts — Assembly of Parts*: 'Certain parts (including Engine Critical Parts; see CS-E 515) as may be required by the Agency must be marked and the constructor must maintain records related to this marking such that it is possible to establish the relevant manufacturing history of the parts.'

Another typical case is for any part subject to an individually specified life limit or inspection requirement when it is also possible for that part to be removed from one serial number of the associated product during maintenance and installed on another serial number of the same product. In this case, the traceability of the part, which is necessary for continued airworthiness management purposes, is not assured through the serial number of the product alone, and it is necessary to maintain records for the part through its serial number.

GM1 21L.A.252(c) Identification of parts produced under Subpart R

ED Decision 2023/013/R

The intent of point 21L.A.252(c) is to prevent a part produced for a declared aircraft and produced under Subpart R from being installed on a type-certified aircraft particularly after a part has been maintained and subsequently released on an EASA Form 1.

To achieve this, the letter 'R' is added to the part number. The ICAs and parts catalogue should include an 'R' at the end of the part number that is assigned to the part.

If a part is similar to a part that is normally installed on a type-certified aircraft, it is expected that the ICAs and parts catalogue for the type-certified aircraft will include a part number that does not contain an 'R' at the end. Therefore, an installer would be prevented from installing a part with a part number ending in 'R' because the part number would not match the ICAs and parts catalogue for the type-certified aircraft.

21L.A.253 Identification of products

Regulation (EU) 2022/1358

(a) Any natural or legal person who produces products under Subpart G of Section A of Annex I (Part 21) or under Subpart G or R of this Annex for which the design has been approved or declared in accordance with this Annex shall identify that product as specified in accordance with 21L.A.252 by means of a fireproof marking on a fireproof plate.

(b) The identification plate shall be secured in such a manner that it is accessible and legible, and will not likely be defaced or removed during normal service, or lost or destroyed in an accident, and in the case of a propeller, propeller blade, or propeller hub, placed on a non-critical surface of the item.

(c) For manned balloons, the identification plate shall be secured to the balloon envelope and shall be located, if practicable, where it is legible to the operator when the balloon is inflated. In addition, the basket, load frame assembly and any heater assembly shall be permanently and legibly marked with the name of the production organisation, part number, or its equivalent, and the serial number, or its equivalent.

21L.A.254 Handling of identification data

Regulation (EU) 2022/1358

(a) Any natural or legal person performing maintenance work in accordance with Regulation (EU) No 1321/2014 may, in accordance with methods, techniques and practices established by the Agency:

1. remove, change, or place the identification information referred to in point 21L.A.253; or
2. remove or install an identification plate referred to in point 21L.A.253, when necessary during maintenance operations.

(b) Unless for the purposes stated in point (a) of point 21L.A.254, no person shall remove, change, or place the identification information referred to in point (a) of point 21L.A.253.

(c) Unless for the purposes stated in point (a) of point 21L.A.254, no person shall remove or install any identification plate referred to in point (a) of point 21L.A.253.

(d) No person shall install an identification plate removed in accordance with point (a)(2) on any aircraft, engine, propeller, propeller blade, or propeller hub other than the one from which it was removed.

21L.A.255 Identification of parts

Regulation (EU) 2022/1358

Any natural or legal person who produces parts under Subpart G of Section A of Annex I (Part 21) or under Subpart G or R of this Annex for a product for which the design has been approved or declared in accordance with this Annex shall permanently and legibly mark that part as specified in accordance with point 21L.A.252.

SUBPART R — STATEMENT OF CONFORMITY FOR AIRCRAFT AND AUTHORISED RELEASE CERTIFICATE (EASA FORM 1) FOR ENGINES AND PROPELLERS, OR PARTS THEREOF, WHICH CONFORM TO A DECLARATION OF DESIGN COMPLIANCE

21L.A.271 Scope

Regulation (EU) 2022/1358

This Subpart establishes the procedures for the issuance of statements of conformity for aircraft (EASA Form 52B) and authorised release certificates (EASA Form 1) for engines and propellers, or parts thereof, that have been produced in conformity with the design data of a declaration of design compliance, and the rights and obligations of the declarant.

21L.A.272 Eligibility

Regulation (EU) 2022/1358

Any natural or legal person who is granted access to the applicable design data and is able to undertake the obligations stated in point 21L.A.275 may issue a statement of conformity (EASA Form 52B) for an aircraft or an authorised release certificate (EASA Form 1) for an engine or propeller, or a part thereof, under the conditions laid down in this Subpart.

AMC1 21L.A.272 Eligibility

ED Decision 2023/013/R

ACCESS TO APPLICABLE DESIGN DATA

(a) If the declarant of a declaration of design compliance and the natural or legal person that plans to issue the statement of conformity or the authorised release certificate are the same entity, then access to the relevant design data is considered to have been granted without any need for a formal arrangement or contract.

(b) If the declarant of a declaration of design compliance and the natural or legal person that plans to issue the statement of conformity or the authorised release certificate are different entities, then access to the relevant design data should be formalised. This can be achieved by establishing a contract or arrangement between the two entities in which the declarant of a declaration of design compliance identifies the applicable design data and commits to transfer (or otherwise ensure access to) this data to the natural or legal person that plans to issue the statement of conformity or the authorised release certificate.

Note 1: The applicable design data is that identified according to point 21L.A.46 for the respective aircraft, engine, propeller, or part thereof.

Note 2: To formalise the access to applicable design data, the two entities may use GM1 21L.A.122(c) as guidance, customised to their specific needs.

21L.A.273 Production control system

Regulation (EU) 2022/1358

A natural or legal person issuing a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1) with the applicable declared design data of an aircraft, engine or propeller, or a part thereof, that they have produced, shall establish, implement and maintain a system for controlling production that:

(a) includes processes and procedures that ensure that the aircraft, engine or propeller, and any part thereof, conforms with the applicable declared design data;

(b) ensures that each statement of conformity (EASA Form 52B) or authorised release certificate (EASA Form 1) is only signed by authorised persons;

(c) if flight tests are necessary within the scope of production, has processes in place that ensure that any flight tests are conducted in a safe manner;

(d) ensures that the natural or legal person is in receipt of all the necessary airworthiness and environmental compatibility data to determine conformity;

(e) has procedures in place that ensure that the airworthiness and environmental compatibility data is correctly incorporated in its production data, kept up to date and made available to all the personnel who need access to such data to perform their duties;

(f) includes an inspection system that ensures that any aircraft, engine or propeller, and any part thereof, that are produced by the natural or legal person including their partners, or are supplied from or subcontracted to outside parties, conform with the applicable declared design data and are in a condition for safe operation;

(g) includes an archiving system that records the requirements that have been placed on other organisations such as suppliers and subcontractors. The archived data shall be made available to the competent authority for continuing airworthiness purposes;

(h) ensures that the maintenance of a newly manufactured aircraft is conducted in accordance with the applicable maintenance instructions and that the aircraft is kept in an airworthy condition, and if applicable, a certificate of release to service is issued for any maintenance that has been completed;

(i) includes an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of the occurrence reports collected in accordance with point 21L.A.3 in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include the evaluation of relevant information relating to occurrences and the promulgation of the related information.

GM1 21L.A.273(a);(f) Production control system

ED Decision 2023/013/R

MEANS OF CHECKING OF THE PRODUCTION PROCESSES

The production control system should include appropriate means of checking that production processes, whether performed by the natural or legal person that produce under Subpart R or by subcontractors under its control, are performed in accordance with the applicable production data and ensure:

(a) there is a system for the control and authorised amendment of data provided for the production, inspections and tests to ensure that data is complete and up to date at the point of use;

(b) the availability of personnel with suitable qualifications, experience, and training for each required production, inspection, and test task (special attention should be paid to tasks that require specialised knowledge and skills, e.g. NDT/NDI, welding, etc.);

(c) a working area is provided where the working conditions and environment are controlled as appropriate in respect of cleanliness, temperature, humidity, ventilation, lighting, space/access, protection against noise and pollution; and

(d) the equipment and tools are sufficient to enable all specified tasks to be accomplished in a safe and repeatable manner without any detrimental effects on the items under production; it should be demonstrated that the calibration control of the equipment and tools used complies with, and is traceable to, national or international standards.

GM2 21L.A.273(a);(f) Production control system

ED Decision 2023/013/R

CONFORMITY OF SUPPLIED ITEMS

(a) The natural or legal person that produces under Subpart R is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of raw materials, subcontracted works, and supplied products or parts, whether to be used in production or delivered to customers as spare parts. This responsibility also includes items of buyer-furnished equipment (BFE).

(b) The following techniques are examples for the production control:

- first-article inspection of supplied parts, including destruction, if necessary, to verify that the article conforms to the applicable data for the new production line or the new supplier;
- incoming inspections and tests of supplied parts, materials or equipment that can be satisfactorily inspected on receipt;
- review of incoming documentation and data relevant to the showing of conformity to be included in the certification documents;
- any additional work, tests or inspections that may be needed for parts that are to be delivered as spare parts and that are not subject to the checks normally performed during subsequent production or inspection stages.

(c) The natural or legal person that produces under Subpart R may rely upon an EASA Form 1 issued in accordance with Part 21 or Part 21 Light if provided as evidence of conformity with the applicable design data.

(d) For suppliers that do not hold an approval under Part 21 Subpart G (POA) or that have not declared their production capability under Subpart G of this Annex, the inspection system of the natural or legal person that produces under Subpart R should include a system for the control of incoming parts which would allow that natural or legal person to inspect and test such items at the supplier's facility, if the item cannot or will not be completely inspected upon receipt.

GM3 21L.A.273(a);(f) Production control system

ED Decision 2023/013/R

IDENTIFICATION OF INCOMING MATERIALS AND PARTS

The natural or legal person that produces under Subpart R should inspect all parts and materials supplied from external parties to ascertain that:

— they are identified;

— they have not been damaged during transport or unpacking;

— the incoming parts and materials have the appropriate and correct accompanying documentation; and

— the configuration and condition of the parts and materials are as laid down in the applicable design data.

Only upon completion of these checks and of any incoming further verifications laid down in the procurement specification, the natural or legal person that produces under Subpart R may accept the parts or materials for warehousing and used in production.

This acceptance should be certified by an inspection statement.

A suitable recording system should allow reconstruction at any time of the history of every material or part.

The areas where the incoming checks are carried out and the materials or parts are stored pending completion of the checks should be physically segregated from other departments.

GM1 21L.A.273(c) Production control system

ED Decision 2023/013/R

TESTS

If relevant, the natural or legal person that produces under Subpart R should perform functional, ground and flight tests of the manufactured products.

The production ground and flight tests for a new aircraft are specified by the declarant of the declaration of design compliance. These tests typically include:

— a check on the handling qualities;

— a check on flight performance (using normal aircraft instrumentation);

— a check on the proper functioning of all aircraft equipment and systems;

— a determination that all instruments are properly marked, and that all placards and required flight manuals are installed before the flight test;

— a check of the operational characteristics of the aircraft on the ground; and

— a check on any other items peculiar to the aircraft being tested.

For production flight-test activities, the natural or legal person that produces under Subpart R may consider establishing a flight test operations manual (FTOM) (refer to AMC1 21L.A.127(b) and to point 21L.A.177(b)).

If the design compliance of the engine is covered by the declaration of the aircraft design compliance, then the declarant of the aircraft design compliance should also provide the specifications for the functional test required for a new engine. These will normally include at least the following:

— break-in runs that include the determination of fuel and oil consumption and the determination of power characteristics at rated maximum continuous power and, if applicable, at rated take-off power;

— a period of operation at rated maximum continuous power; for engines that have a rated take-off power, part of that period should be at rated take-off power.

The test equipment used for the test run should be capable of an output determination of accuracy sufficient to assure that the engine output delivered complies with the specified rating and operational limitations.

If the design compliance of the propeller is covered by the declaration of the aircraft design compliance, then the declarant of the aircraft design compliance should also provide the specifications for the functional test required for a new propeller. These will normally include several complete cycles of control throughout the propeller pitch and rotational speed ranges. In addition, for feathering and/or reversing propellers, several cycles of feathering operation and reversing operation from the lowest normal pitch to the maximum reverse pitch should normally be required.

After functional testing, each engine or propeller will need to be inspected to determine that the engine or propeller is in condition for safe operation. Such inspections are specified by the declarant of the aircraft design compliance and are normally including internal inspection and examination. The degree of internal inspections should normally be determined on the basis of the positive results of previous inspections conducted on the first-produced engine or propeller, and on the basis of in-service experience.

GM1 21L.A.273(e) Production control system

ED Decision 2023/013/R

PROCEDURES FOR THE PRODUCTION DATA

(a) When a natural or legal person that produces under Subpart R develops its own manufacturing data from the design data package delivered by a declarant of design compliance, the procedures should ensure the correct transcription of the original design data.

(b) The procedures should define the manner in which applicable design data is used to issue and update the production/inspection data, which determines the conformity of products and parts. These procedures should also define the traceability of such data to each individual product or part for the purpose of stating the condition for safe operation and for issuing a statement of conformity (EASA Form 52B) or an EASA Form 1.

(c) During execution, all work performed should be accompanied by documentation that gives either directly or by means of appropriate references the description of the work as well as the identification of the personnel in charge of inspection and execution of the tasks for each of the different work phases.

GM1 21L.A.273(f) Production control system

ED Decision 2023/013/R

INSPECTION OF PARTS IN PROCESS

The purpose of the production inspection system is to carry out checks at suitable points during production and provide objective evidence that the correct specifications are used, and that processes are carried out strictly in accordance with those specifications.

During the manufacturing process, each part should be inspected in accordance with an inspection plan that identifies the nature of all inspections required and the production stages at which they occur. The inspection plan should also identify any particular skills or qualifications required for personnel that carry out the inspections (e.g. NDT personnel).

If the parts are such that if damaged, they could compromise the safety of the aircraft, additional inspections for such damages should be performed at the completion of each production stage.

GM1 21L.A.273(g) Production control system

ED Decision 2023/013/R

ARCHIVING SYSTEM

For guidance regarding archiving systems, please refer to GM1 21.A.7(a) and (b).

GM1 21L.A.273(h) Production control system and 21L.A.275(e) Obligations of a natural or legal person issuing a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1)

ED Decision 2023/013/R

MAINTENANCE ACTIVITIES

Point 21L.A.273(h) requires the natural or legal person that produces under Subpart R to have procedures that cover maintenance activities of new aircraft it has manufactured, as necessary to keep them in an airworthy condition. The natural or legal person that produces under Subpart R should not maintain a newly manufactured aircraft beyond the point at which the applicable operational rules require maintenance to be performed by an approved maintenance organisation (point 21L.A.275(e)). If the production organisation intends to maintain the aircraft beyond that point, it should apply for and obtain an appropriate maintenance approval (see Articles 3 and 4 of Regulation (EU) No 1321/2014).

MAINTENANCE OF AIRCRAFT

Examples of such maintenance activities are the following:

— preservation, periodic inspection visits, etc.;

— embodiment of a service bulletin (SB);

— application of airworthiness directives (ADs);

— repairs;

— maintenance tasks resulting from special flights; and

— maintenance tasks to maintain airworthiness during flight training, demo flights and other non-revenue flights.

Any maintenance activities should be recorded in the aircraft logbook. It should be signed off for attesting the conformity of the work performed with the applicable airworthiness data.

If the aircraft logbook is not available, or if the production organisation prefers to use a separate form (for instance, for a large work package or for delivery of the aircraft to the customer), the production organisation should use EASA Form 53B which should subsequently become part of the aircraft maintenance records.

21L.A.274 Issuance of a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1)

Regulation (EU) 2022/1358

(a) When issuing a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1), the natural or legal person shall include all of the following:

1. a statement that the aircraft, engine or propeller, or any part thereof, conforms to the applicable declared design data and is in a condition for safe operation;
2. for each aircraft, a statement that the aircraft has been ground- and flight-checked;
3. for each engine or variable pitch propeller, a statement that the engine or variable pitch propeller has been subjected to a final functional test;
4. if applicable, a statement that the completed engine is in compliance with the applicable engine exhaust emissions requirements in force on the date of production of the engine.

(b) The natural or legal person shall issue a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1) upon:

1. the initial transfer of the ownership of the aircraft, engine or propeller, or parts thereof; or
2. for aircraft, the application for the issue of the restricted certificate of airworthiness for the aircraft.

GM1 21L.A.274(b) Issuance of a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1)

ED Decision 2023/013/R

It is the responsibility of the natural or legal person that produce under Subpart R to ensure that each and every product and part conforms with the applicable design data and is in a condition for safe operation before issuing and signing the relevant statement of conformity (EASA Form 52B) or authorised release certificate (EASA Form 1).

During manufacture, the natural or legal person is expected to use the facilities, systems, processes and procedures it has established for fulfilling its obligations under points 21L.A.273 and 21L.A.275.

The competent authority should then inspect and investigate the records, products or parts that are necessary to be satisfied that the aircraft is in conformity with the design for which the design compliance has been declared (see points 21L.B.143 and 21L.B.144).

To enable timely inspection and investigation by the competent authority, the statement of conformity should be prepared and submitted to the competent authority immediately upon the satisfactory completion of the final production inspection and test.

21L.A.275 Obligations of a natural or legal person issuing a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1)

Regulation (EU) 2022/1358

The natural or legal person issuing a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1) shall:

(a) inform the competent authority that they intend to produce an aircraft, engine or propeller, or a part thereof, in conformity with the design data of a declaration of design compliance and that they will issue statements of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1) in accordance with this Subpart;

(b) ensure that the details of any completed work are recorded;

(c) maintain, at the place of production, the technical data and drawings necessary to determine whether the aircraft, engine or propeller, or a part thereof, conforms to the applicable declared design data;

(d) provide continuing airworthiness support to the declarant of a declaration of design compliance for any aircraft, engine or propeller, or a part thereof, that they have produced;

(e) for new aircraft that they have produced, ensure that the aircraft is kept in an airworthy condition and that maintenance is performed, unless Regulation (EU) No 1321/2014 requires the maintenance to be performed under such rules, including any necessary repairs in accordance with the applicable design data prior to the issuance of an aircraft statement of conformity (EASA Form 52B);

(f) when issuing a certificate of release to service after such maintenance, determine that each completed aircraft has been subjected to the necessary maintenance and is in a condition for safe operation, prior to issuing the certificate;

(g) undertake the obligations of a natural or legal person issuing statements of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1) of Subpart A of this Annex;

(h) inform the competent authority about the cessation of their activities under this Subpart.

AMC1 21L.A.275(a) Obligations of a natural or legal person issuing a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1)

ED Decision 2023/013/R

INFORMATION TO THE COMPETENT AUTHORITY — FORMAT

The natural or legal person that issues a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1) under Subpart R has the obligation to inform the competent authority that it intends to produce an aircraft, engine or propeller, or a part thereof. To comply with this obligation, the form defined below should be used.

EASA Form 205

	INFORMATION **on the intention to manufacture** pursuant to Commission Regulation (EU) No 748/2012 Annex Ib (Part 21 Light) Subpart R — STATEMENT OF CONFORMITY FOR AIRCRAFT AND AUTHORISED RELEASE CERTIFICATE (EASA FORM 1) FOR ENGINES AND PROPELLERS, OR PARTS THEREOF, THAT CONFORM TO A DECLARATION OF DESIGN COMPLIANCE	
1.	**Name of the natural or legal person**	
2.	**Place of business** Contact details (registered address, phone, email) of the principal place of business:	
3.	**Intended scope of work**	
	3.1 Category of products	
	Design declared under Part 21 Light Subpart C	
	☐ Aeroplanes with a maximum take-off mass (MTOM) of 1 200 kg or less that are not jet powered, and have a seating configuration of maximum 2 persons	
	☐ Sailplanes or powered sailplanes with a MTOM of 1 200 kg or less	
	☐ Balloons designed for not more than 4 persons	
	☐ Hot-air airships designed for not more than 4 persons	
	3.2 Conformity documents (intended to be issued)	
	☐ For complete aircraft, issue EASA Form 52B for new aircraft	
	☐ For other products or parts, issue EASA Form 1	
	☐ Maintain a new aircraft and issue EASA Form 53B	
	3.3 Detailed description of the scope of work *(aircraft type …)* *(parts for aircraft type …)*	
4.	**Date of intended commencement of production:**	
5.	**Statements** I confirm [I / Name of the organisation] [have/has] been granted access by the declarant of the design compliance to the applicable design data. I confirm [I / Name of the organisation] [have/has] established and implemented a production control system in accordance with point 21L.A.273. [I / Name of the organisation] [agree/agrees] to undertake the obligations in accordance with point 21L.A.275.	
6.		
	Date / Location	Signature of the natural person or legal representative of the legal person

GM1 21L.A.275(g) Obligations of a natural or legal person issuing a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1)

ED Decision 2023/013/R

APPLICABLE SUBPART A REQUIREMENTS

The following requirements in Subpart A are applicable to a natural or legal person that issues a statement of conformity (EASA Form 52B) or an authorised release certificate (EASA Form 1):

— points 21L.A.3(b), (c), (d), (e) and (f) Reporting system

— point 21L.A.5 Collaboration between design and production

— point 21L.A.6(b) Marking

— point 21L.A.7(b) Record-keeping

— point 21L.A.10 Access and investigation

— point 21L.A.11 Findings and observations

— point 21L.A.12 Means of compliance

SECTION B - PROCEDURES FOR COMPETENT AUTHORITIES

SUBPART A — GENERAL PROVISIONS

21L.B.11 Oversight documentation

Regulation (EU) 2022/1361

The competent authority shall provide all the legislative acts, standards, rules, technical publications, and related documents to the relevant personnel in order to allow them to perform their tasks and to discharge their responsibilities.

21L.B.12 Exchange of information

Regulation (EU) 2022/1361

(a) The competent authority of the Member State and the Agency shall share the information available to them through their investigation conducted and oversight performed in accordance with this Section, which is relevant for the other party when performing certification, oversight or enforcement tasks under this Section.

(b) The competent authority of the Member State and the Agency shall coordinate a product-focused investigation and oversight of the design and production of products and parts under this Annex, including, where necessary, conducting joint oversight visits.

GM1 21L.B.12 Exchange of information

ED Decision 2023/013/R

COORDINATION WITH OTHER RELATED ACTIVITIES

The purpose of coordination with other related activities is to:

(a) harmonise the effects of various approval and certification/oversight teams, especially when dealing with one organisation/applicant/declarant to prevent conflicts of conclusions;

(b) ensure efficient flow of information among the various approval and certification/oversight teams to facilitate the execution of their duties;

(c) optimise the use of EASA's and the competent authorities' resources to minimise disruption and cost.

Therefore, for a given organisation/applicant/declarant, the responsible Agency teams or staff or the competent authorities of a Member State should arrange for exchange of information with, and provide necessary assistance, as appropriate, to, the relevant competent authority of a Member State or EASA teams or staff — e.g.:

(a) the appropriate certification/oversight teams;

(b) the design organisation oversight team;

(c) the production organisation oversight team;

(d) the maintenance organisation approval team; or

(e) other approval or certification/oversight teams as appropriate.

This is considered vital for activities related to the critical design review / safety review prior to issuing the flight conditions for a permit to fly and also for the activities relating to the first-article inspection.

GM2 21L.B.12 Exchange of information

ED Decision 2023/013/R

COORDINATION

The exchange of information should be performed in accordance with Article 72 of Regulation (EU) 2018/1139 in particular when:

(a) the competent authority of a Member State immediately reacts to a safety problem;

(b) the competent authority of a Member State grants exemptions in accordance with Article 71(1) of Regulation (EU) 2018/1139 (for a period of more than 8 months or when the exemptions become repetitive, and their total duration exceeds 8 months).

21L.B.13 Information to the Agency

Regulation (EU) 2022/1361

(a) The competent authority of the Member State shall notify the Agency in case of any significant problems with the implementation of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, within 30 days from the manifestation of such problems.

(b) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, the competent authority of the Member State shall provide the Agency as soon as possible with any safety-significant information stemming from the occurrence reports stored in the national database as specified in Article 6(6) of Regulation No (EU) 376/2014.

AMC1 21L.B.13(b) Information to the Agency

ED Decision 2023/013/R

EXCHANGE OF SAFETY-SIGNIFICANT INFORMATION WITH THE AGENCY

Each competent authority should appoint a coordinator to act as the point of contact for the exchange of safety-significant information between the competent authority and EASA.

GM1 21L.B.13(b) Information to the Agency

ED Decision 2023/013/R

MEANING OF SAFETY-SIGNIFICANT INFORMATION THAT STEMS FROM OCCURRENCE REPORTS

Safety-significant information that stems from occurrence reports means:

(a) a conclusive safety analysis which summarises individual occurrence data and provides an in-depth analysis of a safety issue, and which may be relevant for EASA's safety action planning; and

(b) individual sets or pieces of occurrence data for cases for which EASA is the competent authority and which fulfils the reporting criteria of GM3 21L.B.13(b).

GM2 21L.B.13(b) Information to the Agency

ED Decision 2023/013/R

RECOMMENDED CONTENT FOR CONCLUSIVE SAFETY ANALYSES

A conclusive safety analysis should contain the following:

(a) a detailed description of the safety issue, including the scenario in which the safety issue occurs; and

(b) an indication of the stakeholders that are affected by the safety issue, including types of operations and organisations;

and, as appropriate:

(c) a risk assessment establishing the severity and probability of all the possible consequences of the safety issue;

(d) information about the existing safety barriers that the aviation system has in place to prevent the likely consequences of the safety issue from occurring;

(e) any mitigating action that is already in place or developed to deal with the safety issue;

(f) recommendations for future actions to control the risk; and

(g) any other element the competent authority considers essential for EASA to properly assess the safety issue.

GM3 21L.B.13(b) Information to the Agency

ED Decision 2023/013/R

OCCURRENCES FOR WHICH THE AGENCY IS THE COMPETENT AUTHORITY

Occurrences that are related to natural or legal persons, organisations or products, which are certified or overseen by EASA, should be notified to EASA if:

(a) the occurrence is defined as a reportable occurrence in accordance with the applicable regulations;

(b) the natural or legal person or organisation responsible for addressing the occurrence is certified or overseen by EASA; and

(c) the competent authority of the Member State has come to the conclusion that:

  (1) the natural or legal person or organisation certified or overseen by EASA to which the occurrence relates was not informed of the occurrence; or

  (2) the occurrence has not been properly addressed or has been left unattended by the natural or legal person or organisation certified or overseen by EASA.

Such occurrence data should be reported in a format compatible with the European Co-ordination Centre for Accident and Incident Reporting Systems (ECCAIRS) and should provide all relevant information for its assessment and analysis, including necessary additional files in the form of attachments.

21L.B.14 Airworthiness directives received from non-Member States

Regulation (EU) 2022/1361

When the competent authority of a Member State receives an airworthiness directive from the competent authority of a non-Member State, that airworthiness directive shall be transferred to the Agency.

21L.B.15 Immediate reaction to a safety problem

Regulation (EU) 2022/1361

(a) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, the competent authority of the Member State shall implement a system to appropriately collect, analyse, and disseminate safety information.

(b) The Agency shall implement a system to appropriately analyse any relevant safety information received, and without undue delay, provide Member States and the Commission with any information, including recommendations or corrective actions to be taken, that is necessary for them to react in a timely manner to a safety problem involving products, parts, persons or organisations that are subject to Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.

(c) Upon receiving the information referred to in points (a) and (b), the competent authority of the Member State shall take adequate measures to address the safety problem.

(d) Measures taken under point (c) of point 21L.B.15 shall immediately be notified to all persons or organisations that need to comply with them under Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof. The competent authority of the Member State shall also notify those measures to the Agency and, when combined action is required, to the other Member States concerned.

21L.B.16 Management system

Regulation (EU) 2022/1361

(a) The competent authority shall establish and maintain a management system, including as a minimum:

1. documented policies and procedures to describe its organisation, means and methods to achieve compliance with Regulation (EU) 2018/1139 and Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on the basis thereof. The procedures shall be kept up to date, and serve as the basic working documents within that competent authority for all related tasks;

2. a sufficient number of personnel to perform its tasks and discharge its responsibilities. A system shall be in place to plan the availability of personnel, in order to ensure the proper completion of all tasks;

3. personnel who are qualified to perform their allocated tasks and who have the necessary knowledge, experience, initial and recurrent training to ensure continuing competency;

4. adequate facilities and office accommodation to perform the allocated tasks;

5. a function to monitor the compliance of the management system with the relevant requirements, and the adequacy of the procedures, including the establishment of an internal audit process, and a safety risk management process. The compliance monitoring function shall include a system to provide feedback about audit findings to the senior management of the competent authority to ensure the implementation of corrective actions as necessary;

6. a person or group of persons having a responsibility to the senior management of the competent authority for the compliance monitoring function.

(b) The competent authority shall, for each field of activity, including the management system, appoint one or more persons with the overall responsibility for the management of the relevant task(s).

(c) The competent authority shall establish procedures for participation in a mutual exchange of all the necessary information with any other competent authorities concerned and provide them with assistance, whether from within the Member State or in other Member States, including on:

1. all the findings raised and any follow-up actions taken as a result of the oversight of persons and organisations that carry out activities in the territory of a Member State, but certified by the competent authority of another Member State, or by the Agency;

2. any information stemming from mandatory and voluntary occurrence reporting as required by point 21L.A.3.

(d) A copy of the procedures related to the management system of the competent authority of the Member State and any amendments to those procedures shall be made available to the Agency for the purpose of standardisation.

AMC1 21L.B.16 Management system

ED Decision 2023/013/R

GENERAL

(a) In deciding upon the required airworthiness organisational structure, the competent authority should review:

(1) the number of certificates, approvals and their scope, declarations and authorisations to be issued;

(2) the number, complexity and size of the organisations under its oversight obligations;

(3) the possible use of qualified entities and of the resources of the competent authorities of other Member States to fulfil the continuing oversight obligations;

(4) the complexity of the aviation industry, taking into consideration the diversity of the products and parts; and

(5) the potential growth of activities in the field of civil aviation.

(b) The competent authority should retain effective control of the important surveillance functions and not delegate them in such a way that organisations, in effect, regulate themselves in airworthiness matters.

(c) The set-up of the organisational structure should ensure that the various tasks and obligations of the competent authority do not solely rely on individuals. The continuous and undisturbed fulfilment of these tasks and obligations of the competent authority should also be guaranteed in cases of illness, accidents or leave of individual employees.

AMC2 21L.B.16 Management system

ED Decision 2023/013/R

GENERAL

(a) The competent authority should be organised in such a way that:

(1) there is specific and effective management authority in the conduct of all the relevant activities;

(2) the functions and processes described in the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, acceptable means of compliance (AMC), certification specifications (CSs), detailed technical specifications and guidance material (GM) may be properly implemented;

(3) the competent authority policies, organisation and operating procedures for the implementation of the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, AMC, CSs and GM are properly documented and applied;

(4) all the personnel of the competent authority involved in the related activities are provided with training where necessary;

(5) specific and effective provision is made for the communication and interface as necessary with EASA and other competent authorities; and

(6) all the functions related to implementing the applicable requirements are adequately described.

(b) A general policy in respect to the activities related to the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis should be developed, promoted and implemented by the manager at the highest appropriate level — for example, the manager at the top of the functional area of the competent authority that is responsible for such activities.

(c) Appropriate steps should be taken to ensure that the policy is known and understood by all the personnel involved, and all the necessary steps should be taken to implement and maintain the policy.

(d) The general policy should, in particular, take into account:

(1) the provisions of Regulation (EU) 2018/1139;

(2) the provisions of the applicable delegated and implementing acts and also the associated AMC, CSs and GM;

(3) the needs of industry; and

(4) the needs of EASA and of the other competent authorities.

(e) The policy should define specific objectives for the key elements of the competent authority's organisation and processes for implementing the related activities, including the corresponding control procedures and the measurement of the achieved standard.

GM1 21L.B.16 Management system

ED Decision 2023/013/R

OVERSIGHT OF DECLARED ORGANISATIONS

The following are the activities which should be covered by the competent authority management system for the oversight of declared organisations (declared production organisations under Section A Subpart G, and declared design organisations under Section A Subpart J of Annex Ib (Part 21 Light)):

(a) appointment of the declared organisation team leader and the team;

(b) verification of the declaration received;

(c) registration of the declaration;

(d) establishment of an oversight programme;

(e) performance of oversight activities;

(f) follow-up of corrective actions;

(g) recommendation on the continuation of the activities conducted by the declared organisation;

(h) registration of the changes notified by the declared organisations under point 21L.A.128 or point 21L.A.178 respectively; and

(i) enforcement measures under point 21L.B.22.

AMC1 21L.B.16(a)(1) Management system

ED Decision 2023/013/R

DOCUMENTED POLICIES AND PROCEDURES

(a) The various elements of the organisation for the activities related to Regulation (EU) 2018/1139 and its delegated and implementing acts should be documented in order to establish a reference source for the establishment and maintenance of such organisation.

(b) The documented procedures should be established in a way that facilitates their use. They should be clearly identified, kept up to date and made readily available to all the personnel involved in the related activities.

(c) The documented procedures should cover, as a minimum, all the following aspects:

(1) policies and objectives;

(2) the organisational structure;

(3) responsibilities and the associated authority;

(4) processes and procedures;

(5) internal and external interfaces;

(6) internal control procedures;

(7) the training of personnel;

(8) cross references to associated documents; and

(9) assistance from other competent authorities or EASA (where required).

(d) It is likely that the information may be held in more than one document or series of documents, and suitable cross-referencing should be provided. For example, the organisational structure and the job descriptions are not usually in the same documentation as the detailed working procedures. In such cases, it is recommended that the documented procedures should include an index of cross references to all such other related information, and the related documentation should be readily available when required.

GM1 21L.B.16(a)(2) Management system

ED Decision 2023/013/R

SUFFICIENT PERSONNEL

(a) This GM on the determination of the required personnel is limited to the performance of certification and oversight tasks, excluding any personnel that are required to perform tasks subject to any national regulatory requirements.

(b) The elements to be considered when determining the required personnel and planning their availability may be divided into quantitative and qualitative elements, and there should be, at least:

(1) quantitative elements in accordance with AMC1 21L.B.16; and

(2) the following qualitative elements:

(i) the size, nature and complexity of the activities of overseen organisations, taking into account:

(A) the privileges of the organisation (if applicable);

(B) the type of the approval (if applicable) and the scope of the approval/declaration;

(C) possible certification to industry standards;

(D) the number of personnel; and

(E) the organisational structure and the existence of subcontractors;

(ii) the safety priorities identified;

(iii) the results of past oversight activities, including audits, inspections and reviews, in terms of risks and regulatory compliance, taking into account:

(A) the number and the levels of findings;

(B) the time frame for the implementation of corrective actions; and

(C) the maturity of the management systems implemented by the organisation, and their ability to effectively manage safety risks; and

(iv) the size and complexity of the Member States' aviation industry, and the potential growth of activities in the field of civil aviation, which may be an indication of the number of new applications, and of changes to existing certificates, approvals, declarations, and authorisations to be expected.

(c) Based on existing data from previous oversight planning cycles, and taking into account the situation within the Member States' aviation industry, the competent authority may estimate:

(1) the standard working time required for processing applications for new certificates, approvals and authorisations, or registration of declarations;

(2) the number of new certificates and approvals to be issued, or registrations of declarations for each oversight planning period; and

(3) the number of changes to existing certificates, approvals, authorisations and declarations to be processed for each oversight planning period.

(d) In line with the competent authority's oversight policy, the following planning data should be determined:

(1) the standard number of audits to be performed per oversight planning cycle;

(2) the standard duration of each audit;

(3) the standard working time for audit preparation, on-site auditing, reporting, and follow-up, per inspector;

(4) the standard number of unannounced inspections to be performed;

(5) the standard duration of inspections, including the preparation, reporting, and follow-up, per inspector; and

(6) the minimum number and required qualifications of inspectors for each audit/inspection.

(e) Standard working time could be expressed either in working hours per inspector, or in working days per inspector. All planning calculations should, then, be based on the same units (hours or working days).

(f) It is recommended to use a spreadsheet application to process the data defined under points (c) and (d) to assist in determining the total number of working hours/days per oversight planning cycle required for certification, oversight and enforcement activities. This application could also serve as a basis for implementing a system for planning the availability of personnel.

(g) The number of working hours/days per planning period for each qualified inspector that may be allocated for certification, oversight and enforcement activities should be determined, taking into account:

(1) purely administrative tasks not directly related to certification and oversight;

(2) training;

(3) participation in other projects;

(4) planned absences; and

(5) the need to include a reserve for unplanned tasks or unforeseeable events.

(h) The determination of working time available for certification, oversight and enforcement activities should also consider, if applicable:

(1) the use of qualified entities;

(2) cooperation with other competent authorities for approvals that involve more than one Member State; and

(3) oversight activities under a bilateral aviation safety agreement.

(i) Based on the elements listed above, the competent authority should be able to:

(1) monitor the dates when audits and inspections are due, and when they were carried out;

(2) implement a system to plan the availability of personnel; and

(3) identify possible gaps between the number and the qualifications of personnel and the required volume of certification and oversight.

Care should be taken to keep planning data up to date in line with changes in the underlying planning assumptions, with a particular focus on risk-based oversight principles.

AMC1 21L.B.16(a)(3) Management system

ED Decision 2023/013/R

QUALIFICATIONS AND TRAINING — GENERAL

(a) It is essential for the competent authority to have the full capability to adequately assess the compliance and performance of an organisation by ensuring that the whole range of activities is assessed by appropriately qualified personnel.

(b) For each inspector, the competent authority should:

(1) define the competencies required to perform the allocated certification and oversight tasks;

(2) define the associated minimum qualifications that are required;

(3) establish initial and recurrent training programmes in order to maintain and to enhance the competency of inspectors at the level that is necessary to perform the allocated tasks; and

(4) ensure that the training provided meets the established standards and is regularly reviewed and updated as necessary.

(c) The competent authority should ensure that training is provided by qualified trainers with appropriate training skills.

AMC2 21L.B.16(a)(3) Management system

ED Decision 2023/013/R

QUALIFICATIONS AND TRAINING — INSPECTORS

(a) Competent authority inspectors should have:

(1) practical experience and expertise in the application of aviation safety standards and safe operating practices;

(2) comprehensive knowledge of:

(i) the relevant parts of Regulation (EU) 2018/1139 and its delegated and implement acts and the related AMC, CSs and GM;

(ii) the competent authority's procedures;

(iii) their rights and obligations of an inspector;

(iv) systems based on the EU management system requirements (including compliance monitoring) and on ICAO Annex 19;

(v) design or production standards, as applicable; and

(vi) design- or production- (as applicable) related human-factors and human-performance principles;

(3) training in auditing techniques and assessing and evaluating management systems and safety-related processes and procedures;

(4) relevant work experience to be allowed to work without supervision as an inspector; this may include experience gained during training to obtain the qualifications described in following point (5); and

(5) a relevant engineering degree with additional education; 'relevant engineering degree' means an engineering degree from aeronautical, mechanical, electrical, electronic, avionics or other studies relevant to the design and production of aircraft / aircraft components.

(b) In addition to their technical competency, inspectors should have a high degree of integrity, be impartial in carrying out their tasks, be tactful, and have a good understanding of human nature.

(c) A programme for recurrent training should be developed to ensure that inspectors remain competent to perform their allocated tasks; as a general policy, it is not desirable for inspectors to obtain technical qualifications from those entities that are under their direct regulatory oversight.

AMC3 21L.B.16(a)(3) Management system

ED Decision 2023/013/R

INITIAL AND RECURRENT TRAINING FOR INSPECTORS

(a) Initial training programme

The initial training programme for inspectors should include, to an extent appropriate to their role, current knowledge, experience and skills, at least all the following:

(1) aviation legislation, organisation, and structure;

(2) the Chicago Convention, the relevant ICAO annexes and documents;

(3) Regulation (EU) No 376/2014 on the reporting, analysis and follow-up of occurrences in civil aviation;

(4) an overview of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis, and the related AMC, CSs and GM;

(5) specific knowledge of Regulation (EU) No 748/2012 as well as of any other applicable requirements;

(6) management systems, including the assessment of the effectiveness of a management system, in particular hazard identification and risk assessment, and non-punitive reporting techniques in the context of the implementation of a just culture;

(7) auditing techniques;

(8) procedures of the competent authority that are relevant to the inspector's tasks;

(9) human-factors principles;

(10) the rights and obligations of inspecting personnel of the competent authority;

(11) on-the-job training relevant to the inspector's tasks; and

(12) technical training appropriate to the role and tasks of the inspector, in particular for those areas that require approvals.

Note: The duration of the on-the-job training should take into account the scope and complexity of the inspector's tasks. The competent authority should assess whether the required level of competence has been achieved before an inspector is authorised to perform a task without supervision.

(b) Recurrent training programme

Once qualified, the inspector should receive training periodically, as well as whenever it is deemed necessary by the competent authority, in order to remain competent to perform their allocated tasks. The recurrent training programme for inspectors should include, as appropriate to their role, at least the following topics:

(1) changes in aviation legislation, the operational environment and technologies;

(2) procedures of the competent authority that are relevant to the inspector's tasks;

(3) technical training that is appropriate to the role and tasks of the inspector; and

(4) results from past oversight activities.

(c) Assessments of an inspector's competency should take place at regular intervals that do not exceed 3 years. The results of these assessments, as well as any actions taken following these assessments, should be recorded.

AMC1 21L.B.16(a)(5) Management system

ED Decision 2023/013/R

SAFETY RISK MANAGEMENT PROCESS

(a) The safety risk management process required by point 21L.B.16 should be documented. The following should be defined in the related documentation:

(1) the means used for hazard identification and the related data sources, taking into account data that comes from other competent authorities with which the competent authority interfaces in the State or from the competent authorities of other Member States;

(2) risk management steps including:

(i) analysis (in terms of the probability and severity of the consequences of hazards and occurrences);

(ii) assessment (in terms of the tolerability); and

(iii) control (in terms of the mitigation) of risks to an acceptable level;

(3) who has the responsibility for hazard identification and risk management;

(4) who has the responsibility for the follow-up of risk-mitigation actions;

(5) the levels of management that have the authority to make decisions regarding the tolerability of risks;

(6) the means to assess the effectiveness of risk-mitigation actions; and

(7) the link with the compliance-monitoring function.

(b) To demonstrate that the safety risk management process is operational, competent authorities should be able to provide evidence that:

(1) the persons involved in internal safety risk management activities are properly trained;

(2) hazards that could impact on the authority's capabilities to perform its tasks and discharge its responsibilities have been identified, and the related risk assessment is documented;

(3) regular meetings take place at appropriate levels of management of the competent authority to discuss the risks identified and to decide on the risk tolerability and possible risk-mitigation actions;

(4) in addition to the initial hazard identification exercise, the risk management process is triggered as a minimum whenever changes occur that may affect the competent authority's capability to perform any of the tasks required by Part 21 Light;

(5) a record of the actions taken to mitigate risks is maintained, showing the status of each action and the owner of the action;

(6) there is follow-up on the implementation of all risk-mitigation actions;

(7) risk-mitigation actions are assessed for their effectiveness;

(8) the results of risk assessments are periodically reviewed to check whether they remain relevant.

GM1 21L.B.16(a)(5) Management system

ED Decision 2023/013/R

SAFETY RISK MANAGEMENT PROCESS

The purpose of safety risk management, as part of the management system framework for competent authorities, is to ensure the effectiveness of the management system. As for any organisation, hazard identification and risk management are expected to contribute to effective decision-making, to guide resource allocation and contribute to organisational success.

The safety risk management process required by point 21L.B.16 is intended to address safety risks that are directly related to the competent authority's organisation and processes, and which may affect its capability to perform its tasks and discharge its responsibilities. This process is not intended to be a substitute for the State safety risk management Standards and Recommended Practices (SARPs) defined in ICAO Annex 19 Chapter 3. This does not mean, however, that the competent authority may not use information and data obtained through its State Safety Programme (SSP), including oversight data and information, for the purpose of safety risk management as part of its management system.

The safety risk management process is also to be applied to the management of changes (point 21L.B.18), which is intended to ensure that the management system remains effective whenever changes occur.

AMC1 21L.B.16(d) Management system

ED Decision 2023/013/R

PROCEDURES AVAILABLE TO THE AGENCY

(a) Copies of the procedures related to the competent authority's management system, and their amendments, which should be made available to EASA for the purpose of standardisation, should provide at least the following information:

(1) The competent authority's organisational structure for the continuing oversight functions that it undertakes, with a description of the main processes. This information should demonstrate the allocation of responsibilities within the competent authority, and that the competent authority is capable of carrying out the full range of tasks regarding the size and complexity of a particular Member State's aviation industry. It should also consider the overall proficiency and the scope of authorisation of the competent authority's personnel;

(2) For personnel that are involved in oversight activities, the minimum required professional qualification and level of experience, and the principles that guide their appointment (e.g. assessment);

(3) How the following are carried out: assessments of applications and evaluations of compliance; the issuance of certificates, approvals, and authorisations; continuing oversight activities; the follow-up of findings; enforcement measures; and the resolution of safety concerns;

(4) The principles used to manage exemptions and derogations;

(5) The processes that are in place to distribute applicable safety information for timely reaction to a safety problem;

(6) The criteria for planning continuing oversight activities (i.e. an oversight programme), including the management of interfaces when conducting continuing oversight activities; and

(7) An outline of the initial training of newly recruited oversight personnel (taking future activities into account), and the basic framework for the recurrent training of oversight personnel.

(b) As part of the continuous monitoring of a competent authority, EASA may request details of the working methods used, in addition to a copy of the procedures of the competent authority's management system (and of any amendments to it). These additional details are the procedures and related guidance material that describe the working methods for the personnel of the competent authority that conduct oversight activities.

(c) Information related to the competent authority's management system may be submitted in an electronic format.

21L.B.17 Allocation of tasks to qualified entities

Regulation (EU) 2022/1361

(a) A competent authority may allocate the tasks related to the initial certification or to the continuing oversight of products and parts, and of natural or legal persons subject to Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, to qualified entities. When allocating tasks, the competent authority shall ensure that it has:

1. put a system in place to initially and continuously assess whether the qualified entity complies with Annex VI 'Essential requirements for qualified entities' to Regulation (EU) 2018/1139. This system and the results of the assessments shall be documented;

2. established a documented agreement with the qualified entity, approved by both parties at the appropriate management level, which defines:

   (i) the tasks to be performed;

   (ii) the declarations, reports, and records to be provided;

(iii) the technical conditions to be met in performing such tasks;

(iv) the related liability coverage;

(v) the protection given to the information acquired in carrying out such tasks.

(b) The competent authority shall ensure that the internal audit process and the safety risk management process required by point (a)(5) of point 21L.B.16 cover all the certification and continuing oversight tasks performed on its behalf by the qualified entity.

GM1 21L.B.17 Allocation of tasks to qualified entities

ED Decision 2023/013/R

CERTIFICATION TASKS

The tasks that may be performed by a qualified entity on behalf of the competent authority include those that are related to the initial certification and the continuing oversight of persons and organisations as defined in Regulation (EU) No 748/2012.

21L.B.18 Changes in the management system

Regulation (EU) 2022/1361

(a) The competent authority shall have a system in place to identify changes that affect its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU) 2018/1139 and Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on the basis thereof. This system shall enable it to take the action necessary to ensure that its management system remains adequate and effective.

(b) The competent authority shall update its management system to reflect any change to Regulation (EU) 2018/1139 and Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on the basis thereof in a timely manner, so as to ensure its effective implementation.

(c) The competent authority of the Member State shall notify the Agency of any changes affecting its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU) 2018/1139 and Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on the basis thereof.

21L.B.19 Resolution of disputes

Regulation (EU) 2022/1361

The competent authority of the Member State shall establish a process for the resolution of disputes within its documented procedures.

GM1 21L.B.19 Resolution of disputes

ED Decision 2023/013/R

PRINCIPLES FOR THE RESOLUTION OF DISPUTES

It is essential for the efficient accomplishment of the activities related to Part 21 Light of the competent authority of the Member State that all decisions regarding the resolution of disputes be taken at as low a level as possible. In addition, the documented procedures for the resolution of disputes should clearly identify the chain of escalation.

21L.B.20 Record-keeping

Regulation (EU) 2022/1361

(a) The competent authority shall establish a system of record-keeping that allows the adequate storage, accessibility, and reliable traceability of:

1. the management system's documented policies and procedures;
2. the training, qualifications, and authorisation of its personnel;
3. the allocation of tasks covering the elements required by point 21L.B.17, as well as the details of the tasks allocated;
4. certification processes and the continuing oversight of certified and declared organisations, including:
   (i) applications for a certificate;
   (ii) declarations of capability;
   (iii) declarations of design compliance;
   (iv) the competent authority's continuing oversight programme, including all assessments, audits and inspection records;
   (v) the certificates issued, including any changes to them;
   (vi) a copy of the oversight programme listing the dates when audits are due and when audits were carried out;
   (vii) copies of all formal correspondence;
   (viii) recommendations for the issue or continuation of a certificate or continuation of the registration of a declaration, details of findings, and actions taken by organisations to close these, including the date of closure of each item, enforcement actions, and observations;
   (ix) any assessment, audit or inspection report issued by another competent authority;
   (x) copies of all organisation handbooks, procedures and processes or manuals and amendments to them;
   (xi) copies of any other documents approved by the competent authority;
5. statements of conformity of aircraft (EASA Form 52B) or authorised release certificates (EASA Form 1) for engines, propellers or parts that it has inspected according to Subpart R of this Annex.

(b) The competent authority of the Member State shall include in the record-keeping:

1. the evaluation and notification to the Agency of any alternative means of compliance proposed by organisations, and the assessment of any alternative means of compliance used by the competent authority itself;
2. safety information in accordance with point 21L.B.13 and follow-up measures;
3. the use of safeguard and flexibility provisions in accordance with Articles 71(1) and 76(4) of Regulation (EU) 2018/1139.

(c) The competent authority shall maintain a list of all the certificates that it has issued and any declarations that it has registered.

(d) All the records referred to in points (a), (b) and (c) shall be kept for a minimum period of 5 years, subject to the applicable data protection law.

(e) All the records referred to in points (a), (b) and (c) shall be made available upon request to the competent authorities of another Member State or the Agency.

AMC1 21L.B.20(a) Record-keeping

ED Decision 2023/013/R

GENERAL

(a) The record-keeping system should ensure that all records are accessible within a reasonable time whenever they are needed. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.

(b) All records that contain sensitive data on applicants, declarants or organisations should be stored in a secure manner with controlled access, to ensure their confidentiality.

(c) The records should be kept in paper form, or in an electronic format, or a combination of both. Records that are stored on microfilm or optical discs are also acceptable. The records should remain legible and accessible throughout the required retention period. The retention period starts when the record is created.

(d) Paper record systems should use robust material that can withstand normal handling and filing. Computer record systems should have at least one backup system that should be updated within 24 hours of any new entry. Computer record systems should include safeguards to prevent unauthorised personnel from altering the data.

(e) All the computer hardware that is used to ensure the backup of data should be stored in a different location from the one that contains the working data and in an environment that ensures that the data remains in a good condition. When hardware or software changes take place, special care should be taken that all the necessary data continues to be accessible throughout at least the full period that is specified in point 21L.B.20(d).

AMC1 21L.B.20(a)(1);(a)(2) Record-keeping

ED Decision 2023/013/R

COMPETENT AUTHORITY MANAGEMENT SYSTEM

The records that are related to the competent authority's management system should include, as a minimum and as applicable:

(a) the documented policies and procedures;

(b) the files of the competent authority's personnel, with the supporting documents related to their training and qualifications;

(c) the results of the competent authority's internal audits and safety risk management processes, including audit findings, as well as any corrective, preventive, and risk-mitigation action; and

(d) the contracts that are established with the qualified entities that perform certification or oversight tasks on behalf of the competent authority.

21L.B.21 Findings and observations

Regulation (EU) 2022/1361

(a) When the competent authority, during investigation or oversight or by any other means, detects a non-compliance with the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, of a procedure or manual required by those Regulations, or of a certificate or declaration issued in accordance with those Regulations, it shall, without prejudice to any additional action required by those Regulations, raise a finding.

(b) The competent authority shall have a system to analyse findings for their safety significance.

A level 1 finding shall be issued by the competent authority when any significant non-compliance is detected which lowers safety or seriously endangers flight safety, or in the case of design organisations may lead to an uncontrolled non-compliance and to a potential unsafe condition as per point 21L.B.23; level 1 findings shall also include but not be limited to the following:

1. any failure to grant the competent authority access to the organisation's or natural or legal person's facilities as defined in point 21L.A.10 during normal operating hours and after two written requests;
2. providing wrong information or falsification of documentary evidence;
3. any evidence of malpractice or of fraudulent use of a certificate, declaration or statement issued in accordance with this Annex;
4. the lack of an accountable manager or head of the design organisation, as applicable.

A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, of a procedure or manual required by those Regulations, or of a declaration issued in accordance with those Regulations, which is not classified as a level 1 finding.

(c) The competent authority shall communicate the finding to the organisation or the natural or legal person in writing, and request corrective action to address the non-compliance(s) identified.

(d) If there are any level 1 findings, the competent authority shall take immediate and appropriate action in accordance with point 21L.B.22, unless the finding is on a design organisation which has declared its design capabilities, in which case the Agency shall first grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, which in any case shall not be more than 21 working days. The period shall commence from the date of the written communication of the finding to the organisation, requesting corrective action to address the non-compliance identified. If the level 1 finding directly relates to an aircraft, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

(e) For level 2 findings, the competent authority shall grant the organisation or the natural or legal person a corrective action implementation period that is appropriate to the nature of the finding. The period shall commence from the date of the written communication of the finding to the organisation or the natural or legal person, requesting corrective action to address the non-compliance identified. At the end of this period, and subject to the nature of the finding, the competent authority may extend the period, provided that a corrective action plan has been agreed by the competent authority.

The competent authority shall assess the corrective action and the implementation plan proposed by the organisation or the natural or legal person, and if the assessment concludes that they are sufficient to address the non-compliance(s), accept these.

If an organisation or natural or legal person fails to submit an acceptable corrective action plan, or to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to a level 1 finding, and action shall be taken as laid down in point (d).

(f) The competent authority may issue observations for those cases not requiring level 1 or level 2 findings:

1. for any item the performance of which has been assessed to be ineffective;
2. when it has been identified that an item has the potential to cause a non-compliance; or
3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

Observations issued under this point shall be communicated to the organisation or the natural or legal person in writing and recorded by the competent authority.

AMC1 21L.B.21(c) Findings and corrective actions

ED Decision 2023/013/R

NOTIFICATION OF FINDINGS

In the case of a level 1 finding, confirmation should be obtained in a timely manner that the accountable manager has taken note of the finding and its details.

Level 1 and level 2 findings require timely and effective oversight by the competent authority to ensure the completion of the corrective action. That oversight may include intermediate communication, such as letters, as necessary, to remind the natural or legal person to verify that the corrective action plan is followed.

GM1 21L.B.21(f) Findings and observations

ED Decision 2023/013/R

DIFFERENCE BETWEEN A 'LEVEL 2 FINDING' AND AN 'OBSERVATION'

'Findings' are issued for a non-compliance with the applicable regulation, whereas 'observations' may be issued to a natural or legal person ('organisation') that remains compliant with the applicable regulation while additional input to the organisation may be considered for continuous improvement (see points (1), (2) and (3) of point 21L.B.21(f)).

However, the competent authority may decide to issue a 'level 2' finding when the 'observations' process is not managed correctly or is overlooked.

21L.B.22 Enforcement measures

Regulation (EU) 2022/1361

(a) The competent authority shall:

1. suspend a certificate if the competent authority considers that there are reasonable grounds that such action is necessary to prevent a credible threat to aircraft safety;
2. issue an airworthiness directive under the conditions of point 21L.B.23;
3. suspend, revoke or limit a certificate if such action is required pursuant to point (d) of point 21L.B.21;
4. suspend or revoke a certificate of airworthiness or a restricted certificate of airworthiness when the conditions specified in point (b) of point 21L.B.163 are met;
5. suspend or revoke a noise certificate or a restricted noise certificate when the conditions specified in point (b) of point 21L.B.173 are met;
6. take immediate and appropriate action necessary to limit or prohibit the activities of an organisation or natural or legal person if the competent authority considers that there are reasonable grounds that such action is necessary to prevent a credible threat to aircraft safety;
7. limit or prohibit the activities of an organisation or a natural or legal person that have declared their capabilities to design or produce products or parts in accordance with Section A or that issue statements of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1) in accordance with Subpart R of Section A of this Annex pursuant to point (d) of point 21L.B.21;
8. not register a declaration of design compliance as long as there are unresolved findings from the initial oversight investigation;
9. temporarily or permanently de-register a declaration of design compliance or a declaration of capability pursuant to point (d) of point 21L.B.21;
10. take any further enforcement measures necessary in order to ensure the termination of a non-compliance with the essential requirements set out in Annex II to Regulation (EU) 2018/1139 and with this Annex, and, where necessary, remedy the consequences thereof.

(b) Upon taking an enforcement measure in accordance with point (a), the competent authority shall notify it to the addressee, state the reasons for it, and inform the addressee of their right to appeal.

GM1 21L.B.22 Enforcement measures

ED Decision 2023/013/R

LINK BETWEEN FINDINGS AND LIMITATION OR SUSPENSION

It is expected that any natural or legal person will move quickly to re-establish compliance with Part 21 Light and will not risk the possibility of their approval or the registration of their declaration of design compliance or declaration of design or production capability being suspended.

Level 1 findings are those which may lead, if not properly addressed, to limitation, suspension or revocation of the approval. If appropriate, these negative decisions on the approval may be taken immediately or after the organisation fails to comply within the time period agreed by the competent authority.

The type of the negative decision (i.e. limitation, suspension or revocation) should depend upon the contents and the extent of the level 1 finding. Normally, a limitation or a suspension should be considered first.

GM1 21L.B.22 Enforcement measures

ED Decision 2023/013/R

(a) GENERAL

Decisions on the suspension or revocation of a certificate, approval, and registration and deregistration of a declaration of design compliance or declaration of design or production capability will always be actioned in such a way as to comply with any applicable national laws or regulations related to appeal rights and the conduct of appeals.

In case of Agency decisions, as competent authority, the rules for appeal are included in Regulation (EU) 2018/1139.

(b) LIMITATION

A limitation is an amendment to a certificate, approval, or to a registration of a declaration of design compliance or declaration of design or production capability that partially limits the activities of the organisation.

(c) SUSPENSION OF CERTIFICATES AND APPROVALS

A suspension is a temporary withdrawal of a natural or legal person's ('organisation's') ability to conduct their activities under a certificate or an approval. No activities that invoke the certificate or approval may take place while the suspension is in force. The normal activities of the natural or legal person may be reinstated when the circumstances that caused the suspension are corrected and the natural or legal person can once again demonstrate full compliance with the applicable requirements.

(d) DEREGISTRATION OF DECLARATIONS

In the case of declarations, point 21L.B.22 provides that a declaration may be temporarily or permanently deregistered. No activities that invoke the declaration may take place while the declaration is deregistered. The normal activities of the natural or legal person may be reinstated when the circumstances that caused the deregistration are corrected and the natural or legal person can once again demonstrate full compliance with the applicable requirements.

21L.B.23 Airworthiness directives

Regulation (EU) 2022/1361

(a) An airworthiness directive means a document issued or adopted by the Agency which mandates actions to be performed on an aircraft to restore an acceptable level of safety when evidence shows that the safety level of this aircraft may otherwise be compromised.

(b) The Agency shall issue an airworthiness directive when:

1. an unsafe condition has been determined by the Agency to exist in an aircraft as a result of a deficiency in the aircraft, or an engine, propeller or part installed on this aircraft; and

2. that condition is likely to exist or develop in other aircraft.

(c) An airworthiness directive shall contain at least information identifying:

1. the unsafe condition;
2. the affected aircraft;
3. the action(s) required;
4. the compliance time for the required action(s);
5. the date of entry into force.

AMC1 21L.B.23(b) Airworthiness directives

ED Decision 2023/013/R

UNSAFE CONDITION

An unsafe condition exists if there is factual evidence (from in-service experience, analysis or tests) that:

(a) an event may occur that would result in fatalities, usually with the loss of the aircraft, or reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be:

(i) a large reduction in safety margins or functional capabilities; or

(ii) physical distress or excessive workload such that the flight crew cannot be relied upon to perform their tasks accurately or completely; or

(iii) serious or fatal injury to one or more occupants,

unless it is shown that the probability of such an event is within the limit defined by the applicable certification specifications; or

(b) there is an unacceptable risk of serious or fatal injury to persons other than occupants; or

(c) design features intended to minimise the effects of survivable accidents do not perform their intended function.

Note 1: Non-compliance with the applicable certification specifications or technical specifications is generally considered as an unsafe condition, unless it is shown that possible events resulting from this non-compliance do not constitute an unsafe condition as defined under points (a), (b) and (c).

Note 2: An unsafe condition may exist even though applicable airworthiness requirements are complied with.

Note 3: The definition in points (a), (b) and (c) covers the majority of cases where EASA considers there is an unsafe condition. There may be other cases where overriding safety considerations may lead EASA to issue an airworthiness directive.

Note 4: There may be cases where events can be considered as an unsafe condition if they occur too frequently (significantly beyond the applicable safety objectives) and could eventually lead to the consequences listed in point (a) in specific operating environments. Although having less severe immediate consequences than those listed in point (a), the referenced events may reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be, for example, a significant reduction in safety margins or functional capabilities, a significant increase in crew workload, or in conditions impairing crew efficiency, or discomfort to occupants, possibly including injuries.

GM1 21L.B.23(b) Airworthiness directives

ED Decision 2023/013/R

DETERMINATION OF AN UNSAFE CONDITION

It is important to note that these guidelines are not exhaustive. However, this material is intended to provide guidelines and examples that will cover most cases, taking into account the applicable certification requirements or technical specifications.

1. INTRODUCTION

The certification, approval or declaration of a product is a demonstration of compliance with the applicable requirements which are intended to ensure an acceptable level of safety. This demonstration, however, includes certain accepted assumptions and predicted behaviours, such as:

- fatigue behaviour is based on analysis supported by test;
- modelling techniques are used for aircraft flight manual (AFM) performance calculations;
- the systems' safety analyses give predictions of what the systems' failure modes, effects and probabilities may be;
- the system components' reliability figures are predicted values derived from general experience, tests or analyses;
- the crew is expected to have the skills to apply the procedures correctly; and
- the aircraft is assumed to be maintained in accordance with the prescribed instructions for continued airworthiness (ICAs) (or maintenance programme).

In-service experience, additional testing, further analysis, etc., may show that certain initially accepted assumptions are not correct. Thus, certain conditions initially demonstrated as safe, are revealed by experience as unsafe. In this case, it is necessary to mandate corrective actions in order to restore a level of safety consistent with the applicable certification requirements or technical specifications.

To support the determination of an unsafe condition, the investigation may need to include examinations of worn, damaged and time-expired parts / analysis / demonstrations / tests / statistical analysis, and comparison with the design assumptions.

See AMC1 21L.B.23(b) for the definition of 'unsafe condition' used in point 21L.A.3(a)(3) and (b)(3).

2. GUIDELINES FOR ESTABLISHING WHETHER A CONDITION IS UNSAFE

The following points give general guidelines for analysing the reported events and determining whether an unsafe condition exists, and are provided for each type of product subject to a specific airworthiness approval (type certificates (TCs) or supplemental type certificates (STCs)) for aircraft, engines or propellers or a declaration of design compliance for an aircraft.

This analysis may be qualitative or quantitative, i.e. formal and quantitative safety analyses may not be available. In such cases, the level of analysis should be consistent with that required by the certification specifications or technical specifications and may be based on engineering judgement supported by in-service experience data.

2.1 Analysis method for aircraft

2.1.1 Accidents or incidents without any aircraft, engine, system, propeller or part malfunction or failure

When an accident/incident does not involve any component malfunction or failure but when a human factor of the crew has been a contributing factor, this should be assessed from a man–machine interface standpoint to determine whether the design is adequate or not. Point 2.5 gives further details on this aspect.

2.1.2 Events involving an aircraft, engine, system, propeller or part failure, malfunction or defect

The general approach for analysis of in-service events caused by malfunctions, failures or defects will be to analyse the actual failure effects, taking into account previously unforeseen failure modes or improper or unforeseen operating conditions revealed by in-service experience.

These events may have occurred in service, or have been identified during maintenance, or have been identified as a result of subsequent tests, analyses or quality control.

They may result from a design or production deficiency (non-conformity with the applicable design data), or from improper maintenance. In this case, it should be determined whether improper maintenance is limited to one aircraft, in which case an airworthiness directive may not be issued, or if it is likely to be a general problem due to improper design and/or maintenance procedures, as detailed in point 2.5.

2.1.2.1 Flight

An unsafe condition exists if:

— there is a significant shortfall of the actual performance compared to the approved or declared performance (taking into account the accuracy of the performance calculation method); or

— the handling qualities, although having been found to comply with the applicable certification specifications at the time of initial approval or declared as being compliant with the applicable technical specifications, are subsequently shown by in-service experience not to comply.

2.1.2.2 Structural or mechanical systems

An unsafe condition exists if the deficiency may lead to a structural or mechanical failure which could exist in a principal structural element. Principal structural elements are those which contribute significantly to carrying flight, ground, and pressurisation loads, and whose failure could result in a catastrophic failure of the aircraft.

They could reduce the structural stiffness to such an extent that the required flutter, divergence or control reversal margins are no longer achieved.

They could result in the loss of a structural piece that could damage vital parts of the aircraft, cause serious or fatal injuries to persons other than occupants.

They could, under ultimate load conditions, result in the liberation of items of mass that may injure the aircraft occupants.

They could jeopardise the proper operation of systems and may lead to hazardous or catastrophic consequences, if this effect has not been taken adequately into account in the initial certification safety assessment.

2.1.2.3 Systems

The consequences of reported system components' malfunctions, failures or defects should be analysed.

For this analysis, the certification or design data may be used as supporting material, in particular systems' safety analyses (if applicable).

The general approach for analysis of in-service events caused by systems' malfunctions, failures or defects will be to analyse the actual failure effects.

As a result of this analysis, an unsafe condition will be assumed if it cannot be shown that the safety objectives for hazardous and catastrophic failure conditions are still achieved, taking into account the actual failure modes and rates of the components affected by the reported deficiency.

The failure probability of a system component may be affected by:

— a design deficiency (the design does not meet the specified reliability or performance);

— a production deficiency (non-conformity with the certified type design or declared design data) that affects either all components, or a certain batch of components;

— improper installation (for instance, insufficient clearance of pipes to surrounding structure);

— susceptibility to adverse environment (corrosion, moisture, temperature, vibrations etc.);

— ageing effects (component failure rate increases when the component ages);

— improper maintenance.

When the failure of a component is not immediately detectable (hidden or latent failures), it is often difficult to have a reasonably accurate estimation of the component failure rate since the only data available are usually results of maintenance or flight crew checks. This failure probability should, therefore, be conservatively assessed.

As it is difficult to justify that the safety objectives for the following systems are still met, a deficiency that affect these types of systems may often lead to a mandatory corrective action:

— backup emergency systems; or

— fire detection and protection systems (including shut-off means).

Deficiencies that affect the systems used during an emergency evacuation (emergency exits, evacuation assist means, emergency lighting system, etc.) and to locate the site of a crash (emergency locator transmitter (ELT)) will also often lead to mandatory corrective action.

2.1.2.4 Others

In addition to the above, the following conditions are considered unsafe:

— There is a deficiency in certain components which are involved in fire protection or which are intended to minimise/retard the effects of fire/smoke in a survivable crash, preventing them to perform their intended function (for instance, deficiency in cargo liners or cabin material leading to non-compliance with the applicable flammability requirements).

— There is a deficiency in the lightning or the high-intensity radiated field (HIRF) protection of a system which may lead to hazardous or catastrophic failure conditions.

— There is a deficiency which could lead to a total loss of power or thrust due to common mode failure.

2.2 Engines

The consequences and probabilities of engine failures should be assessed at the aircraft level in accordance with point 2.1, and also at the engine level for those failures considered as 'hazardous' in CS E-510, CS E-210, CS-22 Subpart H or the applicable technical specifications.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.3 Propellers

The consequences and probabilities of propeller failures should be assessed at the aircraft level in accordance with point 2.1, and also at the propeller level for those failures considered as 'hazardous' in CS P-150, CS-22 Subpart J or the applicable technical specifications.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.4 Parts

The consequences and probabilities of equipment failures should be assessed at the aircraft level in accordance with point 2.1.

2.5 Human-factors aspects in establishing and correcting unsafe conditions

This point provides guidance on the way to treat an unsafe condition that results from a maintenance or crew error observed in service.

It is recognised that human-factors techniques are under development. However, the following is a preliminary guidance on the subject.

Systematic review should be used to assess whether the crew or maintenance error raises issues that require regulatory action (whether in design or other areas) or should be noted as an isolated event without intervention. This may need the establishment of a multidisciplinary team (designers, crews, human-factors experts, maintenance experts, aircraft operators, etc.).

The assessment should include at least the following:

— Characteristics of the design intended to prevent or discourage incorrect assembly or operation.

— Characteristics of the design that allow or facilitate incorrect operation.

— Unique characteristics of a design feature differing from established design practices.

— The presence of indications or feedback that alerts the operator to an erroneous condition.

— The existence of similar previous events, and whether or not they resulted (on those occasions) in unsafe conditions.

— Complexity of the system, associated procedures and training (has the crew a good understanding of the system and its logic after a standard crew qualification programme?).

— Clarity/accuracy/availability/currency and practical applicability of manuals and procedures.

— Any issues arising from interactions among personnel, such as shift changeover, dual inspections, team operations, supervision (or lack of it), or fatigue.

Apart from a design change, the corrective actions, if found necessary, may consist of modifications of the manuals, inspections, training programmes, and/or information to the operators about particular design features. The Agency may decide to make mandatory such corrective action if necessary.

21L.B.24 Means of compliance

Regulation (EU) 2022/1361

(a) The Agency shall develop acceptable means of compliance ('AMC') that may be used to establish compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.

(b) Alternative means of compliance may be used to establish compliance with this Regulation.

(c) Competent authorities shall inform the Agency of any alternative means of compliance used by natural or legal persons under their oversight for establishing compliance with this Regulation.

GM1 21L.B.24 Means of compliance

ED Decision 2023/013/R

ALTERNATIVE MEANS OF COMPLIANCE — GENERAL

(a) A competent authority may establish alternative means to comply with the Regulation, which are different from the AMC that are established by EASA.

In that case, the competent authority is responsible for demonstrating how those alternative means of compliance (AltMoC) establish compliance with the Regulation.

(b) AltMoC that are used by a competent authority, or by an organisation under its oversight, may be used by other competent authorities, or another organisation, only if they are processed by those authorities in accordance with point 21L.B.24, and by that organisation in accordance with point 21L.A.12.

(c) AltMoC that are issued by the competent authority may cover the following cases:

(1) AltMoC to be used by organisations under the oversight of the competent authority and which are made available to those organisations; and

(2) AltMoC to be used by the authority itself to discharge its responsibilities.

AMC1 21L.B.24(a);(b) Means of compliance

ED Decision 2023/013/R

PROCESSING THE ALTERNATIVE MEANS OF COMPLIANCE

To meet the objectives of points (b) and (c) of point 21L.B.24:

(a) the competent authority should establish the means to consistently evaluate over time that all the AltMoC that are used by itself or by organisations under its oversight allow for the establishment of compliance with the Regulation;

(b) if the competent authority issues AltMoC for itself or for the organisations under its oversight, it should:

(1) make them available to all relevant organisations; and

(2) notify EASA of the AltMoC as soon as they are issued, including the information that is described in point (d) of this AMC;

(c) the competent authority should evaluate the AltMoC that are proposed by an organisation by analysing the documentation provided and, if considered necessary, by inspecting the organisation; when the competent authority finds that the AltMoC are in accordance with the Regulation, it should:

(1) notify the applicant that the AltMoC are approved;

(2) indicate that those AltMoC may be implemented, and agree when the organisation's processes and procedures are to be amended accordingly; and

(3) notify EASA of the AltMoC approval as soon as they are approved, including the information that is described in point (d) of this AMC; and

(d) the competent authority should provide EASA with the following information:

(1) a summary of the AltMoC;

(2) the content of the AltMoC;

(3) a statement that compliance with the Regulation is achieved; and

(4) in support of that statement, an assessment that demonstrates that the AltMoC reach an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding Agency's AMC.

(e) All these elements that describe the AltMoC are an integral part of the records to be kept, which are managed in accordance with point 21L.B.20.

GM1 21L.B.24(b);(c) Means of compliance

ED Decision 2023/013/R

CASES IN WHICH THERE IS NO CORRESPONDING AGENCY AMC

When there is no Agency AMC to a certain requirement in the Regulation, the competent authority may choose to develop national guides or other types of documents to assist the organisations under its oversight in compliance demonstration. The competent authority may inform EASA so that such guides or other types of documents may be later considered for incorporation into an AMC that is published by EASA using the EASA rulemaking process.

SUBPART B — TYPE CERTIFICATES

21L.B.41 Certification specifications

Regulation (EU) 2022/1358

The Agency, in accordance with Article 76(3) of Regulation (EU) 2018/1139, shall issue certification specifications and other detailed specifications, including certification specifications for airworthiness, and environmental compatibility that competent authorities, organisations and personnel may use to demonstrate the compliance of products and parts with the relevant essential requirements set out in Annexes II, IV and V to that Regulation, as well as with those for environmental protection set out in Article 9(2) of and Annex III to that Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates are to be issued, amended or supplemented.

21L.B.42 Initial investigation

Regulation (EU) 2022/1358

(a) Upon receiving an application for a type certificate under this Annex, the Agency shall verify whether the product is within the scope established in point 21L.A.21 and whether the applicant is eligible in accordance with point 21L.A.22 to apply for a type certificate for the product.

(b) When the conditions of point (a) are not fulfilled, the Agency shall reject the application.

21L.B.43 Type-certification basis for a type certificate

Regulation (EU) 2022/1358

(a) The Agency shall establish the type-certification basis and notify it to the applicant. The type-certification basis shall consist of:

1. the certification specifications for airworthiness designated by the Agency from those applicable to the product at the date of application for that certificate, unless:

   (i) the applicant chooses to comply with certification specifications which became applicable after the date of the application; if an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or

   (ii) the Agency accepts any alternative to a designated certification specification that cannot be complied with, for which compensating factors have been found that provide an equivalent level of safety; or

   (iii) the Agency accepts or prescribes other means that demonstrate compliance with the essential requirements of Annex II to Regulation (EU) 2018/1139;

2. any special condition prescribed by the Agency in accordance with point 21L.B.44(a).

(b) The Agency may amend the type-certification basis at any point before the issuance of the type certificate if it has determined that experience from other similar products in service, or products that have similar design features, has shown that unsafe conditions may develop, and the type-certification basis that was established and notified to the applicant does not address this unsafe condition.

GM1 21L.B.43(a) Type-certification basis for a type certificate

ED Decision 2023/013/R

1. INTRODUCTION

This GM addresses the type-certification basis for a type certificate (TC).

2. APPLICABLE CERTIFICATION SPECIFICATIONS (CSs)

The type-certification basis for a TC consists of the airworthiness CSs that were effective on the date of application and were applicable for the particular certificate.

3. ELECT TO COMPLY (see point 21L.B.43(a)(1)(i))

It is also possible for an applicant to elect to comply with a CS that became applicable after the date on which the applicant has submitted the application.

The Agency should assess whether the proposed certification basis is appropriate to ensure that the 'elect to comply' proposal includes any other CSs that are 'directly related' to one or several of the CSs in it. Directly related CSs are those that are deemed to contribute to the same safety objective by building on each other's requirements, addressing complementary aspects of the same safety concern, etc. Typically, they are adopted simultaneously with, or prior to, the CSs with which the applicant has elected to comply.

4. EQUIVALENT LEVEL OF SAFETY (see point 21L.B.43(a)(1)(ii))

In cases in which the applicable CSs cannot be literally complied with, either fully or in part, EASA may accept a suitable alternative which provides an equivalent level of safety through the use of appropriate compensating factors.

In cases in which the requirements contain not only objectives but also prescriptive parts, an equivalent level of safety may be accepted if:

— the objectives are met by designs or features other than those required in the CSs; or

— suitable compensating factors are proposed.

5. ALTERNATIVE MEANS OF COMPLIANCE (see point 21L.B.43(a)(1)(iii))

If the intent of the CSs defined in point 21L.B.43(a)(1) cannot be met, EASA may accept mitigating factors to the CSs, provided that the safety objective is met.

In the case of a TC, the alternative means should provide a demonstration of compliance with the essential requirements for airworthiness laid down in Annex II to Regulation (EU) 2018/1139.

Note: 'Alternative means of compliance' should not be confused with 'AMC'.

6. SPECIAL CONDITIONS (see point 21L.B.43(a)(2))

The Agency may also prescribe special conditions in accordance with point 21L.B.44. Guidance on special conditions is provided in GM1 21L.B.44.

21L.B.44 Special conditions

Regulation (EU) 2022/1358

(a) The Agency shall prescribe special detailed technical specifications, named 'special conditions', for a product if the related certification specifications do not contain adequate or appropriate safety standards for the product because:

1. the product has novel or unusual design features relative to the design practices on which the applicable certification specifications are based;
2. the intended use of the product is unconventional; or
3. experience from other similar products in service or products having similar design features or newly identified hazards have shown that unsafe conditions may develop.

(b) Special conditions contain such safety standards as the Agency finds necessary in order to establish a level of safety equivalent to that of the applicable certification specifications.

GM1 21L.B.44 Special conditions

ED Decision 2023/013/R

GENERAL

The term 'novel or unusual design features' should be judged in view of the applicable certification basis for a particular product. A design feature, in particular, should be judged to be a 'novel or unusual design feature' when the certification basis does not sufficiently cover it.

The term 'unsafe condition' is used with the same meaning as described in AMC1 21L.B.23(b) 'Airworthiness directives'.

The term 'newly identified hazards' is intended to address new risks that may be recognised in the design (e.g. questionable features) or its operational characteristics (e.g. volcanic ash) for which there is not yet enough in-service experience.

21L.B.45 Designation of the applicable environmental protection requirements for a type certificate

Regulation (EU) 2022/1358

The Agency shall designate and notify to the applicant for a type certificate for an aircraft or for an engine, the applicable environmental requirements in accordance with point 21.B.85 of Annex I (Part 21).

21L.B.46 Investigation

Regulation (EU) 2022/1358

Upon receiving an application for a type certificate under this Annex, the Agency shall:

(a) conduct a review of the initial compliance demonstration plan and any subsequent update provided by the applicant in order to establish the completeness of the plan and the appropriateness of the proposed means and methods of demonstrating compliance with the type-certification basis established in accordance with point 21L.B.43 and with the applicable environmental protection requirements designated in accordance with point 21L.B.45; if the compliance demonstration plan is incomplete or the means and methods are not appropriate to achieve compliance demonstration, the Agency shall inform the applicant and request an amendment of it;

(b) when satisfied that the compliance demonstration plan provided is appropriate so that the applicant can demonstrate compliance, approve the compliance demonstration plan and any subsequent updates of the compliance demonstration plan;

(c) after receiving the declaration of compliance in accordance with point (f) of point 21L.A.25, conduct a physical inspection and assessment of the first article of that product in the final configuration, taking into consideration the critical design review carried out in accordance with point (a) of point 21L.B.242, in order to verify the compliance of the product with the applicable type-certification basis and the applicable environmental protection requirements; the Agency shall verify the compliance of the product, considering the likelihood of an unidentified non-compliance with the type-certification basis or the applicable environmental protection requirements, and the potential impact of that non-compliance on the safety or environmental compatibility of the product;

(d) if during the establishment of the type-certification basis, designation of the applicable environmental protection requirements or during the review of the compliance demonstration plan the Agency determines that the product design contains any element for which an unidentified non-compliance with the type-certification basis or the applicable environmental protection requirements may have an adverse impact on the safety or environmental compatibility of the product, the Agency shall determine which investigations are necessary in addition to those described in point (c) in order to verify the compliance demonstration; the Agency shall notify the applicant of any additional investigations and which elements of the design would be subject to those investigations.

AMC1 21L.B.46(c) Investigation

ED Decision 2023/013/R

PHYSICAL INSPECTION AND CRITICAL DESIGN REVIEW

Prior to the approval of the flight conditions to support the issuance of a permit to fly, a physical inspection and a critical design review is conducted with the applicant and the competent authority for conformity (production) under point 21L.B.242(a). The experience and outcome of this activity should be used by EASA to determine the scope and particular aspects of the design that should be the focus of the physical inspection and assessment of the first article of that product (first-article inspection) that is conducted under point 21L.B.46(c) prior to the issuance of the type certificate for a particular product.

AMC2 21L.B.46(c) Investigation

ED Decision 2023/013/R

PHYSICAL INSPECTION AND ASSESSMENT OF THE FIRST ARTICLE OF A PRODUCT (FIRST-ARTICLE INSPECTION)

1. Purpose

The purposes of the first-article inspection (of the article that is in conformance with the proposed type design for certification) prior to the issuance of the type certificate for a particular aircraft, propeller or engine design are:

a. for EASA to verify the completion of the demonstration-of-compliance activities conducted by the applicant under point 21L.A.25 and in accordance with the approved compliance-demonstration plan;

b. for EASA to verify[1] with a risk-based approach that the type design complies with the type-certification basis and the applicable environmental protection requirements;

c. in case the applicant is a declared design organisation, for EASA to conduct a further oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the applicant is able to discharge its obligations.

2. Methodology and evidence

The first-article inspection should be conducted by EASA at an appropriate location(s) selected by the applicant for a type certificate. This (these) location(s) should include the physical location of the aircraft, engine or propeller for which the type certificate has been requested and should be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

The Agency should conduct a physical inspection of the aircraft, engine or propeller for which the type certificate has been requested. This inspection, along any other activity that is considered necessary should ensure that the objectives mentioned in point 1 are met. Evidence to support compliance will be gathered by EASA prior to and during the first-article inspection. The physical inspection of the aircraft and, if applicable, of the engine and the propeller will provide substantial evidence that the design is in compliance with the type-certification basis and that the applicant (if a declared design organisation) is able to discharge its obligations.

Additional sources of evidence to support the determination of compliance of the design that are available to EASA prior to and during the first-article inspection include:

a. witnessing or participating in live testing (including flight testing) of the aircraft, engine, propeller, systems or components;

b. evaluation of the final compliance-demonstration plan produced by the applicant and how it relates to the final design;

c. evaluation of the completeness of the declaration of compliance submitted by the applicant;

d. evaluation of supporting compliance documentation and test reports;

e. discussions with key design and production personnel;

f. review of design processes and procedures (for non-approved organisations).

If the applicant selects to use flight testing to demonstrate compliance (see MC6 in Appendix A to AMC1 21L.A.24(b)), EASA may decide to conduct flight testing to verify compliance for applications for an aircraft type certificate. An appropriate flight-test plan should be developed and proposed by the applicant prior to the first-article inspection and agreed by EASA in order to ensure that there are no adverse flight characteristics.

Flight testing could be a combination of:

a. a predefined flight-test plan that is not specific to the particular aircraft type;

b. specific flight testing to focus on targeted aspects after a review of the applicant's flight-testing data/reports.

The above list of additional sources of evidence is not exhaustive.

[1] The verification of compliance is limited to the scope of the activities that can be conducted under point 2 and the elements of the design that are selected for review based upon a risk-based approach to compliance.

It is possible that during the first-article inspection EASA may discover evidence that:

a. the design is not in compliance with the type-certification basis or the applicable environmental protection requirements (this could be due to the applicant misinterpreting or misunderstanding the applicable design requirements);

b. the applicant has not fulfilled its design obligations as a declared design organisation;

c. there are shortfalls in the applicant's design management system (in accordance with point 21.A.239 or 21L.A.174) that result in a non-compliance or a loss of control of the design.

If such evidence is discovered, EASA may require a more in-depth investigation into the compliance documentation and/or the design practices of the design organisation. The purpose of this in-depth investigation should be to determine whether or not compliance was demonstrated, the root cause(s) and to establish corrective actions. This investigation should also serve to prevent a reoccurrence of the issue.

3. Aircraft condition and configuration

The aircraft, engine or propeller presented to EASA should be in the final configuration for which a type certificate has been requested and the compliance demonstration has been declared.

The applicant could arrange visits with EASA prior to the declaration of compliance (in accordance with point 21L.A.25(f)) (for example, for noise testing).

Any differences between the configuration presented to EASA for the first-article inspection and the final configuration in the declaration of compliance (in accordance with point 21L.A.25(f)) should be justified by the applicant and should be subject to detailed scrutiny during the first-article inspection.

4. Availability of supporting documentation and key personnel

The supporting documentation and compliance data should be available at the time EASA visits the applicant's facilities or at any other time upon request by EASA. Key design personnel will be made available to EASA in case of need. If this is not the case, EASA might not be in a position to issue the type certificate.

5. Findings and resolution

If a non-compliance is discovered by EASA in the process of the activities mentioned in point 2, an appropriate finding or observation should be raised against the aircraft, engine or propeller or declared design organisation in accordance with point 21L.B.21, which may result in the enforcement measures contained in point 21L.B.22. Findings of non-compliance should be resolved before the type certificate is issued. Depending upon their nature, findings against the declared design organisation may need to be resolved before the type certificate is issued.

21L.B.47 Issuance of a type certificate

Regulation (EU) 2022/1358

(a) The Agency shall issue without undue delay an aircraft, engine or propeller type certificate, provided that:

1. the applicant has complied with point 21L.A.27;

2. the Agency, through the investigation carried out pursuant to point 21L.B.46, has not found any non-compliance with the type-certification basis or with the applicable environmental protection requirements;

3. there are no unresolved issues from the investigation carried out pursuant to point (c) of point 21L.B.46 of that product in the final configuration;

4. no feature or characteristic has been identified that may make the product unsafe or environmentally incompatible for the uses for which the certification is requested.

(b) The type certificate shall include:

1. the type design;

2. the operating limitations;

3. the instructions for continued airworthiness;

4. the type certificate data sheet for airworthiness and, if applicable, the record of engine exhaust emissions compliance;

5. the applicable type-certification basis and the applicable environmental protection requirements with which the Agency records compliance;

6. if applicable, the type certificate data sheet for noise; and

7. any other conditions or limitations prescribed for the product in the applicable type-certification basis and the applicable environmental protection requirements.

21L.B.48 Continuing airworthiness oversight of products for which a type certificate has been issued

Regulation (EU) 2022/1358

If the Agency, through its continuing airworthiness oversight, including through reports received in accordance with point 21L.A.3, or by any other means, detects a non-compliance with the type-certification basis or the applicable environmental protection requirements, the Agency shall raise a finding in accordance with point 21L.B.21, or issue an airworthiness directive under the conditions of point 21L.B.23.

21L.B.49 Transfer of a type certificate

Regulation (EU) 2022/1358

(a) When the Agency receives an application for verification of whether a type certificate can be transferred by its holder in accordance with point 21L.A.29 or when the Agency considers a request to adopt a type certificate in accordance with point 21L.A.29, the Agency shall verify corresponding to points 21L.B.42 and 21L.B.46 whether the transferee is eligible to be a type-certificate holder in accordance with point 21L.A.22 and is able to undertake the obligations of a type-certificate holder under point 21L.A.28.

(b) When the Agency concludes that the conditions referred to in point (a) are met by the transferee, it shall inform the type-certificate holder or the natural or legal person requesting to adopt a type certificate that a transfer of the type certificate to that natural or legal person is accepted by the Agency.

SUBPART C — DECLARATIONS OF DESIGN COMPLIANCE

21L.B.61 Detailed technical specifications and applicable environmental protection requirements for declarations of product design compliance

Regulation (EU) 2022/1358

(a) The Agency, in accordance with Article 76(3) of Regulation (EU) 2018/1139, shall establish and make available the detailed technical specifications that natural and legal persons can use to demonstrate compliance with the relevant essential requirements set out in Annex II to that Regulation when declaring compliance of the aircraft design in accordance with Subpart C of Section A of this Annex.

(b) The detailed technical specifications referred to in point (a) shall provide design standards which reflect the state of the art and best design practices, and which build on the best available experience and scientific and technical progress, and on the best available evidence and analysis of aircraft design, for aircraft that are within the scope established under point 21L.A.41. These detailed technical specifications may include or refer to:

1. certification specifications established by the Agency in accordance with point 21.B.70 of Annex I (Part 21) for the airworthiness of the aircraft design;
2. special conditions that have been prescribed by the Agency in accordance with point 21.B.75 of Annex I (Part 21) or point 21L.B.44 for other aircraft and which are of a general nature;
3. detailed technical standards developed by standardisation and other industry bodies.

(c) For the purposes of ensuring the environmental compatibility of the design, the Agency shall establish and make available the environmental protection requirements to be used as the basis for the declaration of design compliance, which shall include:

1. environmental protection requirements for the relevant product categories as contained in Annex 16 to the Convention on International Civil Aviation, Volumes I to III, at an amendment level referred to in Article 9(2) of Regulation (EU)2018/1139; for this purpose, the references to:
   (i) the date of application for a type certificate contained in those volumes shall be understood as references to the date on which the declaration of design compliance is made by the declarant; and
   (ii) the certification requirements contained in those volumes shall be understood as requirements for the declaration of design compliance.
2. [reserved]

GM1 21L.B.61(b) Detailed technical specifications for declarations of design compliance

ED Decision 2023/013/R

The acceptable detailed technical specifications that should be used by a declarant to design an aircraft (including engine and propeller, if applicable), and then declare compliance with are published on the EASA website. The declarant should regularly check that the acceptable detailed technical specifications have not changed, and the declarant is encouraged to contact EASA to establish whether a change to the acceptable detailed technical specifications is pending or forthcoming to avoid any issues at the time of submission of the declaration of design compliance.

GM1 21L.B.61(c)(1) Detailed technical specifications and applicable environmental protection requirements for declarations of design compliance

ED Decision 2023/013/R

APPLICABLE ENVIRONMENTAL PROTECTION REQUIREMENTS

The applicable environmental protection requirements are the Standards and Recommended Practices (SARPs) in Volume I 'Aircraft Noise', Volume II 'Aircraft Engine Emissions' and Volume III 'Aeroplane CO_2 Emissions' of Annex 16 to the Chicago Convention for products for which the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139 applies. The applicable levels of amendments to Annex 16 to the Chicago Convention are those adopted in the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139.

Related guidance material is provided in the attachments to these Annex 16 volumes and in ICAO Doc 9501 'Environmental Technical Manual', Volume I 'Procedures for the Noise Certification of Aircraft', Volume II 'Procedures for the Emissions Certification of Aircraft Engines' and Volume III 'Procedures for the CO_2 Emissions Certification of Aeroplanes'.

However, these SARPs apply only to certain categories of products and as such do not necessarily apply to all products that are within the scope of Subpart C. The applicability of the SARPs is provided in the administration chapters and in the specific applicability sections of the chapters of Annex 16 Volumes I, II and III.

21L.B.62 Initial oversight investigation

Regulation (EU) 2022/1358

(a) Upon receiving a declaration of design compliance, the Agency shall verify that the aircraft is within the scope of Subpart C of Section A of this Annex and that the declaration contains all the information specified in point 21L.A.43. The Agency shall acknowledge the receipt of the declaration, including the assignment of an individual declaration of design compliance reference number to the declarant for that aircraft configuration.

(b) The Agency shall conduct a physical inspection and assessment of the first article of that aircraft in the final configuration, taking into consideration the safety review carried out in accordance with point (a)(2) of point 21L.B.242. If the Agency finds evidence, in the declaration or through the physical inspection and assessment carried out in accordance with the first sentence, indicating that the aircraft could be incapable of conducting a safe flight or could be environmentally incompatible during in-service operations, the Agency shall raise a finding in accordance with point 21L.B.21.

AMC 21L.B.62(b) Physical inspection and assessment of the first article of a given aircraft in the final configuration (first-article inspection) prior to the registration of a declaration of design compliance

ED Decision 2023/013/R

1. Purpose

The purposes of the first-article inspection (of the article that is in conformance with the proposed type design for certification) prior to the registration of a declaration of design compliance for a particular aircraft design are:

a. for EASA to ensure the completion of the demonstration-of-compliance activities conducted by the declarant under point 21L.A.44 in accordance with the information provided in accordance with point 21L.A.43 and in particular the compliance-demonstration plan;

b. for EASA to ensure[1] that the designed aircraft is capable of conducting safe flight during in-service operations and does not have any environmental incompatibilities;

c. in case the declarant is a declared design organisation, for EASA to conduct further oversight in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the declarant is able to discharge its obligations;

Note: Under Subpart C of Section A there is no obligation for a declarant of an aircraft declaration of design compliance to submit a declaration of design capability.

2. Methodology and evidence

The first-article inspection should be conducted by EASA at an appropriate location(s) selected by the declarant. This (these) location(s) should include the physical location of the aircraft for which the declaration of design compliance has been submitted under point 21L.A.43 and should be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

The Agency should conduct a physical inspection of the aircraft, engine or propeller for which the registration of a declaration of design compliance has been requested. This inspection, along with any other activity that EASA deems necessary (see point 21L.A.44(f)), should ensure that the objectives mentioned in point 1 are met. Evidence to support compliance should be gathered by EASA prior to and during the first-article inspection. The physical inspection of the aircraft and, if applicable, of the engine and propeller will provide substantial evidence that the aircraft is capable of conducting a safe flight and is environmentally compatible during in-service operations and that the declarant (if a declared design organisation) is able to discharge its obligations.

Additional sources of evidence during the visit at the declarant's facilities may include:

a. witnessing or participating to live testing (including flight testing) of the aircraft, engine, propeller, systems or components;

b. review of the completeness of the compliance-demonstration plan produced by the declarant and how it relates to the final design;

[1] This is limited to the scope of the activities that can be conducted under point 2 and the elements of the design that are selected for review based upon a risk-based approach to safety and environmental incompatibility.

c. determination of the completeness of supporting compliance documentation and test reports and how they relate to the first article under inspection;

d. discussions with key design and production personnel;

e. in case of need and if relevant, a review of the design processes and procedures in order to determine root causes of any issues that are discovered.

It will be necessary for EASA to conduct flight testing of the final configuration of the aircraft. The flight testing will be performed according to a plan proposed by the declarant prior to the first-article inspection and agreed by EASA.

Flight testing could be a combination of:

a. a predefined flight-test plan that is not specific to the particular aircraft type;

b. specific flight testing to focus on targeted aspects after a review of the declarant's flight-testing data/reports.

The above list of additional sources of evidence is not exhaustive.

It is possible that during the first-article inspection EASA may discover evidence that indicates that the declarant has:

a. misunderstood, misinterpreted or not demonstrated compliance with the applicable technical specifications or the applicable environmental protection requirements, which could lead to an unsafe or an environmentally incompatible design;

b. not fulfilled its design obligations as a declared design organisation (if applicable);

c. not utilised good design management principles to ensure compliance or control of the design.

If such evidence is discovered, EASA may wish to conduct a more in-depth investigation into the compliance documentation and/or the design practices of the declarant. This in-depth investigation should determine whether or not compliance was demonstrated, the root cause(s) and the corrective actions. This investigation should also aim to prevent a reoccurrence of the issue.

3. Aircraft condition and configuration

The aircraft presented to EASA should be in the final configuration for which the declarant has submitted a declaration of design compliance.

It is possible that the declarant could arrange visits with EASA prior to the declaration of the compliance demonstration being submitted (for example, for noise testing).

Any differences between the configuration presented to EASA for the first-article inspection and the final configuration in the declaration of compliance demonstration should be justified by the declarant and should, therefore, be subject to detailed scrutiny during the first-article inspection.

5. Findings and resolution

If a non-compliance is discovered by EASA in the process of the activities mentioned in point 2, an appropriate finding or observation should be raised by EASA against the given aircraft or, if applicable, the declared design organisation in accordance with point 21L.B.21 which, may result in the enforcement measures contained in point 21L.B.22. These findings should be resolved before the declaration of design compliance is registered.

21L.B.63 Registration of a declaration of design compliance

Regulation (EU) 2022/1358

The Agency shall register a declaration of design compliance for an aircraft provided that:

(a) the declarant has declared compliance in accordance with point (a) of point 21L.A.43;

(b) the declarant has provided to the Agency the documents required in accordance with point (c) of point 21L.A.43;

(c) the declarant has made a commitment that the obligations in accordance with point 21L.A.47 will be undertaken;

(d) there are no unresolved findings from the physical inspection and assessment of the first article of the aircraft in the final configuration carried out in accordance with point (b) of point 21L.B.62.

GM1 21L.B.63(b) Registration of a declaration of design compliance

ED Decision 2023/013/R

COMPLETENESS OF COMPLIANCE DOCUMENTATION AND DATA PROVIDED TO THE AGENCY

Prior to the registration of the declaration of design compliance, EASA should ensure that:

(a) its document management system contains the compliance documentation required by point 21L.A.43(c);

(b) the declarant has provided the data for the data sheet for noise required by point 21L.A.43(b)11 using EASA's Part 21 Light database of declared noise levels and that the data provided is reasonable and consistent prior to publication.

21L.B.64 Continuing airworthiness oversight of aircraft for which design compliance has been declared

Regulation (EU) 2022/1358

If the Agency, through its continuing airworthiness oversight, including through reports received in accordance with point 21L.A.3, or by any other means, detects a non-compliance with the applicable detailed technical specifications or the applicable environmental protection requirements, the Agency shall raise a finding in accordance with point 21L.B.21, or issue an airworthiness directive under the conditions of point 21L.B.23.

SUBPART D — CHANGES TO TYPE CERTIFICATES

21L.B.81 Type-certification basis and applicable environmental protection requirements for a major change to a type certificate

Regulation (EU) 2022/1358

(a) The Agency shall establish the type-certification basis for a major change to a type certificate and notify it to the applicant.

(b) For a major change to a type certificate and the areas affected by the change, the type-certification basis shall consist of the certification specifications incorporated by reference in the type certificate, unless:

1. the Agency finds that the certification specifications referenced in the type certificate do not provide adequate standards with respect to the proposed change, therefore the change and the areas affected by the change shall also comply with any special conditions, and amendments to those special conditions, prescribed by the Agency in accordance with point 21L.B.44, to provide a level of safety equivalent to that established by the certification specifications applicable on the date of the application for the change;

2. an applicant chooses to comply with a certification specification set out in an amendment that is applicable on the date of the application for the change.

(c) The Agency shall designate the applicable environmental protection requirements for the major change to a type certificate in accordance with point 21.B.85 of Annex I (Part 21) and notify them to the applicant.

21L.B.82 Investigation and issuance of an approval of a minor change to a type certificate

Regulation (EU) 2022/1358

(a) Upon receiving an application for the approval of a minor change to a type certificate under this Annex, the Agency shall approve the minor change when:

1. the applicant has provided the substantiation data and justifications, and has demonstrated and declared the compliance of the change with the applicable type-certification basis and the applicable environmental protection requirements, or with the certification specifications chosen in accordance with point 21L.A.67;

2. the Agency, through its verification of the demonstration of compliance, taking into account the design features, complexity and overall criticality of the design or technology, as well as previous experience of design activities with the applicant, has not found:

(i) any non-compliances with the type-certification basis or, where applicable, with the applicable environmental protection requirements, or with the certification specifications chosen;

(ii) any feature or characteristic of the change that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested.

(b) An approval of a minor change to a type certificate shall be limited to the specific configuration(s) in the type certificate to which the change relates.

21L.B.83 Investigation of a major change to a type certificate

Regulation (EU) 2022/1358

Upon receiving an application for a major change to a type certificate under this Annex, the Agency shall:

(a) conduct a review of the initial compliance demonstration plan and any subsequent update provided by the applicant in order to establish the completeness of the plan and the appropriateness of the proposed means and methods of demonstrating compliance with the type-certification basis and the applicable environmental protection requirements established and designated in accordance with point 21L.B.81; if the compliance demonstration plan is incomplete or the means and methods are not appropriate to achieve compliance demonstration, the Agency shall inform the applicant and request an amendment of it;

(b) when satisfied that the compliance demonstration plan provided is appropriate so that the applicant can demonstrate compliance, approve the compliance demonstration plan and also approve any subsequent updates of the compliance demonstration plan;

(c) determine the likelihood of an unidentified non-compliance of the major change with the type-certification basis or with the applicable environmental protection requirements, and the potential impact of that non-compliance on the safety or environmental compatibility of the product, and determine on that basis whether a physical inspection and assessment of the first article of that product in the final changed configuration is necessary in order to verify the compliance of the product with the applicable type-certification basis and the applicable environmental protection requirements, taking into consideration the critical design review if carried out in accordance with point (a)(3) of point 21L.B.242; the Agency shall notify the applicant before conducting this inspection and assessment;

(d) if during the establishment of the type-certification basis, the designation of the applicable environmental protection requirements or during the review of the compliance demonstration plan, the Agency determines that the design of the major change contains any element for which an unidentified non-compliance with the type-certification basis or the applicable environmental protection requirements may have an adverse impact on the safety or environmental compatibility of the changed product, the Agency shall determine which investigations are necessary in addition to those of point (c) in order to verify the compliance demonstration; the Agency shall notify the applicant of those additional investigations and which elements of the design would be subject to investigation.

AMC1 21L.B.83(c) Investigation of a major change to a type certificate

ED Decision 2023/013/R

PHYSICAL INSPECTION AND CRITICAL DESIGN REVIEW

Depending upon the nature of the design change, prior to the approval of the flight conditions to support the issuance of a permit to fly, a physical inspection and a critical design review should be conducted with the applicant and the competent authority for conformity (production) under point 21L.B.242(a). The experience and outcome of this activity should be used by EASA to determine the need for a physical inspection and assessment of the first article of that changed product (first-article inspection) that may be conducted under point 21L.B.83(d) prior to the issuance of the supplemental type certificate for the change.

AMC1 21L.B.83(d) Investigation of a major change to a type certificate

ED Decision 2023/013/R

PHYSICAL INSPECTION AND ASSESSMENT OF THE FIRST ARTICLE OF THE CHANGED PRODUCT (FIRST-ARTICLE INSPECTION)

If EASA determines that there is a need to conduct a first-article inspection of the changed product under point 21L.B.83(c), then AMC2 21L.B.46(c) provides the description of this activity for EASA.

21L.B.84 Issuance of an approval of a major change to a type certificate

Regulation (EU) 2022/1358

(a) The Agency shall approve the major change when:

1. the applicant has demonstrated that the change and the areas affected by the change comply with the type-certification basis and the applicable environmental protection requirements, as established and designated by the Agency in accordance with point 21L.B.81;
2. the applicant has demonstrated and declared compliance in accordance with point (f) of point 21L.A.66;
3. the Agency through its verification of the demonstration of compliance has not found:
   (i) any non-compliances with the type-certification basis or, where applicable, with the applicable environmental protection requirements;
   (ii) any feature or characteristic of the change that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested.

(b) An approval of a major change to a type certificate shall be limited to the specific configuration(s) in the type certificate to which the change relates.

21L.B.85 Continuing airworthiness oversight of changed products for which a type certificate has been issued

Regulation (EU) 2022/1358

If the Agency, through its continuing airworthiness oversight, including through reports received in accordance with point 21L.A.3, or by any other means, detects a non-compliance with the type-certification basis or the applicable environmental protection requirements of a product for which a change to a type certificate has been approved, the Agency shall raise a finding in accordance with point 21L.B.21, or issue an airworthiness directive under the conditions of point 21L.B.23.

SUBPART E — SUPPLEMENTAL TYPE CERTIFICATES

21L.B.101 Type-certification basis and applicable environmental protection requirements for a supplemental type certificate

Regulation (EU) 2022/1358

(a) The Agency shall establish the type-certification basis for a supplemental type certificate and notify it to the applicant.

(b) For major changes to a type certificate in the form of a supplemental type certificate, the type-certification basis for the areas affected by the change shall be that which is incorporated by reference in the type certificate, unless:

1. the Agency finds that the certification specifications referenced in the type certificate do not provide adequate standards with respect to the proposed change, therefore the change and the areas affected by the change shall also comply with any special conditions, and amendments to those special conditions, prescribed by the Agency in accordance with point 21L.B.44, to provide a level of safety equivalent to that established by the certification specifications applicable on the date of the application for the change;

2. an applicant chooses to comply with a certification specification set out in an amendment that is applicable on the date of the application for the change.

(c) The Agency shall designate the applicable environmental protection requirements for a major change to a type certificate in accordance with point 21.A.85 of Annex I (Part 21) and notify them to the applicant.

21L.B.102 Investigation

Regulation (EU) 2022/1358

Upon receiving an application for a supplemental type certificate under this Annex, the Agency shall:

(a) conduct a review of the initial compliance demonstration plan and any subsequent update provided by the applicant in order to establish the completeness of the plan and the appropriateness of the proposed means and methods of demonstrating compliance with the type-certification basis and the applicable environmental protection requirements established and designated in accordance with point 21L.B.101; if the compliance demonstration plan is incomplete or the means and methods are not appropriate to achieve compliance demonstration, the Agency shall inform the applicant and request an amendment of it;

(b) when satisfied that the compliance demonstration plan provided is appropriate so that the applicant can demonstrate compliance, approve the compliance demonstration plan and any subsequent updates of the compliance demonstration plan;

(c) determine the likelihood of an unidentified non-compliance of the major change with the type-certification basis or the applicable environmental protection requirements, and the potential impact of that non-compliance on the safety or environmental compatibility of the product, and determine on that basis whether a physical inspection and assessment of the first article of that product in the final changed configuration is necessary in order to verify the compliance of the product with the applicable type-certification basis and the applicable environmental protection requirements, taking into consideration the critical design review if

carried out in accordance with point (a) of point 21L.B.242; the Agency shall notify the applicant before conducting this inspection and assessment;

(d) if during the establishment of the type-certification basis, the designation of the applicable environmental protection requirements or during the review of the compliance demonstration plan, the Agency determines that the major change to the design contains any element for which an unidentified non-compliance with the type-certification basis or the applicable environmental protection requirements may have an adverse impact on the safety or environmental compatibility of the changed product, the Agency shall determine which investigations are necessary in addition to those of point (c) in order to verify the compliance demonstration; the Agency shall notify the applicant of those additional investigations and which elements of the design would be subject to this investigation.

AMC1 21L.B.102(c) Investigation

ED Decision 2023/013/R

PHYSICAL INSPECTION AND CRITICAL DESIGN REVIEW

Depending upon the nature of the design change, prior to the approval of the flight conditions to support the issuance of a permit to fly, a physical inspection and a critical design review should be conducted with the applicant and the competent authority for conformity (production) under point 21L.B.242(a). The experience and outcome of this activity should be used by EASA to determine the need for a physical inspection and assessment of the first article of that changed product (first-article inspection) that may be conducted under point 21L.B.102(d) prior to the issuance of the supplemental type certificate for the change.

AMC1 21L.B.102(d) Investigation

ED Decision 2023/013/R

PHYSICAL INSPECTION AND ASSESSMENT OF THE FIRST ARTICLE OF THE CHANGED PRODUCT (FIRST-ARTICLE INSPECTION)

If EASA determines that there is a need to conduct a first-article inspection of the changed product under point 21L.B.102(c), then AMC2 21L.B.46(c) provides the description of this activity for EASA.

21L.B.103 Issuance of a supplemental type certificate

Regulation (EU) 2022/1358

(a) Upon receiving an application for a supplemental type certificate under this Annex, the Agency shall issue a supplemental type certificate when:

1. the applicant has demonstrated that the change and the areas affected by the change comply with the type-certification basis and the applicable environmental protection requirements, as established and designated by the Agency in accordance with point 21L.B.101;

2. the applicant has demonstrated and declared compliance in accordance with point (f) of point 21L.A.85;

3. the owner of the type-certificate data, if the applicant has specified in accordance with point (b)(2) of 21L.A.84 that the certification data has been providedon the basis of an arrangement with the owner of the type-certificate data, has:

   (i) no technical objection to the information submitted under point (a)(2) of point 21L.B.103; and

   (ii) agreed to collaborate with the holder of the repair design approval to discharge all the obligations for the continued airworthiness of the product with the repair design through compliance with point 21L.A.88;

4. the Agency, through its verification of the demonstration of compliance, has not found:

   (i) any non-compliances with the type-certification basis or, where applicable, the applicable environmental protection requirements;

   (ii) any feature or characteristic of the change that may make the changed product unsafe or environmentally incompatible for the uses for which certification is requested.

(b) A supplemental type certificate shall be limited to the specific configuration(s) in the type certificate to which the related major change relates.

21L.B.104 Continuing airworthiness oversight of products for which a supplemental type certificate has been issued

Regulation (EU) 2022/1358

If the Agency, through its continuing airworthiness oversight, including through reports received in accordance with point 21L.A.3, or by any other means, detects a non-compliance with the type-certification basis or the applicable environmental protection requirements of a product for which a supplemental type certificate has been issued, the Agency shall raise a finding in accordance with point 21L.B.21, or issue an airworthiness directive under the conditions of point 21L.B.23.

SUBPART F — CHANGES TO AIRCRAFT FOR WHICH DESIGN COMPLIANCE HAS BEEN DECLARED

21L.B.121 Initial oversight investigation of a declaration of design compliance of a major change to the design of an aircraft for which design compliance has been declared

Regulation (EU) 2022/1358

(a) Upon receiving a declaration of design compliance for a major change to the design of an aircraft for which design compliance has been declared, the Agency shall verify that the change is within the scope of point 21L.A.101 and that the declaration contains all the information specified in point 21L.A.107. The Agency shall acknowledge the receipt of the declaration, including the assignment of an individual declaration of design compliance reference number to the declarant.

(b) The Agency shall assess, based upon the risk of a non-compliance leading to a design that is not capable of safe flight or being environmentally incompatible, whether a physical inspection and assessment of the changed product is needed, and subsequently inform the declarant if that is the case. This assessment of the risk shall take into consideration:

1. the complexity of the major change and the overall effect on the aircraft structures, flight characteristics and systems;
2. previous experience of physical inspections of aircraft and major changes that have been designed by the declarant;
3. the response by the declarant to any previous findings that have been raised for non-compliances for the specific aircraft or similar aircraft designed by the declarant that have also been subject to a declaration of design compliance.

(c) If the Agency finds evidence in the declaration, or through the physical inspection and assessment if carried out in accordance with point (b) of point 21L.B.121, indicating that the changed aircraft could be incapable of conducting a safe flight or could be environmentally incompatible during in-service operations, the Agency shall raise a finding in accordance with point 21L.B.21.

AMC1 21L.B.121 Initial oversight investigation of a declaration of design compliance of a major change to the design of an aircraft for which design compliance has been declared

ED Decision 2023/013/R

PHYSICAL INSPECTION AND ASSESSMENT OF THE FIRST ARTICLE OF THE CHANGED PRODUCT (FIRST-ARTICLE INSPECTION)

If EASA determines that there is a need to conduct a first-article inspection of the changed product under point 21L.B.121(b), then AMC 21L.B.62(b) provides the description of this activity for EASA.

21L.B.122 Registration of a declaration of design compliance for a major change to an aircraft design

Regulation (EU) 2022/1358

(a) The Agency shall register a declaration of design compliance for a major change to the design of an aircraft for which design compliance has been declared, provided that:

1. the declarant has declared compliance in accordance with point (a) of point 21L.A.107;
2. the declarant has provided to the Agency the documents required in accordance with point (d) of point 21L.A.107;
3. the declarant has made a commitment that the obligations in accordance with point 21L.A.47 will also be undertaken in respect of the changed aircraft design;
4. there are no unresolved issues from the physical inspection, if carried out in accordance with point (b)

(b) The Agency shall only register a declaration of a major change to the design of an aircraft for which design compliance has been declared if it is limited to the specific configuration(s) in the registered declaration of design compliance to which the change relates.

21L.B.123 Continuing airworthiness oversight of a changed aircraft for which design compliance has been declared

Regulation (EU) 2022/1358

If the Agency, through its continuing airworthiness oversight, including through reports received in accordance with point 21L.A.3, or by any other means, detects a non-compliance with the applicable detailed technical specifications or the applicable environmental protection requirements of a change for which design compliance has been declared, the Agency shall act in accordance with point 21L.B.64.

SUBPART G – DECLARED PRODCUTION ORGANISATIONS

21L.B.141 Initial oversight investigation

Regulation (EU) 2022/1361

(a) Upon receiving a declaration from an organisation declaring their production capability, the competent authority shall verify that:

1. the declarant is eligible to declare their production capability in accordance with point 21L.A.122;
2. the declaration contains all the information specified in point (c) of point 21L.A.123; and
3. the declaration does not contain information that indicates a non-compliance with the requirements of Subpart G of Section A of this Annex.

(b) The competent authority shall acknowledge the receipt of the declaration, including the assignment of an individual declared production organisation reference number to the declarant.

AMC1 21L.B.141 Initial oversight investigation

ED Decision 2023/013/R

Upon receiving a declaration from an organisation that declares its production capability, the competent authority should appoint a suitable member of its technical staff as the team leader (i.e. focal point) to be in charge of the verification and registration of the declaration and, subsequently, the oversight of the organisation. If needed, the team leader should be supported by one or more team members.

The competent authority should perform sufficient verification activities to be satisfied that the declarant is compliant with the requirements of Subpart G of Section A of this Annex.

21L.B.142 Registration of a declaration of production capability

Regulation (EU) 2022/1361

The competent authority shall register the declaration of production capability on a suitable database, including the declared scope of work, provided that:

(a) the declarant has declared their capability in accordance with point 21L.A.123;

(b) the declarant has made a commitment that the obligations in accordance with point 21L.A.127 will be undertaken;

(c) there are no unresolved issues in accordance with point 21L.B.141.

AMC1 21L.B.142 Registration of a declaration of production capability

ED Decision 2023/013/R

REGISTRATION NUMBER

The competent authority should assign a unique and consecutive declared production organisation (DPO) reference number to the declarant.

The reference number should have the following format: commencing with the UN country code of the State of the competent authority to which the declaration is submitted, followed by the term '.DPO.' and a consecutive numbering (example: 'AT.DPO.001').

21L.B.143 Oversight

Regulation (EU) 2022/1361

(a) The competent authority shall oversee the declared production organisation in order to verify the continuous compliance of the declared production organisation with the applicable requirements of Section A and the implementation of safety measures mandated according to points (c) and (d) of point 21L.B.15.

(b) The oversight shall include a first article inspection of every new aircraft, engine, propeller or part design that is produced for the first time and, as determined by the oversight programme in accordance with point 21L.B.144, inspections of further produced aircraft, engines, propellers and parts that are produced by the declared production organisation.

AMC1 21L.B.143(b) Oversight

ED Decision 2023/013/R

FIRST-ARTICLE INSPECTION FOR A NEW AIRCRAFT, ENGINE, PROPELLER OR PART PRODUCED FOR THE FIRST TIME

(a) Purpose

The purpose of first-article inspection (of the article that is in conformance with the proposed type design for certification) when a new aircraft, engine, propeller or part is produced and released for the first time is for the competent authority to:

— ensure the conformity of the aircraft, engine, propeller or part with the applicable design data;

— conduct an oversight visit to the declared production organisation in order to ensure that the declared production organisation is capable of consistently producing, or controlling the production of, aircraft, products and parts that conform with the applicable design data;

— ensure that the declared production organisation is able to discharge its obligations and responsibilities as regards production.

(b) Methodology and evidence

The first-article inspection should be conducted by the competent authority at an appropriate location(s) selected by the declared production organisation. This (these) location(s) should include the physical location of the aircraft, engine, propeller or part under inspection and should be in the principal place of business (which in accordance with Article 9(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

The main focus of the activities to gather evidence to ensure the objectives mentioned in point (a) are satisfied should be through a physical inspection of the aircraft, engine, propeller or part that has been produced in accordance with the approved design data.

Additional sources of evidence during the visit to the declared production organisation's facilities may include:

(1) the review of supporting conformity documentation and test reports;

(2) the review of applicable design data and how it is used;

(3) discussions with key production personnel;

(4) the review of production processes and procedures.

The above list of additional sources of evidence is not exhaustive.

It is possible that during the first-article inspection the competent authority may discover 'evidence' that indicates that the declared production organisation has:

(1) misunderstood, misinterpreted or not achieved conformity with the applicable design data;

(2) not discharged its production obligations as a declared production organisation;

(3) not followed good production practices to ensure conformity or control of a product or a part it has produced.

If such 'evidence' is discovered, the competent authority may perform a more in-depth investigation into the production practices of the production organisation to determine the root cause(s) and to establish corrective actions to prevent a reoccurrence of the issue.

(c) Condition and conformity of the aircraft, engine, propeller or part to be inspected

The aircraft, engine, propeller or part presented to the competent authority for inspection should be in the final condition for release and in conformity with the applicable design data.

(d) Availability of supporting documentation and key personnel

The supporting documentation and conformity data should be made available by the declared production organisation at the time of the visit by the competent authority to the facilities of the declared production organisation. Key production personnel should be made available to the competent authority by the declared production organisation in case of need.

(e) Findings and resolution

If a non-compliance is discovered by the competent authority in the process of the activities mentioned in point (b), an appropriate finding may be raised against the declared production organisation in accordance with point 21L.B.21 and enforcement actions implemented in accordance with point 21L.B.22. Depending upon its nature, such finding may need to be resolved before the initial and subsequent aircraft, engine(s), propeller(s) or part(s) can be released or the first certificate of airworthiness (or restricted certificate of airworthiness in the case of a declared aircraft) is issued.

(f) Duration and schedule

First-article inspection relating to the initial type certificate of a product

The declared production organisation should coordinate with the competent authority so that, as far as practicable, the first-article-inspection activities to be conducted under point 21L.B.143(b) are conducted at the same time as the first-article inspection activities conducted under point 21L.B.46(c) or point 21L.B.62(b). If this is not appropriate or practicable (for example, because a partial first-article inspection would be beneficial at an earlier stage of production (e.g. for major assemblies)), then the applicant may arrange this with the competent authority.

Note: For a modified or repaired product, when determined under points 21L.B.83(c), 21L.102(c) or 21L.B.203(c) respectively, EASA may require and coordinate with the competent authority on the need for a first-article inspection.

First-article inspection relating to a part that is produced for the first time by the production organisation

For the first-article inspection of every part that is produced for the first time by the declared production organisation, it is possible that this is arranged without the need for coordination with EASA.

If such a part relates to a major change/repair for which EASA has determined the need for a first-article inspection under points 21L.B.83(c), 21L.102(c) or 21L.B.203(c), then EASA may require and coordinate with the competent authority on the need for a first-article inspection.

21L.B.144 Oversight programme

Regulation (EU) 2022/1361

(a) The competent authority shall establish and maintain an oversight programme in order to ensure compliance with point 21L.B.143. This oversight programme shall take into account the specific nature of the organisation, the complexity of its activities and the results of past certification and/or oversight activities, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including as appropriate:
   (i) management system assessments and process audits;
   (ii) product audits of a relevant sample of the products and parts that are under the scope of the organisation;
   (iii) sampling of the work performed; and
   (iv) unannounced inspections;
2. meetings convened between the accountable manager and the competent authority to ensure that they both remain informed of any significant issues.

(b) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(c) An oversight planning cycle that does not exceed 24 months shall be applied.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;
2. the organisation has continuously demonstrated compliance with point 21L.A.128 and that it has full control over all changes to the management system for production;
3. no level 1 findings have been issued;
4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as defined in point 21L.B.21.

(e) Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions provided in point (d), the organisation has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(f) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the activities conducted by the declared production organisation based on its declaration of production capability, reflecting the results of the oversight.

AMC1 21L.B.144 and 21L.B.184 Oversight programme

ED Decision 2023/013/R

ANNUAL REVIEW

The oversight planning cycle and the related oversight programme for each organisation should be reviewed annually to ensure they remain adequate regarding any changes in the nature, complexity or performance of the organisation.

When reviewing the oversight programme, the competent authority should also consider any relevant information collected in accordance with points 21L.A.3 and 21L.B.12.

AMC1 21L.B.144(a) and 21L.B.184(a) Oversight programme

ED Decision 2023/013/R

SPECIFIC NATURE AND COMPLEXITY OF THE ORGANISATION — RESULTS OF PAST OVERSIGHT ACTIVITIES

When determining the oversight programme, including for product audits, the relevant sample of products and parts that are within the scope of the organisation, the competent authority should consider in particular the following elements, as applicable:

(a) the effectiveness of the organisation's management system in identifying and addressing non-compliances;

(b) the implementation by the organisation of any industry standards that are directly relevant to the organisation's activities subject to Part 21 Light;

(c) any specific procedures implemented by the organisation that are related to any alternative means of compliance used (see point 21L.B.24(b));

(d) the number of locations and the activities performed at each location;

(e) the number and type of any subcontractors which perform production or design tasks as appropriate;

(f) the volume of activity for each product or part; and

(g) the number and nature of significant changes notified under points 21L.A.128 or 21L.A.178, as relevant.

AMC2 21L.B.144(a) and 21L.B.184(a) Oversight programme

ED Decision 2023/013/R

SUBCONTRACTED ACTIVITIES

If a declared production or design organisation subcontracts some of its tasks, the competent authority should determine whether the subcontracted organisations need to be audited and included in the oversight programme, taking into account the specific nature and complexity of the subcontracted activities, the results of previous oversight activities of the declared production or design organisation, and based on the assessment of the associated risks.

For such an audit, the competent authority inspector should ensure that they are accompanied throughout the audit by a representative of the declared production or design organisation.

GM1 21L.B.144(a) Oversight programme

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An oversight programme typically consists of the elements detailed in this GM.

(a) Planned continued surveillance

In the planned continued surveillance, the total surveillance actions are split into several audits that are carried out at planned intervals during the oversight cycle. One aspect may be audited once or several times, depending on its importance. All relevant aspects are audited at least once within an oversight cycle.

(b) Planned inspections of produced aircraft, engines, propellers and parts

For the first-article inspection (of a new product or part produced for the first time), refer to AMC1 21L.B.143(b).

For serial production, in order to perform the inspections effectively and efficiently, the competent authority should integrate a sampling plan, as part of the planning of the continued surveillance activities, which is appropriate to the scope and size of the declared production organisation. A flexible sampling plan allows to accommodate changes in the production rate and consider the results obtained from other samples or investigation activities.

(c) Unplanned reviews

Unplanned reviews are specific additional investigations of a declared production organisation related to surveillance findings or external needs. The competent authority is responsible for deciding when a review is necessary, taking into account any changes in the scope of work, changes in personnel, reports on the organisation's performance submitted by other EASA or competent authorities' teams, and reports on the in-service products.

AMC1 21L.B.144(d);(e) and 21L.B.184(d);(e) Oversight programme

ED Decision 2023/013/R

EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS

(a) Part 21 Light Subparts G and J do not require the implementation of a safety management system by the respective declared organisations. However, a declared production organisation or a declared design organisation may decide to introduce certain elements of a safety management system as defined in Part 21 points 21.A.139 and 21.A.239 (e.g. safety risk management, safety performance monitoring and measurement). When such elements are voluntarily introduced, the competent authority may consider them to substantiate an extension of the oversight planning cycle beyond 24 months, as specified in points 21L.B.144(d) and (e) and in points 21L.B.184(d) and (e).

(b) If the competent authority applies an extended oversight planning cycle (i.e. that exceeds 24 months), it should perform, at a minimum, one annual review (see AMC1 21L.B.144 and point 21L.B.184 'Oversight programme') to validate the oversight programme.

(c) If the results of the annual review indicate a decrease in the safety performance of the organisation, the competent authority should revert to a 24-month (or shorter) oversight planning cycle and review the oversight programme accordingly.

21L.B.145 Oversight activities

Regulation (EU) 2022/1361

(a) When the competent authority verifies the compliance of the declared production organisation in accordance with point 21L.B.143 and the oversight programme established in accordance with point 21L.B.144, it shall:

1. provide the personnel responsible for oversight with guidance to perform their functions;
2. conduct assessments, audits, inspections, and, if needed, unannounced inspections;
3. collect the evidence needed in case further action is required, including the measures provided for in points 21L.B.21 and 21L.B.22;
4. inform the declared production organisation about the results of the oversight activities.

(b) If the facilities of the declared production organisation are located in more than one State, the competent authority identified in point 21L.2 may agree to have oversight tasks performed by the competent authority(ies) of the Member State(s) where other facilities are located, or by the Agency for facilities that are located in a non-Member State. Any declared production organisation that is subject to such an agreement shall be informed of its existence and of its scope.

(c) For any oversight activities that are performed by the competent authority at facilities located in a Member State other than where the organisation has its principal place of business, the competent authority shall inform the competent authority of that Member State before performing any on-site audit or inspection of the facilities.

(d) The competent authority shall collect and process any information deemed necessary for conducting oversight activities.

(e) If the competent authority detects a non-compliance of the declared production organisation with the applicable requirements of Section A and the implementation of safety measures mandated according to points (c) and (d) of point 21L.B.15, the competent authority shall act in accordance with points 21L.B.21 and 21L.B.22.

21L.B.146 Changes to declarations

Regulation (EU) 2022/1361

(a) Upon receiving a notification of changes in accordance with point 21L.A.128, the competent authority shall verify the completeness of the notification in accordance with point 21L.B.141.

(b) The competent authority shall update its oversight programme established according to point 21L.B.144 and investigate whether it is necessary to establish any conditions under which the organisation may operate during the change.

(c) When the change affects any aspect of the declaration that is registered in accordance with point 21L.B.142, the competent authority shall update the register.

(d) Upon completion of the activities required by points (a) to (c), the competent authority shall acknowledge the receipt of the notification to the declared production organisation.

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

21L.B.161 Investigation

Regulation (EU) 2022/1361

(a) The competent authority of the Member State of registry shall prepare procedures for its investigations, covering at least the following elements:

1. evaluation of the eligibility of the applicant;
2. evaluation of the conditions for the application;
3. classification of airworthiness certificates;
4. evaluation of the documentation received with the application;
5. inspections of aircraft;
6. determination of the necessary conditions, restrictions or limitations to the certificate.

(b) Upon receiving an application for a certificate of airworthiness or a restricted certificate of airworthiness, the competent authority of the Member State of registry shall verify whether the aircraft is within the scope established in point 21L.A.141.

(c) The competent authority of the Member State of registry shall perform sufficient investigation activities to justify the issuance, maintenance, amendment, suspension or revocation of the certificate of airworthiness or restricted certificate of airworthiness. When conducting investigations related to the issuance of a certificate of airworthiness or a restricted certificate of airworthiness for a newly produced aircraft, the competent authority of the Member State of registry shall evaluate the need to conduct a physical inspection of the aircraft to ensure the conformity and safety of flight of the aircraft prior to the issuance of a certificate of airworthiness or a restricted certificate of airworthiness. This evaluation shall take into account:

1. the results of the physical inspection of the first article of that product in the final configuration, conducted in accordance with point (b) of point 21L.B.143 or point (b) of point 21L.B.251 by the competent authority of the Member State of registry, or by the competent authority overseeing the organisation or the natural or legal person that produced this aircraft, if different;
2. the time period since the last physical inspection conducted by the competent authority of the Member State of registry of an aircraft produced by the organisation, or the natural or legal person that produced that aircraft;
3. the results of the oversight conducted under Subpart G of this Annex or under Subpart G of Section B of Annex I (Part 21) of the organisation issuing the statement of conformity for the aircraft, or the verification conducted under Subpart R of Section A of this Annex of other statements of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1) that were issued by the same signatory;
4. the time period since the last oversight visit of the organisation in accordance with Subpart G of this Annex, or Subpart G of Section B of Annex I (Part 21), or since the last verification conducted under Subpart R of Section A of this Annex of a statement of conformity (EASA Form 52B) or authorised release certificate (EASA Form 1) issued by the same signatory.

GM1 21L.B.161(a)(6) Investigation

ED Decision 2023/013/R

CONDITIONS, RESTRICTIONS OR LIMITATIONS TO THE CERTIFICATE

The competent authority of the Member State of registry may issue under its own legislation a document to list and identify all necessary conditions, restrictions and limitations to a certificate that result from the investigation by EASA and/or from the legislation of the competent authority of the Member State of registry. This document could take the form of an addendum to the approved flight manual or operating instructions or comparable document, and should be referenced in Block 5 (limitations/remarks) of the appropriate certificate of airworthiness.

GM1 21L.B.161(c) Investigation

ED Decision 2023/013/R

INVESTIGATIONS

In the case that the applicant for a certificate of airworthiness or restricted certificate of airworthiness issues an EASA Form 52 or an EASA Form 52B under the privileges granted as an approved production organisation under points (b) and (d) respectively of point 21.A.163 of Annex I to Regulation (EU) No 748/2012, then no further action (i.e. no further showing) to investigate the conformity of a particular aircraft is required before issuing the certificate.

EVALUATION OF THE NEED TO CONDUCT A PHYSICAL INSPECTION OF THE AIRCRAFT TO ENSURE THE CONFORMITY AND SAFETY OF FLIGHT OF THE AIRCRAFT

In the case where the production organisation has not been granted the privileges under points (b) and (d) of point 21.A.163 of Annex I (Part 21) to Regulation (EU) No 748/2012, the evaluation of the need to conduct a physical inspection of the aircraft prior to issuing a certificate of airworthiness or restricted certificate of airworthiness will depend on the factors detailed in points (1) to (4) of point 21L.B.161(c). Further explanations on how these factors will influence the need to conduct a physical inspection are provided below:

(a) Results of the physical inspection of the first-article inspection by the competent authority of the Member State of manufacture

Under points 21L.B.143(b) and 21L.B.251(b) the competent authority of the Member State of manufacture is required to conduct a first-article inspection of an aircraft that has been produced for the first time by the production organisation or the natural or legal person that has issued an EASA Form 52B. This first-article inspection should be considered to provide sufficient investigation to issue the first certificate of airworthiness or restricted certificate of airworthiness by the competent authority of the Member State of registry provided there are no findings raised during the first-article inspection. If findings are raised, then the competent authority of the Member State of registry, in direct coordination with the competent authority of the Member State of manufacture, should determine whether there is a need to conduct a further physical inspection to ensure that the findings have been resolved to enable the issuance of the first certificate of airworthiness or restricted certificate of airworthiness by the competent authority. It is foreseen that any findings that affect the airworthiness or safety of flight of the aircraft that was inspected should be resolved to the satisfaction of the competent authority of the Member State of registry in direct coordination with the competent authority of the Member State of manufacture before the first certificate of airworthiness or restricted certificate of airworthiness can be issued.

The results of the first-article inspection should be shared by the competent authority of the Member State of manufacture with any other competent authority that has been requested to issue a certificate of airworthiness or restricted certificate of airworthiness in order for them to determine whether there is a need to conduct a physical inspection prior to issuing the certificate.

(b) Time period since the last physical inspection conducted by the competent authority of the Member State of registry

If the production organisation or the natural or legal person that has issued an EASA Form 52B has a low annual production rate (and, therefore, does not often request a certificate of airworthiness or a restricted certificate of airworthiness), then the competent authority of the Member State of registry may wish to conduct a larger number of physical inspections of the aircraft that are produced (e.g. higher sample rate) prior to issuing the certificate.

Conversely, if the production organisation or the natural or legal person that has issued an EASA Form 52B has a high production rate and frequently issues EASA Forms 52B (and, therefore, requests a certificate of airworthiness or a restricted certificate of airworthiness more often from the competent authority of the Member State of registry), and provided there are no issues, then the competent authority of the Member State of registry may decide to conduct a smaller number of physical inspections of the aircraft that are produced (e.g. lower sample rate) prior to issuing the certificate.

If the production organisation or the natural or legal person that has issued an EASA Form 52B has not produced an aircraft and has not issued an EASA Form 52B for a long time or has been dormant (and, therefore, has not requested a certificate of airworthiness or a restricted certificate of airworthiness for a long time), then the competent authority of the Member State of registry may wish to conduct a physical inspection more frequently (e.g. higher sample rate) until sufficient trust can be restored in the production organisation or the natural or legal person.

The exchange of information among the competent authorities of the Member States of registry on the outcome and results of physical inspections that have been conducted prior to issuing a certificate of airworthiness or a restricted certificate of airworthiness will help to facilitate the decision to conduct a physical inspection or not. If the competent authority of a Member State of registry has recently conducted (or is frequently conducting) a physical inspection, then the results may be shared with other competent authorities to avoid duplication or a larger than necessary number of physical inspections (e.g. the overall sample rate among all competent authorities is too high).

(c) Results of oversight activities conducted by the competent authority of the Member State of manufacture

During the evaluation of the need to conduct a physical inspection of an aircraft, the outcome of oversight activities of the production organisation or the natural or legal person that has issued an EASA Form 52B by the competent authority of the Member State of manufacture should be taken into consideration. For example, if level 1 findings or multiple level 2 findings have been raised by the competent authority of the Member State of manufacture in the past, then it is logical that the competent authority of the Member State of registry will want to conduct a physical inspection more frequently (possibility focusing more on the identified weaknesses that resulted in the findings being raised). Likewise, if the production organisation or the natural or legal person that has issued an EASA Form 52B is performing well and no issues have been discovered during oversight by the competent authority of the Member State of manufacture, then this will have an influence and the competent authority of the Member State

of registry will decide to conduct physical inspections less frequently (e.g. lower sample rate) prior to issuing a certificate of airworthiness or a restricted certificate of airworthiness.

The competent authority of the Member State of manufacture should provide, upon request, the outcome, results and any findings as a result of oversight activities of the production organisation or the natural or legal person that has issued an EASA Form 52B to the competent authority of the Member State of registry to enable it to determine the need to conduct a physical inspection of an aircraft prior to issuing a certificate of airworthiness or a restricted certificate of airworthiness. This information exchange will help the competent authority of the Member State of registry to avoid a larger than necessary number of physical inspection of manufacturers that perform well during oversight.

(d) Time period since the last oversight visit conducted by the competent authority of the Member State for manufacture

If the competent authority of the Member State of manufacture has recently conducted an oversight of the production organisation or the natural or legal person, and provided no issues have been discovered, then there would be a reduced need for the competent authority of the Member State of registry to conduct a physical inspection of an aircraft shortly afterwards. Conversely, if it has been a while since the last oversight visit conducted by the competent authority of the Member State of manufacture, then there may be a greater need for the competent authority of the Member State of registry to conduct a physical inspection of the aircraft prior to issuing a certificate of airworthiness or a restricted certificate of airworthiness.

The competent authority of the Member State of manufacture should, upon request, provide the time period (and any other relevant information) since the last oversight visit of the production organisation or the natural or legal person that has issued an EASA Form 52B to the competent authority of the Member State of registry in order to allow it to determine the need to conduct a physical inspection prior to issuing a certificate of airworthiness or a restricted certificate of airworthiness. This information exchange will help avoid unnecessary physical inspections of aircraft (e.g. physical inspections conducted of aircraft that have been produced by a production organisation or a natural or legal person that has recently had an oversight visit).

21L.B.162 Issuance or amendment of a certificate of airworthiness or a restricted certificate of airworthiness

Regulation (EU) 2022/1361

(a) The competent authority of the Member State of registry shall issue or amend a certificate of airworthiness (EASA Form 25, see Appendix VI to Annex I (Part 21)) without undue delay when the applicant has provided the documentation required by point 21L.A.143 and complies with the obligations in point 21L.A.144, and when it is satisfied:

1. for new aircraft, that the aircraft, and its engine and propeller if applicable, conforms to a design approved in accordance with Subpart B of this Annex and is in a condition for safe operation;

2. for used aircraft, that:

(i) the aircraft, and its engine and propeller if applicable, conforms to a type design approved in accordance with Subpart B of this Annex and any supplemental type certificate, change or repair approved in accordance with Subpart D, E or M of this Annex;

(ii) the applicable airworthiness directives have been complied with; and

(iii) the aircraft, and its engine and propeller if applicable, has been inspected in accordance with Annex I (Part-M) or Annex Vb (Part-ML) to Regulation (EU) No 1321/2014.

(b) The competent authority of the Member State of registry shall issue or amend a restricted certificate of airworthiness (EASA Form 24B, see Appendix I) without undue delay when the applicant has provided the documentation required by point 21L.A.143 and complies with the obligations in point 21L.A.144, and when it is satisfied:

1. for new aircraft, that the aircraft, and its engine and propeller if applicable, conforms to an aircraft design for which design compliance has been declared in accordance with Subpart C of Section A of this Annex which is registered by the Agency in accordance with point 21L.B.63 at the time of application, and is in a condition for safe operation;

2. for used aircraft, that:

(i) the aircraft, and its engine and propeller if applicable, conforms to an aircraft design for which design compliance has been declared in accordance with Subpart C of Section A of this Annex, and which is registered by the Agency in accordance with point 21L.B.63 at the time of application, along with any design changes or repair design changes for which design compliance has been declared in accordance with Subpart F or N of Section A of this Annex which are registered by the Agency in accordance with point 21L.B.122 or point 21L.B.222, or by the declarant in accordance with point (c) of point 21L.A.105;

(ii) the applicable airworthiness directives have been complied with; and

(iii) the aircraft has been inspected in accordance with Annex I (Part-M) or Annex Vb (Part-ML) to Regulation (EU) No 1321/2014.

(c) By derogation from points (a) and (b) of point 21L.B.162, for a used aircraft originating from another Member State, the competent authority of the new Member State of registry shall issue the certificate of airworthiness or restricted certificate of airworthiness when the applicant has provided the documentation required by point (b) of point 21L.A.145 and when it is satisfied that the applicant complies with point (a) of point 21L.A.144.

(d) For new aircraft, and used aircraft originating from a non-Member State, in addition to the appropriate airworthiness certificate referred to in point (a) or (b), the competent authority of the Member State of registry shall issue:

1. for aircraft subject to Annex I (Part-M)

2. for new aircraft subject to Annex Vb (Part-ML) to Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15c, Appendix II);

3. for used aircraft originating from a non-Member State and subject to Annex Vb (Part-ML) to Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15c, Appendix II), when the competent authority has performed the airworthiness review.

(e) A certificate of airworthiness or a restricted certificate of airworthiness shall be issued for an unlimited duration. It may be amended only by the competent authority of the Member State of registry.

GM1 21L.B.162(b) Issuance or amendment of a certificate of airworthiness or a restricted certificate of airworthiness

ED Decision 2023/013/R

In accordance with Article 18(2)(a) of Regulation (EU) 2018/1139, a restricted certificate of airworthiness is issued for individual aircraft that conform to a design that has been subject to a declaration of design compliance in accordance with Subpart C of Annex Ib (Part 21 Light). This should not be confused with a restricted certificate of airworthiness issued under Annex I (Part 21) to Regulation (EU) No 748/2012.

The term 'registered by the Agency in accordance with point 21L.B.63 at the time of application' means that the declaration of design compliance is registered and published on the EASA website, or registered in a repository for declarations of design compliance at the time of the application.

The competent authority should ensure that the relevant declaration of design compliance is still registered by EASA prior to issuing a restricted certificate of airworthiness. It is possible that EASA has either temporarily or permanently deregistered the declaration of design compliance in the event of discovering an issue that affects safety in accordance with point 21L.B.22(a)(9).

Following the joint first-article inspection conducted by EASA in accordance with point 21L.B.62(b) and the competent authority of the Member State of manufacture in accordance with either point 21L.B.143(b) or point 21L.B.251(b), it is possible that there could be a short delay in EASA conducting the necessary administrative actions to register the declaration of design compliance. In the interim, and to avoid any delays in issuing the first restricted certificate of airworthiness, the competent authority of the Member State of registry may directly contact EASA to confirm that there are no outstanding actions preventing the registration of the declaration of design compliance thereby enabling the competent authority of the Member State of registry to issue the first restricted certificate of airworthiness.

GM1 21L.B.162(d) Issuance or amendment of a certificate of airworthiness or a restricted certificate of airworthiness

ED Decision 2023/013/R

INITIAL AIRWORTHINESS REVIEW CERTIFICATE

In accordance with the applicable continuing airworthiness requirements, a certificate referred to in point 21L.B.162(a) and (b) is valid only if a valid airworthiness review certificate is attached to it. For new aircraft, the competent authority should issue the airworthiness review certificate when issuing the certificate referred to in point 21L.B.162(a) and (b).

21L.B.163 Oversight

Regulation (EU) 2022/1361

(a) Upon evidence of a violation of any of the conditions under which the certificate of airworthiness or the restricted certificate of airworthiness was issued, or that the holder does not comply with the relevant requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof or with the applicable type design or with the applicable design data of an aircraft for which design compliance has been declared, or with the continuing airworthiness requirements, the competent authority of the Member State of registry shall issue a finding in accordance with point 21L.B.21.

(b) When the type certificate under which the certificate of airworthiness was issued is suspended or revoked, or otherwise becomes invalid in accordance with point 21L.A.30, or the declaration of design compliance under which the restricted certificate of airworthiness was issued is not any longer registered in accordance with point 21L.B.63, the competent authority of the Member State of registry shall take action in accordance with point 21L.B.22.

SUBPART I — NOISE CERTIFICATES

21L.B.171 Investigation

Regulation (EU) 2022/1361

(a) The competent authority of the Member State of registry shall prepare procedures for its investigations, covering at least the following elements:

1. evaluation of the eligibility of the applicant;
2. evaluation of the conditions for the application;
3. evaluation of the documentation received with the application;
4. inspections of aircraft.

(b) Upon receiving an application for a noise certificate or a restricted noise certificate, the competent authority of the Member State of registry shall verify whether the aircraft is within the scope established in point 21L.A.161.

(c) The competent authority of the Member State of registry shall perform sufficient investigation activities for an applicant for, or a holder of, a noise certificate or a restricted noise certificate to justify the issuance, maintenance, amendment, suspension or revocation of the certificate.

GM1 21L.B.171(c) Investigation

ED Decision 2023/013/R

INVESTIGATION

In the case that the applicant for a noise certificate or a restricted noise certificate issues an EASA Form 52 or an EASA Form 52B under the privileges granted as an approved production organisation under point 21.A.163(b) of Annex I (Part 21) to Regulation (EU) No 748/2012, then no further action (i.e. no further showing) during the investigation of the aircraft is required before issuing the relevant certificate.

21L.B.172 Issuance or amendment of noise certificates

Regulation (EU) 2022/1361

(a) The competent authority of the Member State of registry shall issue or amend noise certificates (EASA Form 45, see Appendix VII to Annex I (Part 21)) and restricted noise certificates (EASA Form 45B, see Appendix II) without undue delay when the applicant has provided the documentation required by point 21L.A.163, and when it is satisfied that the aircraft is in conformity with the applicable noise information determined in accordance with the applicable noise requirements.

(b) For used aircraft originating from another Member State, the noise certificate or restricted noise certificate shall be issued against the corresponding data that is provided by the Agency database on noise levels.

(c) A noise certificate or a restricted noise certificate shall be issued for an unlimited duration. It may be amended only by the competent authority of the Member State of registry.

AMC1 21L.B.172(a) Issuance or amendment of noise certificates

ED Decision 2023/013/R

COMPLETION OF EASA FORM 45B

In order to complete and issue a restricted noise certificate, the competent authority should consult the EASA Part 21 Light database of declared noise levels, which contains all the noise data that has been provided and declared by the declarant of the declaration of design compliance under Subpart C of Annex Ib (Part 21 Light). The competent authority should frequently review the EASA Part 21 Light database of declared noise levels to ensure that the declared noise data is still valid and has not changed.

This AMC provides recommendations to the competent authority of the Member State of registry that issues restricted noise certificates.

Block 1: Member State of registry

The competent authority should state its name and country, which should be the same as on the certificate of registration and restricted certificate of airworthiness.

Block 2: Restricted noise certificate (declared)

The title of the EASA Form 45B is 'Restricted Noise Certificate (declared)'

Block 3: Document No

The competent authority should enter a unique number that identifies each restricted noise certificate in its administration. Such a number facilitates any enquiries with respect to the document.

Block 4: Registration marks

The nationality and registration marks that are the same as on the certificate of registration and restricted certificate of airworthiness should be entered.

Block 5: Manufacturer and designation of aircraft

The type and model of the particular aircraft that are the same as on the certificate of registration and restricted certificate of airworthiness should be entered.

Block 6: Aircraft serial No

The aircraft serial number as given by the manufacturer of the aircraft and that is the same as on the certificate of registration and restricted certificate of airworthiness should be entered.

Block 7: Designation of engine

For the identification and verification of the aircraft configuration, the designation (including type and model) of the installed engine(s) in accordance with the applicable design data should be entered.

Block 8: Designation of propeller

For the identification and verification of the aircraft configuration in case of propeller-driven aeroplanes, the designation (including type and model) of the installed propeller(s) in accordance with the applicable design data should be entered.

Block 9: Maximum take-off mass (kg)

The maximum take-off mass (in kilograms) associated with the declared noise levels of the aircraft should be entered. The unit (kg) should be specified explicitly to avoid any misunderstanding. If the primary unit of mass for the Member State of manufacture of the aircraft is different from kilograms, the maximum take-off mass should be converted in kilograms in accordance with Annex 5 to the Chicago Convention.

Block 10: Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards

This item should contain as a minimum all additional modifications to the basic aircraft as defined by Blocks 5, 7 and 8 that are essential in order to ensure that the declared noise levels comply with the noise requirements established and made available by EASA in accordance with point 21L.B.61(c) for the declaration of design compliance. Other modifications that are not essential to ensure compliance with the applicable noise requirements but are needed to attain the declared noise levels as given may also be included at the discretion of the certifying authority. The additional modifications should be given using unambiguous references, such as unique part numbers or type/model designators given by the manufacturer of the modification.

Block 11: Noise certification standard

For the purposes of this form, 'noise certification standard' means the noise requirements established and made available by EASA in accordance with point 21L.B.61(c) for the declaration of design compliance of the aircraft. This block should specify the applicable noise requirement(s) and the related noise limit(s) (e.g. 'ICAO Annex 16, Chapter 10 (10.4b)').

Block 12: Take-off noise level

The take-off noise level determined in accordance with the applicable noise requirements should be entered to the nearest tenth of a dB(A). The unit should be specified.

Block 13: Statement of compliance

Block 14: Date of issue

The date on which the document is issued should be entered.

Block 15: Signature

The officer that issues the restricted noise certificate should sign it. Other items may be added, such as seal, stamp, etc.

Additional information:

1. Logo and name of the issuing authority

   To improve its identification, the competent authority may add its logo or symbol and its name in the box 'For use by the Member State of registry'.

2. Language

   If the competent authority issues a restricted noise certificate in a language other than English, it should provide an English translation of that certificate.

21L.B.173 Oversight

Regulation (EU) 2022/1361

(a) Upon evidence of a violation of any of the conditions under which the noise certificate or the restricted noise certificate was issued, or that the holder does not comply with the relevant requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof or with the applicable type design or with the applicable design data of an aircraft for which design compliance has been declared, the competent authority of the Member State of registry shall issue a finding in accordance with point 21L.B.21.

(b) When the type certificate under which the noise certificate was issued is suspended or revoked, or otherwise becomes invalid in accordance with point 21L.A.30, or the declaration of design compliance under which the restricted noise certificate was issued is not any longer registered in accordance with point 21L.B.63, the competent authority of the Member State of registry shall take action in accordance with point 21L.B.22.

SUBPART J — DECLARED DESIGN ORGANISATIONS

21L.B.181 Initial oversight investigation

Regulation (EU) 2022/1358

(a) Upon receiving a declaration from an organisation declaring their design capability, the Agency shall verify that:

1. the declarant is eligible to declare their design capability in accordance with point 21L.A.172;
2. the declaration contains all the information specified in point (c) of point 21L.A.173; and
3. the declaration does not contain information that indicates a non-compliance with the requirements of Subpart J of Section A of this Annex.

(b) The Agency shall acknowledge the receipt of the declaration, including the assignment of an individual declared design organisation reference number to the declarant.

AMC1 21L.B.181 Initial oversight investigation

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Upon receiving a declaration from an organisation that declares its design capability, EASA should appoint a suitable member of its technical staff as the team leader (i.e. focal point) to be in charge of the verification and registration of the declaration and, subsequently, the oversight of the organisation.

If needed, the team leader should be supported by one or more team members.

EASA should perform sufficient verification activities to be satisfied that the declarant is compliant with the requirements of Subpart J Section A of this Annex.

21L.B.182 Registration of a declaration of design capability

Regulation (EU) 2022/1358

The Agency shall register the declaration of design capability on a suitable database, including the declared scope of work, provided that:

(a) the declarant has declared their capability in accordance with point 21L.A.173;

(b) the declarant has made a commitment that the obligations in accordance with point 21L.A.177 will be undertaken;

(c) there are no unresolved issues in accordance with point 21L.B.181.

AMC1 21L.B.182 Registration of a declaration of production capability

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REGISTRATION NUMBER

EASA should assign a unique and consecutive declared design organisation ('DDO') reference number to the declarant.

EASA should publish an up-to-date list of the registered declarations of design capability. This list should include the declared scope of work of those declared design organisations.

21L.B.183 Oversight

Regulation (EU) 2022/1358

(a) The Agency shall oversee the declared design organisation in order to verify the continuous compliance of the organisation with the applicable requirements of Section A.

(b) The oversight shall include a product critical design review or physical inspection, and a first article inspection of every new design of the declared design organisation.

GM1 21L.B.183(b) Oversight

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CRITICAL DESIGN REVIEW, PHYSICAL INSPECTION AND FIRST-ARTICLE INSPECTION

The oversight of a declared design organisation should be built around the product design and the investigations performed by EASA during the certification or the registration of a declaration of design compliance.

These investigations are performed as follows:

(a) for the certification of design compliance:

(1) a critical design review is performed, as applicable, before the approval of the flight conditions (see point 21L.B.242(a)(1) and (a)(3));

(2) a physical inspection is performed, as applicable, before the approval of the flight conditions (see point 21L.B.242(a)(1) and (a)(3)); and

(3) a physical inspection of the first article (first-article inspection) is performed, as applicable, after receiving the declaration of compliance and before the issuance of the respective product design certificate or approval (see points 21L.B.46(c), 21L.B.83(c), 21L.B.102(c) and 21L.B.203(c));

(b) for a declaration of design compliance:

(1) a physical inspection is performed, as applicable, before the approval of the flight conditions (see point 21L.B.242(a)(2) and (a)(4)); and

(2) a physical inspection of the first article (first-article inspection) is performed, as applicable, after receiving the declaration of design compliance and before the registration of the respective declaration (see points 21.B.62(b), 21.B.121(b) and 21L.B.221(b)).

Note: The physical inspections mentioned above are:

— for a certified product: compliance inspections during which EASA verifies that the product is compliant with the applicable type-certification basis and the applicable environmental protection requirements;

— for a declared aircraft: safety inspections during which EASA ensures that the aircraft is capable of safe flight and environmentally compatible; these physical inspections may include ground, functional and flight tests, as relevant.

For the contents and methodology to perform critical design reviews, physical inspections and first-article inspections, refer to AMC2 21L.B.46(c), AMC1 21L.B.62(b), AMC1 21L.B.241(a)(1) and point 21L.B.242(a)(1), and AMC 21L.B.241(a)(2) and point 21L.B.242(a)(2).

21L.B.184 Oversight programme

Regulation (EU) 2022/1358

(a) The Agency shall establish and maintain an oversight programme in order to ensure compliance with point 21L.B.183. The oversight programme shall take into account the specific nature of the organisation, the complexity of its activities and the results of past certification and/or oversight activities, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including as appropriate:
   (i) management system assessments and process audits;
   (ii) product audits of a relevant sample of the design and certification of the products, and parts that are under the scope of the organisation;
   (iii) sampling of the work performed;
   (iv) unannounced inspections;
2. meetings convened between the head of the design organisation and the Agency to ensure that both remain informed of any significant issues.

(b) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(c) An oversight planning cycle that does not exceed 24 months shall be applied.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the Agency has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;
2. the organisation has continuously demonstrated compliance with point 21L.A.178 and that it has full control over all changes to the design management system;
3. no level 1 findings have been issued;
4. all corrective actions have been implemented within the time period that was accepted or extended by the Agency as defined in point 21L.B.21.

(e) Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions provided in point (d), the organisation has established, and the Agency has approved, an effective continuous system for reporting to the Agency on the safety performance and regulatory compliance of the organisation itself.

(f) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(g) At the completion of each oversight planning cycle, the Agency shall issue a recommendation report on the continuation of the activities conducted by the declared design organisation based on its declaration of design capability, reflecting the results of the oversight.

AMC1 21L.B.144 and 221L.B.184 Oversight programme

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ANNUAL REVIEW

The oversight planning cycle and the related oversight programme for each organisation should be reviewed annually to ensure they remain adequate regarding any changes in the nature, complexity or performance of each organisation.

When reviewing the oversight programme and the oversight planning cycle, the competent authority should also consider any relevant information collected in accordance with points 21L.A.3 and 21L.B.12.

AMC1 21L.B.144(a) and 21L.B.184(a) Oversight programme

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SPECIFIC NATURE AND COMPLEXITY OF THE ORGANISATION — RESULTS OF PAST OVERSIGHT ACTIVITIES

When determining the oversight programme, including for product audits, the relevant sample of products and parts within the scope of the organisation the competent authority should consider in particular the following elements, as applicable:

(a) the effectiveness of the organisation's management system in identifying and addressing non-compliances;

(b) the implementation by the organisation of any industry standards that are directly relevant to the organisation's activities subject to Part 21 Light;

(c) any specific procedures implemented by the organisation that are related to any alternative means of compliance used (see point 21L.B.24(b));

(d) the number of locations and the activities performed at each location;

(e) the number and type of any subcontractors which perform production or design tasks as appropriate; and

(f) the volume of activity for each product or part.

(g) the number and nature of significant changes notified under point 21L.A.128 or 21L.A.178, as relevant.

AMC2 21L.B.144(a) and 21L.B.184(a) Oversight programme

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SUBCONTRACTED ACTIVITIES

If a declared production or design organisation subcontracts some of tasks, the competent authority should determine whether the subcontracted organisations need to be audited and included in the oversight programme, taking into account the specific nature and complexity of the subcontracted activities, the results of previous oversight activities of the declared organisation, and based on the assessment of the associated risks.

For such an audit, the competent authority inspector should ensure that they are accompanied throughout the audit by a representative of the declared production or design organisation.

GM1 21L.B.184(a) Oversight programme

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The oversight programme typically consists of the elements detailed in this GM.

(a) Planned continued surveillance

In the planned continued surveillance, the total surveillance actions are split into several audits that are carried out at planned intervals during the oversight cycle. One aspect may be audited once or several times, depending on its importance. All relevant aspects are audited at least once within an oversight cycle.

(b) Planned critical design reviews, physical inspections and first-article inspections as defined for each new product design.

(c) Unplanned reviews

Unplanned reviews are specific additional investigations of a declared design organisation related to surveillance findings or external needs. EASA is responsible for deciding when a review is necessary, taking into account any changes in the scope of work, changes in personnel, reports on the organisation's performance submitted by other EASA or competent authorities' teams, and reports on the in-service products.

AMC1 21L.B.144(d);(e) and 21L.B.184(d);(e) Oversight programme

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EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS

(a) Part 21 Light Subparts G and J do not include requirements for the implementation of a safety management system. However, a declared production organisation or a declared design organisation may decide to introduce certain elements of a safety management system as defined in Part 21 points 21.A.139 and 21.A.239 (e.g. safety risk management, safety performance monitoring and measurement). When such elements are voluntarily introduced, the competent authority may consider them to substantiate an extension of the oversight planning cycle beyond 24 months, as specified in points 21L.B.144(d) and (e) and in points 21L.B.184(d) and (e).

(b) If the competent authority applies an extended oversight planning cycle (i.e. that exceeds 24 months), it should perform, at a minimum, one annual review (see AMC1 21L.B.144 and point 21L.B.184 'Oversight programme') to validate the oversight programme.

(c) If the results of the annual review indicate a decrease in the safety performance of the organisation, the competent authority should revert to a 24-month (or shorter) oversight planning cycle and review the oversight programme accordingly.

21L.B.185 Oversight activities

Regulation (EU) 2022/1358

(a) When the Agency verifies the compliance of the declared design organisation in accordance with point 21L.B.183 and the oversight programme established in accordance with point 21L.B.184, it shall:

1. provide the personnel responsible for oversight with guidance to perform their functions;
2. conduct assessments, audits, inspections, and, if needed, unannounced inspections;
3. collect the evidence needed in case further action is required, including the measures provided for in point 21L.B.21 and 21L.B.22;
4. inform the declared design organisation about the results of the oversight activities.

(b) The Agency shall collect and process any information deemed necessary for conducting oversight activities.

(c) If the Agency detects a non-compliance of the declared design organisation with the applicable requirements of Section A, with a procedure or manual required by Section A, or with the declaration submitted, the Agency shall act in accordance with points 21L.B.21 and 21L.B.22.

21L.B.186 Changes to declarations

Regulation (EU) 2022/1358

(a) Upon receiving a notification of changes in accordance with point 21L.A.178, the Agency shall verify the completeness of the notification in accordance with point 21L.B.181.

(b) The Agency shall update its oversight programme established according to point 21L.B.184 and investigate whether it is necessary to establish any conditions under which the organisation may operate during the change.

(c) When the change affects any aspect of the declaration that is registered in accordance with point 21L.B.182, the Agency shall update the register.

(d) Upon completion of the activities required by points (a) to (c), the Agency shall acknowledge the receipt of the notification to the declared design organisation.

SUBPART K — PARTS (RESERVED)

SUBPART M — DESIGN OF REPAIRS TO TYPE-CERTIFIED PRODUCTS

21L.B.201 Type-certification basis and applicable environmental protection requirements for a repair design approval

Regulation (EU) 2022/1358

The Agency shall designate any amendments to the type-certification basis and the applicable environmental requirements incorporated by reference in, as applicable, either the type certificate or the supplemental type certificate, which the Agency considers necessary for maintaining a level of safety and environmental compatibility equal to that previously established and notify them to the applicant for the approval of a repair design.

21L.B.202 Investigation and issuance of an approval for a minor repair design

Regulation (EU) 2022/1358

(a) Upon receiving an application for the approval of a minor repair design to a type-certified product under this Annex, the Agency shall approve the minor repair design when:

1. the applicant has provided the substantiation data and justifications and has demonstrated and declared the compliance of the repair design with the applicable type-certification basis and the applicable environmental protection requirements established in accordance with point 21L.B.201;

2. the Agency, through its verification of the demonstration of compliance, taking into account the design features of the repair design, complexity and overall criticality of the repair design, as well as previous experience of design activities with the applicant, has not found:

   (i) any non-compliances with the type-certification basis or, where applicable, with the applicable environmental protection requirements;

   (ii) any feature or characteristic of the repair design that may make the product with the repair design unsafe for the uses for which certification is requested.

(b) An approval of a minor repair design shall be limited to the specific configuration(s) in the type certificate to which the repair design relates.

21L.B.203 Investigation of an application for the approval of a major repair design

Regulation (EU) 2022/1358

Upon receiving an application for the approval of a major repair design under this Annex, the Agency shall:

(a) conduct a review of the initial compliance demonstration plan and any subsequent update provided by the applicant in order to establish the completeness of the plan and the appropriateness of the proposed means and methods of demonstrating compliance with the type-certification basis and the applicable environmental protection requirements established and designated in accordance with point 21L.B.201; if the compliance demonstration plan is incomplete or the means and methods are not appropriate to achieve compliance demonstration, the Agency shall inform the applicant and request an amendment of it;

(b) when satisfied that the compliance demonstration plan provided is appropriate so that the applicant can demonstrate compliance, approve the compliance demonstration plan and any subsequent updates of the compliance demonstration plan;

(c) determine the likelihood of an unidentified non-compliance of the major repair design with the type-certification basis or with the applicable environmental protection requirements, and the potential impact of that non-compliance on the safety or environmental compatibility of the product, and determine on that basis whether a physical inspection and assessment of the first article of that product in the final configuration with the repair design is necessary in order to verify the compliance of the product with the applicable type-certification basis; the Agency shall notify the applicant before conducting this inspection and assessment;

(d) if, during the review of the compliance demonstration plan, the Agency determines that the major repair design contains any element for which an unidentified non-compliance with the type-certification basis or with the applicable environmental protection requirements may have an adverse impact on the safety or environmental compatibility of the changed product, the Agency shall determine which investigations are necessary in addition to those of point (c) in order to verify the compliance demonstration; the Agency shall notify the applicant of those additional investigations and which elements of the design would be subject to investigation.

AMC1 21L.B.203(d) Investigation of an application for the approval of a major repair design

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PHYSICAL INSPECTION AND ASSESSMENT OF THE FIRST ARTICLE OF THE CHANGED PRODUCT (FIRST-ARTICLE INSPECTION)

If EASA determines that there is a need to conduct a first-article inspection of the changed product under point 21L.B.203(c), then AMC2 21L.B.46(c) provides the description of this activity for EASA.

21L.B.204 Issuance of an approval of a major repair design

Regulation (EU) 2022/1358

(a) Upon receiving an application for the approval of a major repair design to a type-certified product under this Annex, the Agency shall approve the major repair design when:

1. the applicant has been demonstrated that the repair design and the areas affected by the repair design comply with the type-certification basis and with the applicable environmental protection requirements, as established by the Agency in accordance with point 21L.B.201; and

2. the applicant has demonstrated and declared compliance in accordance with point 21L.A.208;

3. the owner of the type-certificate data, if the applicant has specified in accordance with point 21L.A.205(b)(5) that they provided the certification dataon the basis of an arrangement with the owner of the type-certificate data, has:

   (i) no technical objection to the information submitted under point (a)(2) of point 21L.B.204; and

   (ii) agreed to collaborate with the holder of the repair design approval to discharge all the obligations for the continued airworthiness of the product with the repair design through compliance with point 21L.A.210;

4. the Agency, through its verification of the demonstration of compliance, has not found:

   (i) any non-compliances with the type-certification basis or, where applicable, the applicable environmental protection requirements;

   (ii) any feature or characteristic of the change that may make the product with the repair design unsafe for the uses for which certification is requested.

(b) An approval of a major repair design shall be limited to the specific configuration(s) in the type certificate to which the repair design relates.

21L.B.205 Continuing airworthiness oversight of products for which a repair design has been approved

Regulation (EU) 2022/1358

If the Agency, through its continuing airworthiness oversight, including through reports received in accordance with point 21L.A.3, or by any other means detects a non-compliance of a product, for which a repair design has been approved, with the type-certification basis or with the applicable environmental protection requirements, the Agency shall raise a finding in accordance with point 21L.B.21, or issue an airworthiness directive under the conditions of point 21L.B.23.

21L.B.206 Unrepaired damage

Regulation (EU) 2022/1358

An evaluation of the airworthiness consequences shall be conducted by the Agency, when requested to do under point 21L.A.211, in the event that a damaged product is left unrepaired and is not covered by previously approved data. The Agency shall establish any limitations necessary to ensure a safe flight with the damaged product.

SUBPART N — DESIGN OF REPAIRS TO AIRCRAFT FOR WHICH DESIGN COMPLIANCE HAS BEEN DECLARED

21L.B.221 Initial oversight investigation of a declaration of design compliance of a major repair design to an aircraft for which design compliance has been declared

Regulation (EU) 2022/1358

(a) Upon receiving a declaration of design compliance of a major repair design to an aircraft for which design compliance has been declared, the Agency shall verify that that the repair design is within the scope of point 21L.A.221 and that the declaration contains all the information specified in point 21L.A.226. The Agency shall acknowledge the receipt of the declaration, including the assignment of an individual declaration of design compliance reference number to the declarant.

(b) The Agency shall assess, based upon the risk of a non-compliance leading to a design that is not capable of safe flight or being environmentally incompatible, whether a physical inspection and assessment of the aircraft with the major repair design is needed, and subsequently inform the declarant if that is the case. This assessment of the risk shall take into consideration:

1. the complexity of the major repair design and the overall effect on the aircraft structures, flight characteristics and systems;
2. previous experience of physical inspections of aircraft and major repair designs and changes that have been designed by the declarant;
3. the response by the declarant to any previous findings that have been raised for non-compliances of the specific aircraft or similar aircraft designed by the declarant that have also been subject to a declaration of design compliance.

(c) If the Agency finds evidence in the declaration, or through the physical inspection and assessment if carried out in accordance with point (b) of point 21L.B.221, indicating that the aircraft with the major repair design could be incapable of conducting a safe flight or could be environmentally incompatible during in-service operations, the Agency shall raise a finding in accordance with point 21L.B.21.

AMC1 21L.B.221 Initial oversight investigation of a declaration of design compliance of a major repair design to an aircraft for which design compliance has been declared

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PHYSICAL INSPECTION AND ASSESSMENT OF THE FIRST ARTICLE OF THE REPAIRED PRODUCT (FIRST-ARTICLE INSPECTION)

If EASA determines that there is a need to conduct a first-article inspection of the repaired product under point 21L.B.221(b), then AMC 21L.B.62(b) provides the description of this activity for EASA.

21L.B.222 Registration of a declaration of a major repair design to an aircraft for which design compliance has been declared

Regulation (EU) 2022/1358

(a) The Agency shall register a declaration of a major repair design to an aircraft for which design compliance has been declared provided that:

1. the declarant has declared compliance in accordance with point (a)of point 21L.A.226;
2. the declarant has provided to the Agency the documents required in accordance with point (d) of point 21L.A.226;
3. the declarant has made a commitment that the obligations in accordance with point 21L.A.228 will be undertaken;
4. there are no unresolved issues from the physical inspection, if carried out in accordance with point (b) of point 21L.B.221.

(b) The Agency shall only register a declaration of a major repair design to an aircraft for which design compliance has been declared if it is limited to the specific configuration(s) in the registered declaration of design compliance to which the major repair design relates.

21L.B.223 Continuing airworthiness oversight of a repair design for which design compliance has been declared

Regulation (EU) 2022/1358

If the Agency, through its continuing airworthiness oversight, including through reports received in accordance with point 21L.A.3, or by any other means, detects a non-compliance of a repair design, for which design compliance has been declared, with the applicable detailed technical specifications or with the applicable environmental protection requirements, the Agency shall raise a finding in accordance with point 21L.B.21, or issue an airworthiness directive under the conditions of point 21L.B.23.

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS (RESERVED)

SUBPART P – PERMIT TO FLY

21L.B.241 Investigation prior to the issuance of a permit to fly

Regulation (EU) 2022/1361

(a) Without prejudice to Subpart P of Section B of Annex I (Part 21), when investigating an application for the issuance of a permit to fly for an aircraft which is within the scope of this Annex, the competent authority of the Member State shall conduct a physical inspection of the aircraft and be satisfied that the aircraft conforms to the design defined under point 21.A.708 of that Annex I (Part 21) before flight when the application for a permit to fly relates to:

1. the demonstration of compliance activities in point 21L.A.25 for an aircraft which is, or is intended to be, type-certified;

2. the demonstration of compliance activities in point 21L.A.44 for an aircraft for which design compliance is, or is intended to be, declared.

(b) For all other requests for the issuance of a permit to fly for activities and aircraft within the scope of this Annex, the competent authority shall assess, in accordance with point 21.B.520 of Annex I (Part 21), the need for a physical inspection.

(c) If the competent authority finds evidence indicating that the aircraft does not conform to the design defined under point 21.A.708 of Annex I (Part 21), it shall raise a finding in accordance with point 21L.B.21.

AMC 21L.B.241(a)(1) and 21L.B.242(a)(1) Critical design review of the design and physical inspection and assessment of the aircraft

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PHYSICAL INSPECTION AND CRITICAL DESIGN REVIEW OF PRODUCTS TO BE CERTIFIED

1. Introduction

For the purposes of this AMC, 'physical inspection and critical design review' includes:

a. the investigation prior to the issuance of a permit to fly, which consists of a physical inspection of the aircraft by the competent authority; and

b. the investigation prior to the approval of the flight conditions, which consists of a critical design review of the design and a physical inspection and assessment of the aircraft by the Agency.

Note: The competent authority may determine that it is necessary to conduct an oversight visit at the applicant's facilities prior to the submission of the application for the approval of the flight conditions and the issuance of a permit to fly to ensure the conformity of the aircraft for which a permit to fly has been requested. For example, this could be due to the need to conduct a conformity check of subassemblies prior to their incorporation into the final prototype.

2. Purpose

The purposes of the physical inspection and the critical design review prior to the approval of the flight conditions and the issuance of a permit to fly for a particular aircraft design for which an application for a type certificate has been submitted are:

a. for EASA to verify[1] that the demonstration-of-compliance activities conducted by the applicant under point 21L.A.25 have reached a sufficient level of maturity to progress to flight testing in order to conclude the demonstration of compliance;

b. for EASA to ensure that the design configuration for which the flight conditions have been requested is capable of conducting safe flight during flight testing;

c. in case the applicant is a declared design organisation, for EASA to conduct the first oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the applicant is able to discharge its obligations;

d. for the competent authority to ensure the conformity of the aircraft with the configuration for which the issuance of a permit to fly has been requested;

e. in case the applicant is a declared production organisation, for the competent authority to conduct the first oversight visit in accordance with point 21L.B.143(b) of Subpart G and point 21L.B.241 of Subpart P in order to ensure that the applicant is able to discharge its obligations and is capable of producing or controlling the production of aircraft, products and parts that conform with the design data.

3. Methodology and evidence

The physical inspection and the critical design review should be conducted by EASA and the competent authority at an appropriate location(s) selected by the applicant for the type certificate. This (these) location(s) should include the physical location of the aircraft for which the approval of the flight conditions and the issuance of a permit to fly have been requested and should be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

The Agency and the competent authority should conduct a physical inspection of the aircraft, engine or propeller for which the approval of the flight conditions and the issuance of a permit to fly have been requested. This inspection, along with any other activity that EASA or the competent authority deems necessary (for example, see point 21L.A.25(e)), should ensure that the objectives mentioned in point 2 are met.

Additional sources of evidence during the visit at the applicant's facilities may include:

a. witnessing or participating to live testing of the aircraft, engine, propeller, systems or components;

b. evaluation of the compliance-demonstration plan produced by the applicant;

c. evaluation of supporting compliance documentation and test reports;

[1] The verification is limited to the scope of the activities that can be conducted under point 3 and the elements of the design that are selected for review based upon a risk-based approach to compliance.

d. discussions with key design and production personnel;

e. review of conformity documentation;

f. review of the relevant design or production processes and procedures (for non-approved organisations).

The above list of additional sources of evidence is not exhaustive.

4. Aircraft condition and configuration

The aircraft presented to EASA and the competent authority should be in a condition for first flight and be in the configuration for which the approval of the flight conditions and the issuance of a permit to fly have been requested. If this is not the case, then a judgement should be made whether the critical design review and physical inspection can be conducted or not based upon any differences between the 'as presented' configuration and condition and the configuration that will be used for flight testing.

5. Availability of supporting documentation and key personnel

The applicant is required to make available supporting documentation as well as compliance and conformity data at the time of the visit by EASA and the competent authority at the applicant's facilities. Key design and production personnel should be made available by the applicant to EASA and the competent authority in case of need. The Agency and the competent authority may wish to withhold the approval of the flight conditions and the issuance of the permit to fly if this is not the case.

6. Findings and resolution

If a non-compliance is discovered by EASA or the competent authority in the process of the activities mentioned in point 2, an appropriate finding may be raised against the particular aircraft or declared design organisation or declared production organisation. Depending upon their nature, these findings may need to be resolved before the flight conditions are approved or the permit to fly is issued.

7. Duration and schedule

The physical inspection and the critical design review may be a single visit or, if necessary, multiple visits depending on the complexity of the design, the maturity of the design and any unique characteristics that are identified in the compliance-demonstration plan. It should not solely be viewed as a single one-day event.

AMC 21L.B.241(a)(2) and 21L.B.242(a)(2) Physical inspection and assessment of the aircraft in order to ensure that the aircraft is capable of safe flight, and that flight testing can be conducted safely (physical inspection and safety review)

ED Decision 2023/013/R

PHYSICAL INSPECTION AND SAFETY REVIEW OF AIRCRAFT TO BE DECLARED

1. Introduction

For the purposes of this AMC, 'physical inspection and safety review' includes:

a. the investigation prior to the issuance of a permit to fly, which consists of a physical inspection of the aircraft by the competent authority; and

b. the investigation prior to the approval of the flight conditions, which consists of a physical inspection and assessment of the aircraft by EASA.

2. Purpose

The purposes of the physical inspection and the safety review prior to the approval of the flight conditions and the issuance of a permit to fly for a particular aircraft design for which the declarant intends to submit a declaration of design compliance are:

a. for EASA to ensure[1] that the design configuration, for which the flight conditions have been requested for the compliance-demonstration activities under point 21L.A.44, is capable of conducting safe flight during flight testing and that the design is sufficiently mature so as not to pose an unacceptable level of risk;

b. in case the declarant is a declared design organisation, for EASA to conduct the first oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the declarant is able to discharge its obligations;

Note: Under Subpart C of Section A there is no obligation for a declarant to submit a declaration of design capability and become a declared design organisation.

c. for the competent authority to ensure the conformity of the aircraft with the configuration for which the issue of a permit to fly has been requested.

d. for the competent authority to:

i. either, in case the declarant is a declared production organisation, conduct the first oversight visit in accordance with point 21L.B.143(b) of Subpart G and point 21L.B.241 of Subpart P in order to ensure that the declarant is able to discharge its obligations and is capable of producing or controlling the production of aircraft, products and parts that conform with the design data;

ii. or conduct a first oversight visit of the production organisation that intends to issue statements of conformity for aircraft, which conform to a declaration of design compliance, to ensure that the production organisation is capable of discharging its obligations under Subpart R.

3. Methodology and evidence

The physical inspection and the safety review should be conducted by EASA and the competent authority at an appropriate location(s) selected by the declarant. This (these) location(s) should include the physical location of the aircraft for which the approval of the flight conditions and the issuance of a permit to fly have been requested and should be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

The Agency and the competent authority should conduct a physical inspection of the aircraft, engine or propeller for which the approval of the flight conditions and the issuance of a permit to fly have been requested. This inspection, along with any other activity that EASA or the competent authority deems necessary (for example, see point 21L.A.44(f)), should ensure that the objectives mentioned in point 2 are met.

[1] This is limited to the scope of the activities that can be conducted under point 3 and the elements of the product that are selected for inspection based upon a risk-based approach to safety and environmental incompatibility.

Additional sources of evidence during the visit at the declarant's facilities may include:

a. witnessing or participating to live testing of the aircraft, engine, propeller, systems or components;

b. review of the completeness of the compliance-demonstration plan produced by the declarant;

c. review of the maturity of the supporting compliance documentation and test reports;

d. discussions with key design and production personnel;

e. review of conformity documentation;

f. review of the relevant design or production processes and procedures (for non-approved organisations).

The above list of additional sources of evidence is not exhaustive.

4. Aircraft condition and configuration

The aircraft presented to EASA and the competent authority should be in a condition for first flight and be in the configuration for which the approval of the flight conditions and the issuance of a permit to fly have been requested.

If this is not the case, then a judgement should be made whether the safety review and physical inspection can be conducted or not based upon any differences between the 'as presented' configuration and condition and the configuration that will be used for flight testing.

5. Availability of supporting documentation and key personnel

The declarant is required to make available supporting documentation and conformity data at the time of the visit by EASA and the competent authority at the declarant's facilities. Key design and production personnel should be made available by the declarant to EASA and the competent authority in case of need. The Agency and the competent authority may wish to withhold the approval of the flight conditions and the issue of a permit to fly if this is not the case.

6. Findings and resolution

If a non-compliance is discovered by EASA or the competent authority in the process of the activities mentioned in point 2, an appropriate finding may be raised against the particular aircraft or, if applicable, the declared design organisation or declared production organisation. Depending upon their nature, these findings may need to be resolved before the flight conditions are approved or the permit to fly is issued.

7. Duration and schedule

The physical inspection and safety review may be a single visit or multiple visits depending on the complexity and the maturity of the design. It should not solely be viewed as a single one-day event.

21L.B.242 Investigation prior to issuance of the flight conditions

Regulation (EU) 2022/1361

(a) Without prejudice to Subpart P of Section B of Annex I (Part 21), when investigating an application for the approval of flight conditions for an aircraft which is within the scope of this Annex, the Agency shall:

1. if the application for flight conditions is related to the demonstration of compliance activities in point 21L.A.25 for an aircraft which is, or is intended to be, type-certified, conduct a critical design review of the design and a physical inspection and assessment of the aircraft in order to ensure that the aircraft is capable of safe flight, and that flight testing can be conducted safely;

2. if the application for flight conditions is related to the demonstration of compliance activities in point 21L.A.44 for an aircraft for which design compliance is, or is intended to be, declared, conduct a physical inspection and assessment of the aircraft in order to ensure that the aircraft is capable of safe flight, and that flight testing can be conducted safely;

3. if the application for flight conditions is related to the demonstration of compliance activities for a major change in point 21L.A.66, a supplemental type certificate in point 21L.A.85 or a major repair in point 21L.A.206, based upon the evaluation conducted in point 21L.B.83, point 21L.B.102 and point 21L.B.203, determine the need to conduct a physical inspection and assessment of the aircraft and a critical design review of the design in order to ensure that the aircraft is capable of safe flight, and that flight testing can be conducted safely;

4. if the application for flight conditions is related to the demonstration of compliance activities for a major change in point 21L.A.108 or a major repair in point 21L.A.227, based upon the evaluation conducted in point 21L.B.121 and point 21L.B.221, determine the need to conduct a physical inspection and assessment of the aircraft in order to ensure that the aircraft is capable of safe flight, and that flight testing can be conducted safely.

(b) If the Agency finds evidence indicating that the aircraft could be incapable of conducting a safe flight, the Agency shall raise a finding in accordance with point 21L.B.21.

AMC 21L.B.241(a)(1) and 21L.B.242(a)(1) Critical design review of the design and physical inspection and assessment of the aircraft

ED Decision 2023/013/R

PHYSICAL INSPECTION AND CRITICAL DESIGN REVIEW OF PRODUCTS TO BE CERTIFIED

1. Introduction

For the purposes of this AMC, 'physical inspection and critical design review' includes:

a. the investigation prior to the issuance of a permit to fly, which consists of a physical inspection of the aircraft by the competent authority; and

b. the investigation prior to the approval of the flight conditions, which consists of a critical design review of the design and a physical inspection and assessment of the aircraft by the Agency.

Note: The competent authority may determine that it is necessary to conduct an oversight visit at the applicant's facilities prior to the submission of the application for the approval of the flight conditions and the issuance of a permit to fly to ensure the conformity of the aircraft for which a permit to fly has been requested. For example, this could be due to the need to conduct a conformity check of subassemblies prior to their incorporation into the final prototype.

2. Purpose

The purposes of the physical inspection and the critical design review prior to the approval of the flight conditions and the issuance of a permit to fly for a particular aircraft design for which an application for a type certificate has been submitted are:

a. for EASA to verify[1] that the demonstration-of-compliance activities conducted by the applicant under point 21L.A.25 have reached a sufficient level of maturity to progress to flight testing in order to conclude the demonstration of compliance;

b. for EASA to ensure that the design configuration for which the flight conditions have been requested is capable of conducting safe flight during flight testing;

c. in case the applicant is a declared design organisation, for EASA to conduct the first oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the applicant is able to discharge its obligations;

d. for the competent authority to ensure the conformity of the aircraft with the configuration for which the issuance of a permit to fly has been requested;

e. in case the applicant is a declared production organisation, for the competent authority to conduct the first oversight visit in accordance with point 21L.B.143(b) of Subpart G and point 21L.B.241 of Subpart P in order to ensure that the applicant is able to discharge its obligations and is capable of producing or controlling the production of aircraft, products and parts that conform with the design data.

3. Methodology and evidence

The physical inspection and the critical design review should be conducted by EASA and the competent authority at an appropriate location(s) selected by the applicant for the type certificate. This (these) location(s) should include the physical location of the aircraft for which the approval of the flight conditions and the issuance of a permit to fly have been requested and should be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

The Agency and the competent authority should conduct a physical inspection of the aircraft, engine or propeller for which the approval of the flight conditions and the issuance of a permit to fly have been requested. This inspection, along with any other activity that EASA or the competent authority deems necessary (for example, see point 21L.A.25(e)), should ensure that the objectives mentioned in point 2 are met.

Additional sources of evidence during the visit at the applicant's facilities may include:

a. witnessing or participating to live testing of the aircraft, engine, propeller, systems or components;

b. evaluation of the compliance-demonstration plan produced by the applicant;

[1] The verification is limited to the scope of the activities that can be conducted under point 3 and the elements of the design that are selected for review based upon a risk-based approach to compliance.

c. evaluation of supporting compliance documentation and test reports;

d. discussions with key design and production personnel;

e. review of conformity documentation;

f. review of the relevant design or production processes and procedures (for non-approved organisations).

The above list of additional sources of evidence is not exhaustive.

4. Aircraft condition and configuration

The aircraft presented to EASA and the competent authority should be in a condition for first flight and be in the configuration for which the approval of the flight conditions and the issuance of a permit to fly have been requested. If this is not the case, then a judgement should be made whether the critical design review and physical inspection can be conducted or not based upon any differences between the 'as presented' configuration and condition and the configuration that will be used for flight testing.

5. Availability of supporting documentation and key personnel

The applicant is required to make available supporting documentation as well as compliance and conformity data at the time of the visit by EASA and the competent authority at the applicant's facilities. Key design and production personnel should be made available by the applicant to EASA and the competent authority in case of need. The Agency and the competent authority may wish to withhold the approval of the flight conditions and the issuance of the permit to fly if this is not the case.

6. Findings and resolution

If a non-compliance is discovered by EASA or the competent authority in the process of the activities mentioned in point 2, an appropriate finding may be raised against the particular aircraft or declared design organisation or declared production organisation. Depending upon their nature, these findings may need to be resolved before the flight conditions are approved or the permit to fly is issued.

7. Duration and schedule

The physical inspection and the critical design review may be a single visit or, if necessary, multiple visits depending on the complexity of the design, the maturity of the design and any unique characteristics that are identified in the compliance-demonstration plan. It should not solely be viewed as a single one-day event.

AMC 21L.B.241(a)(2) and 21L.B.242(a)(2) Physical inspection and assessment of the aircraft in order to ensure that the aircraft is capable of safe flight, and that flight testing can be conducted safely (physical inspection and safety review)

ED Decision 2023/013/R

PHYSICAL INSPECTION AND SAFETY REVIEW OF AIRCRAFT TO BE DECLARED

1. Introduction

For the purposes of this AMC, 'physical inspection and safety review' includes:

a. the investigation prior to the issuance of a permit to fly, which consists of a physical inspection of the aircraft by the competent authority; and

b. the investigation prior to the approval of the flight conditions, which consists of a physical inspection and assessment of the aircraft by EASA.

2. Purpose

The purposes of the physical inspection and the safety review prior to the approval of the flight conditions and the issuance of a permit to fly for a particular aircraft design for which the declarant intends to submit a declaration of design compliance are:

a. for EASA to ensure[1] that the design configuration, for which the flight conditions have been requested for the compliance-demonstration activities under point 21L.A.44, is capable of conducting safe flight during flight testing and that the design is sufficiently mature so as not to pose an unacceptable level of risk;

b. in case the declarant is a declared design organisation, for EASA to conduct the first oversight visit in accordance with point 21L.B.183(b) of Subpart J in order to ensure that the declarant is able to discharge its obligations;

Note: Under Subpart C of Section A there is no obligation for a declarant to submit a declaration of design capability and become a declared design organisation.

c. for the competent authority to ensure the conformity of the aircraft with the configuration for which the issue of a permit to fly has been requested.

d. for the competent authority to:

i. either, in case the declarant is a declared production organisation, conduct the first oversight visit in accordance with point 21L.B.143(b) of Subpart G and point 21L.B.241 of Subpart P in order to ensure that the declarant is able to discharge its obligations and is capable of producing or controlling the production of aircraft, products and parts that conform with the design data;

ii. or conduct a first oversight visit of the production organisation that intends to issue statements of conformity for aircraft, which conform to a declaration of design compliance, to ensure that the production organisation is capable of discharging its obligations under Subpart R.

[1] This is limited to the scope of the activities that can be conducted under point 3 and the elements of the product that are selected for inspection based upon a risk-based approach to safety and environmental incompatibility.

3. Methodology and evidence

The physical inspection and the safety review should be conducted by EASA and the competent authority at an appropriate location(s) selected by the declarant. This (these) location(s) should include the physical location of the aircraft for which the approval of the flight conditions and the issuance of a permit to fly have been requested and should be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State).

The Agency and the competent authority should conduct a physical inspection of the aircraft, engine or propeller for which the approval of the flight conditions and the issuance of a permit to fly have been requested. This inspection, along with any other activity that EASA or the competent authority deems necessary (for example, see point 21L.A.44(f)), should ensure that the objectives mentioned in point 2 are met.

Additional sources of evidence during the visit at the declarant's facilities may include:

a. witnessing or participating to live testing of the aircraft, engine, propeller, systems or components;

b. review of the completeness of the compliance-demonstration plan produced by the declarant;

c. review of the maturity of the supporting compliance documentation and test reports;

d. discussions with key design and production personnel;

e. review of conformity documentation;

f. review of the relevant design or production processes and procedures (for non-approved organisations).

The above list of additional sources of evidence is not exhaustive.

4. Aircraft condition and configuration

The aircraft presented to EASA and the competent authority should be in a condition for first flight and be in the configuration for which the approval of the flight conditions and the issuance of a permit to fly have been requested.

If this is not the case, then a judgement should be made whether the safety review and physical inspection can be conducted or not based upon any differences between the 'as presented' configuration and condition and the configuration that will be used for flight testing.

5. Availability of supporting documentation and key personnel

The declarant is required to make available supporting documentation and conformity data at the time of the visit by EASA and the competent authority at the declarant's facilities. Key design and production personnel should be made available by the declarant to EASA and the competent authority in case of need. The Agency and the competent authority may wish to withhold the approval of the flight conditions and the issue of a permit to fly if this is not the case.

6. Findings and resolution

If a non-compliance is discovered by EASA or the competent authority in the process of the activities mentioned in point 2, an appropriate finding may be raised against the particular aircraft or, if applicable, the declared design organisation or declared production organisation. Depending upon their nature, these findings may need to be resolved before the flight conditions are approved or the permit to fly is issued.

7. Duration and schedule

The physical inspection and safety review may be a single visit or multiple visits depending on the complexity and the maturity of the design. It should not solely be viewed as a single one-day event.

SUBPART Q — IDENTIFICATION OF PRODUCTS AND PARTS (RESERVED)

SUBPART R - STATEMENT OF CONFORMITY FOR AIRCRAFT AND AUTHORISED RELEASE CERTIFICATES (EASA FORM 1) FOR ENGINES AND PROPELLERS, AND PARTS THEREOF, WHICH CONFORM TO A DECLARATION OF DESIGN COMPLIANCE

21L.B.251 Oversight

Regulation (EU) 2022/1361

(a) The competent authority shall oversee the natural or legal person issuing statements of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1) under Subpart R of Section A of this Annex in order to verify the continuous compliance of the natural or legal person with the applicable requirements of Section A and the implementation of safety measures mandated according to points (c) and (d) of point 21L.B.15.

(b) The oversight shall include a first article inspection of every new aircraft, engine, propeller or part that is produced for the first time for which the natural or legal person has issued a statement of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1), and, as determined by the oversight programme in accordance with point 21L.B.252, inspections of further aircraft, engines, propellers and parts produced by that natural or legal person.

AMC1 21L.B.251(b) Oversight

ED Decision 2023/013/R

FIRST-ARTICLE INSPECTION FOR A NEW AIRCRAFT, ENGINE, PROPELLER OR PART PRODUCED FOR THE FIRST TIME

(a) Purpose

The purpose of first-article inspection when a new aircraft, engine, propeller or part is produced and released for the first time is for the competent authority to:

(1) ensure the conformity of the aircraft, engine, propeller or part with the applicable design data;

(2) conduct an oversight visit to the natural or legal person that uses Subpart R in order to ensure that the natural or legal is capable of consistently producing, or controlling the production of, aircraft, products and parts that conform with the declared design data;

(3) ensure that the natural or legal person that uses Subpart R is able to discharge its obligations and responsibilities for production.

(b) Methodology and evidence

The first-article inspection should be conducted by the competent authority at an appropriate location(s) selected by the natural or legal person that uses Subpart R. This (these) location(s) should:

(1) be at the physical location of the aircraft, engine, propeller or part under inspection;

(2) be in the principal place of business (which in accordance with Article 8(2) of Regulation (EU) No 748/2012 must be in an EU Member State); and

(3) be in a location that enables the competent authority to conduct the oversight stated in points (a)(2) and (3) above; this location should include the actual production and manufacture of new aircraft, engine, propeller or parts of the aircraft to enable the competent authority to determine that the legal or natural person is in compliance with Subpart R.

Note: The principal place of business is defined as follows: 'The head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised.'

The main focus of the activities to gather evidence to ensure the objectives mentioned in point (a) are satisfied should be through a physical inspection of the aircraft for which a statement of conformity has been issued or the engine, propeller or part for which an authorised release certificate has been issued.

Additional sources of evidence during the visit to the production organisation's facilities may include:

(1) the review of supporting conformity documentation and test reports;

(2) the review of applicable design data and how it is used;

(3) discussions with key production personnel;

(4) the review of production processes and procedures.

The above list of additional sources of evidence is not exhaustive.

It is possible that during the first-article inspection the competent authority may discover 'evidence' that indicates that the production organisation has:

(1) misunderstood, misinterpreted or not achieved conformity with the applicable design data;

(2) not discharged its production obligations;

(3) not followed good production practices to ensure conformity or control of a product or part it has produced.

If such 'evidence' is discovered, the competent authority may perform a more in-depth investigation into the production practices of the production organisation to determine the root cause(s) and to establish corrective actions to prevent a reoccurrence of the issue.

(c) Condition and conformity of the aircraft, engine, propeller or part to be inspected

The aircraft, engine, propeller or part presented to the competent authority for inspection should be in the final condition for release and in conformity with the applicable design data.

(d) Availability of supporting documentation and key personnel

The supporting documentation and conformity data should be made available by the natural or legal person that uses Subpart R at the time of the visit by the competent authority to the facilities of the production organisation. Key production personnel should be made available to the competent authority in case of need.

(e) Findings and resolution

If a non-compliance is discovered by the competent authority in the process of the activities mentioned in point (a), an appropriate finding may be raised. Depending upon its nature, such finding may need to be resolved before the initial and subsequent aircraft, engine(s), propeller(s) or part(s) can be released.

(f) Duration and schedule

First-article inspection relating to the initial declaration of design compliance for an aircraft (including engines and propellers).

The natural or legal person that uses Subpart R should coordinate with the competent authority so that the first-article-inspection activities to be conducted under point 21L.B.251(b) are conducted at the same time as the first-article-inspection activities conducted under point 21L.B.62(b). If this is not appropriate (due to the fact that a partial first-article inspection would be beneficial at an earlier stage of production), then it is possible that the declarant arrange this with the competent authority.

Note: For a modified or repaired product, when determined under points 21L.B.121(b) or 21L.B.221(b) respectively, EASA may require and coordinate with the competent authority on the need for a first-article inspection.

First-article inspection relating to a part that is produced for the first time by the production organisation

For the first-article inspection of every part that is produced for the first time by the natural or legal person that uses Subpart R, it is possible that this is arranged without the need for coordination with EASA.

If such a part relates to a major change/repair for which EASA has determined the need for a first-article inspection under points 21L.B.121(b) or 21L.B.221(b), then EASA may require and coordinate with the competent authority on the need for a first-article inspection.

21L.B.252 Oversight programme

Regulation (EU) 2022/1361

(a) The competent authority shall establish and maintain an oversight programme in order to ensure compliance with point 21L.B.251. This oversight programme shall take into account the specific nature of the natural or legal person, the complexity of their activities and the results of past oversight activities, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including as appropriate:
   - (i) production control system assessments and process audits;
   - (ii) product audits of a relevant sample of the products and parts that are under the scope of the natural or legal person;
   - (iii) sampling of the work performed; and
   - (iv) unannounced inspections;
2. meetings convened between the legal or natural person and the competent authority to ensure that they both remain informed of any significant issues.

(b) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(c) An oversight planning cycle that does not exceed 24 months shall be applied.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the natural or legal person has demonstrated that they can effectively identify aviation safety hazards and manage the associated risks;
2. the natural or legal person has continuously demonstrated compliance with point 21L.A.273 and that they have full control over all changes to the management system for production;
3. no level 1 findings have been issued;
4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as defined in point 21L.B.21.

(e) Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions provided in point (d), the natural or legal person has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the natural or legal person themselves.

(f) The oversight planning cycle may be reduced if there is evidence that the safety performance of the natural or legal person has decreased.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the activities conducted by the natural or legal person, reflecting the results of the oversight.

AMC1 21L.B.252 Oversight programme

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CONTENTS

The oversight programme should be built around conformity inspections of products and parts (performed during manufacture and on the final product).

The oversight programme should consist of:

(a) planned inspections of each new aircraft produced for the first time and for which a permit to fly has been requested (see point 21L.B.241(a));

(b) planned first-article inspections of every new aircraft, engine, propeller or part that is produced for the first time for which the natural or legal person has issued a statement of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1) (see point 21L.B.251(b));

(c) inspections of further aircraft, engines, propellers and parts produced by that natural or legal person; for this to be performed effectively and efficiently, the competent authority should integrate a sampling plan, as part of the planning of the continued surveillance activities, which is appropriate to the scope and size of the activities of the natural or legal person; this sampling plan should be flexible to accommodate changes in the production rate, and consider the results from other samples or investigation activities; and

(d) specific assessments and audits; these might be triggered by the results of the above inspections of products and parts, and the feedback on in-service products received from other competent authorities' and EASA teams.

Note: For the planned inspections of a new aircraft, engine and propeller produced for the first time (see points (a) and (b) above), the competent authority should coordinate as much as possible the related activities with the EASA team(s) involved in the investigation of the respective aircraft's declaration of design compliance.

GM1 21L.B.252(d);(e) Oversight programme

ED Decision 2023/013/R

EXTENSION OF THE OVERSIGHT PROGRAMME PLANNING CYCLE

Compliance with the conditions for the extension of the oversight programme planning cycle in point 21L.B.252(d) and (e) would normally be demonstrated using a safety management system. However, it is not expected that the natural or legal person that produces under Subpart R would implement such a system. Consequently, that natural or legal person is not expected to meet the conditions for the extension of the oversight programme planning cycle

21L.B.253 Oversight activities

Regulation (EU) 2022/1361

(a) When the competent authority verifies the compliance of the natural or legal person in accordance with point 21L.B.251 and the oversight programme established in accordance with point 21L.B.252, it shall:

1. provide the personnel responsible for oversight with guidance to perform their functions;
2. conduct assessments, audits, inspections, and, if needed, unannounced inspections;
3. collect the evidence needed in case further action is required, including the measures provided for in point 21L.B.21 and 21L.B.22;
4. inform the natural or legal person about the results of the oversight activities.

(b) If the facilities of the natural or legal person are located in more than one State, the competent authority identified in point 21L.2 may agree to have oversight tasks performed by the competent authority(ies) of the Member State(s) where other facilities are located, or by the Agency for facilities that are located in a non-Member State. Any natural or legal person who is subject to such an agreement shall be informed of its existence and of its scope.

(c) For any oversight activities that are performed by the competent authority at facilities located in a Member State other than where the natural or legal person has its principal place of business, the competent authority shall inform the competent authority of that Member State before performing any on-site audit or inspection of the facilities.

(d) The competent authority shall collect and process any information deemed necessary for conducting oversight activities.

(e) If the competent authority detects a non-compliance of the natural or legal person issuing statements of conformity (EASA Form 52B) or authorised release certificates (EASA Form 1) with the applicable requirements of Section A and the implementation of safety measures mandated according to points (c) and (d) of point 21L.B.15, the competent authority shall act in accordance with points 21L.B.21 and 21L.B.22.

APPENDICES TO ANNEX IB (PART 21 LIGHT)

EASA FORMS

Regulation (EU) 2022/1358

When the Forms of this Annex are issued in a language other than English they shall include an English translation.

The EASA ('European Union Aviation Safety Agency') Forms referred to in the appendices to this Part shall have the following obligatory features. Member States shall ensure that the EASA Forms they issue are recognisable and shall be responsible for having those Forms printed.

Appendix I EASA Form 24B Restricted certificate of airworthiness

Appendix II EASA Form 45B Restricted noise certificate

Appendix III EASA Form 52B Aircraft statement of conformity

Appendix IV EASA Form 53B Certificate of release to service

Appendix I — EASA Form 24B — Restricted certificate of airworthiness

Regulation (EU) 2022/1358

Appendix I

Restricted Certificate of Airworthiness — EASA Form 24B

Competent authority logo

RESTRICTED CERTIFICATE OF AIRWORTHINESS (DECLARED)

[4]	**[Member State of registry]** **[COMPETENT AUTHORITY OF THE MEMBER STATE]**	4

1. Nationality and registration marks	2. Manufacturer and manufacturer's designation of aircraft	3. Aircraft serial number
4. Categories		
5. This restricted certificate of airworthiness is issued pursuant to Article 18(2)(a) of Regulation (EU) 2018/1139 in respect of the above-mentioned aircraft which is considered to be airworthy when maintained and operated in accordance with the foregoing and the pertinent operating limitations. In addition to above, the following restriction applies: This restricted certificate of airworthiness is issued on the basis of a declaration of design compliance made in accordance with Regulation (EU) No 748/2012 and is valid and recognised in all EU Member States without further requirements or evaluation. This certificate does not comply with all of the applicable Standards of Annex 8 to the Convention on International Civil Aviation and therefore may not be valid for international air navigation over non-EU Member States, unless approved by the state(s) being overflown.		
Date of issue:	Signature:	
6. This restricted certificate of airworthiness is valid unless revoked by the competent authority of the Member State of registry. A current airworthiness review certificate shall be attached to this certificate.		

EASA Form 24B — Issue 1

This certificate shall be carried on board during all flights.

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([4]) [2]For use by the Member State of registry

Appendix II — EASA Form 45B — Restricted noise certificate

Regulation (EU) 2022/1358

Appendix II

Restricted noise certificate — EASA Form 45B

For use by the Member State of registry	1. Member **State of registry**	3. Document No:
2. RESTRICTED NOISE CERTIFICATE (DECLARED)		
4. Registration marks: ……	5. Manufacturer and designation of aircraft: ……	6. Aircraft serial No: ……
7. Designation of engine: ……	8. Designation of propeller: ……	
9. Maximum take-off mass (kg) ……		
10. Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards: ……		
11. Noise certification standard: ……	12. Take-off noise level: ……	
Remarks		
13. This restricted noise certificate is issued pursuant to Article 9 of Regulation (EU) 2018/1139, in respect of the above-mentioned aircraft, which is declared by the declarant of a declaration of design compliance in accordance with Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012 to comply with the indicated noise standard when maintained and operated in accordance with the relevant requirements and operating limitations. 14. Date of issue ……15. Signature ……		

EASA Form 45B — Issue 1

Appendix III —EASA Form 52B — Aircraft statement of conformity

Regulation (EU) 2022/1358

Appendix III

Aircraft statement of conformity — EASA Form 52B

AIRCRAFT STATEMENT OF CONFORMITY			
1. State of manufacture	2. [MEMBER STATE] A Member of the European Union		3. Statement Ref. No:
4. Organisation			
5. Aircraft type		6. Type certificate/Declaration of design compliance refs:	
7. Aircraft registration or mark		8. Production organisation identification No	
9. Engine/propeller details [5]			
10. Modifications and/or service bulletins [1]			
11. Airworthiness directives			
12. Concessions			
13. Exemptions, waivers or derogations [1]			
14. Remarks			
15. Restricted/certificate of airworthiness			
16. Additional requirements			
17. Statement of conformity It is hereby certified that this aircraft conforms fully to the: □ type-certified design; or □ declared design data and to the items above in boxes 9, 10, 11, 12 and 13. The aircraft is in a condition for safe operation. The aircraft has been satisfactorily tested in flight.			
18. Signed	19. Name		20. Date (d/m/y)
21. Declared or approved production organisation reference (if applicable)			

EASA Form 52B — Issue 1

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([5]) Delete as applicable

Instructions for the use of the 'Aircraft statement of conformity — EASA Form 52B'

1. PURPOSE AND SCOPE

1.1. The purpose of the aircraft statement of conformity (EASA Form 52B) issued under Subpart G or Subpart R of Section A of Annex Ib (Part 21 Light) or under Subpart G of Section A of Annex I (Part 21) is to enable the production organisation to apply for an individual aircraft certificate of airworthiness or restricted certificate of airworthiness from the competent authority of the Member State of registry.

2. GENERAL

2.1. The statement of conformity must comply with the model format, including the block numbers and the location of each block. The size of each block may, however, be varied to suit the individual application, but not to the extent that would render the statement of conformity unrecognisable. If in doubt, consult the competent authority.

2.2. The statement of conformity must be either pre-printed or computer generated, but in either case, the printing of lines and characters must be clear and legible. Pre-printed wording is permitted in accordance with the attached model, but no other certification statements are permitted.

2.3. The completion of the statement may be either machine/computer-printed or handwritten, using block letters to allow for easy reading. English, and where relevant, one or more of the official language(s) of the issuing Member State, are acceptable.

2.4. A copy of the statement and all the referenced attachments are to be retained by the approved production organisation.

3. COMPLETION OF THE STATEMENT OF CONFORMITY BY THE ORIGINATOR

3.1. There should be an entry in all blocks to render the document a valid statement.

3.2. A statement of conformity may not be issued to the competent authority of the Member State of registry unless the design of the aircraft and its installed products are approved or the declaration of design compliance is registered with the Agency.

3.3. The information required in blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the production organisation, unless the competent authority agrees otherwise.

3.4. This statement of conformity is not intended to include those items of equipment that may be required to be fitted in order to satisfy the applicable operational rules. However, some of these individual items may be included in block 10 or in the approved type design or the declared aircraft design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operations.

Block 1 Enter the name of the State of manufacture.

Block 2 The competent authority that issues the statement of conformity under its authority.

Block 3 A unique serial number should be pre-printed in this block for statement control and traceability purposes. An exception is in the case of a computer-generated document: the number need not be pre-printed where the computer is programmed to produce and print a unique number.

Block 4 The full name and the address of the location of the organisation that issues the statement. This block may be pre-printed. Logos, etc., are permitted if the logo, etc., can be contained within the block.

Block 5 The aircraft type in full as defined in the type certificate and its associated data sheet or the declared aircraft design as registered by the Agency

Block 6 The type-certificate reference numbers and issue for the subject aircraft or the registration number of the declaration of design compliance

Block 7 If the aircraft is registered, then this mark will be the registration mark. If the aircraft is not registered, then this will be the mark that is accepted by the competent authority of the Member State and, if applicable, by the competent authority of a third country.

Block 8 The identification number assigned by the production organisation for control and traceability and product support purposes. This is sometimes referred to as a 'production organisation serial number' or 'constructor's number'.

Block 9 The engine type and the propeller type(s) in full as defined in the relevant type certificate and its associated data sheet or the registered declaration of design compliance. Their production organisation identification/reference number and the associated location should also be stated.

Block 10 Approved or declared design changes to the aircraft definition

Block 11 A listing of all the applicable airworthiness directives (or equivalent) and a declaration of compliance with the airworthiness directives, together with a description of the method of compliance of the subject individual aircraft, including products and installed parts, appliances and equipment. Any future compliance requirement time should be stated.

Block 12 Approved or declared unintentional deviations from the approved type design or declared design, sometimes referred to as 'concessions', 'divergences' or 'non-conformances'.

Block 13 Only agreed or declared exemptions, waivers or derogations may be included here.

Block 14 Remarks. Any statement, information, particular data or limitation which may affect the airworthiness of the subject aircraft. If there is no such information or data, state 'NONE'.

Block 15 Enter 'certificate of airworthiness', or 'restricted certificate of airworthiness', as the certificate of airworthiness requested.

Block 16 Additional requirements such as those notified by an importing country should be noted in this block.

Block 17 The validity of the statement of conformity is subject to the full completion of all the blocks on the form. A copy of the flight test report, together with any recorded defects and rectification details, should be kept on file by the production organisation. The report should be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g. the test pilot or the flight test engineer.

The flight tests performed are those defined under the control of the quality management element of the production system, as established by either:

1. point (b) of point 21L.A.124; or
2. point (f) of point 21L.A.273,

to ensure that the aircraft conforms to the applicable design data, and is in a condition for safe operation.

The listing of items provided (or made available) to satisfy the aspects of this statement that relate to the safe operation of the aircraft should be kept on file by the production organisation.

Block 18 The statement of conformity may be signed by the person that is authorised to do so by the production organisation in accordance with point (d) of point 21L.A.125 or point (b) of point 21L.A.273. A rubber stamp signature should not be used.

Block 19 The name of the person that signs the statement should be typed or printed in a legible form.

Block 20 The date on which the statement of conformity is signed should be given.

Block 21 The competent authority approval reference should be quoted.

Appendix IV — EASA Form 53B — Certificate of release to service

Regulation (EU) 2022/1358

Appendix IV

Certificate of release to service — EASA Form 53B

CERTIFICATE OF RELEASE TO SERVICE

[PRODUCTION ORGANISATION NAME]

Production organisation reference:

Certificate of release to service in accordance with 21L.A.126(e) or 21L.A.273(8) of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012 (delete as appropriate).

Aircraft: ……..Type: ……Constructor No/Registration: ……

has been maintained as specified in work order: ……..

Brief description of work performed:

Certifies that the work specified was carried out in accordance with 21L.A.126(e) or 21L.A.273(8) of Annex Ib (Part 21 Light) to Regulation (EU) No 748/2012 (delete as appropriate) and in respect to that work the aircraft is considered ready for release to service and therefore is in a condition for safe operation.

Certifying staff (name):

(signature):

Location:

Date: . . - . . - . . . . (day, month, year)

EASA Form 53B — Issue 1

COMPLETION INSTRUCTIONS

The Block BRIEF DESCRIPTION OF WORK PERFORMED appearing in EASA FORM 53B should include a reference to the approved data used to perform the work.

The Block LOCATION appearing in EASA FORM 53B refers to the location where the maintenance has been performed, not to the location of the facilities of the organisation (if different).

ANNEX II

Repealed Regulation with list of its successive amendments

Regulation (EU) No 748/2012

Commission Regulation (EC) No 1702/2003	(OJ L 243, 27.9.2003, p. 6)
Commission Regulation (EC) No 381/2005	(OJ L 61, 8.3.2005, p. 3)
Commission Regulation (EC) No 706/2006	(OJ L 122, 9.5.2006, p. 16)
Commission Regulation (EC) No 335/2007	(OJ L 88, 29.3.2007, p. 40)
Commission Regulation (EC) No 375/2007	(OJ L 94, 4.4.2007, p. 3)
Commission Regulation (EC) No 287/2008	(OJ L 087, 29.3.2008, p. 3)
Commission Regulation (EC) No 1057/2008	(OJ L 283, 28.10.2008, p. 30)
Commission Regulation (EC) No 1194/2009	(OJ L 321, 8.12.2009, p. 5)

ANNEX III

Correlation Table

Regulation (EU) No 748/2012

Regulation (EC) No 1702/2003	This Regulation
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2), points (a) to (h)
-	Article 1(2), points (i) and (j)
Article 2(1) and (2)	Article 2(1) and (2)
Article 2(3)	-
Article 2a(1), introductory wording	Article 3(1), introductory wording
Article 2a(1), points (a) and (b)	Article 3(1), points (a) and (b)
Article 2a(1), points (c) and (d)	-
Article 2a (2) to (5)	Article 3(2) to (5)
Article 2b	Article 4
Article 2c(1)	Article 5
Article 2c(2) and (3)	-
Article 2d	Article 6
Article 2e, first paragraph	Article 7
Article 2e, second paragraph	-
Article 3(1), (2) and the first sentence of point 3	Article 8(1), (2) and (3)
Article 3(3) second sentence, (4) and (5)	-
Article 3(6)	-
Article 4(1), (2) and the first sentence of point 3	Article 9(1), (2) and (3)
Article 4(3) second sentence, (4), (5) and (6)	-
-	Article 10
-	Article 11
Article 5(1)	Article 12
Article 5(2) to (5)	-
Annex	Annex I
-	Annex II
-	Annex III