



Notice of Proposed Amendment 2019-05 (B)

Embodiment of safety management system (SMS) requirements into Part-145 and Part 21

RMT.0251 PHASE II

EXECUTIVE SUMMARY

With reference to Rulemaking Task (RMT).0251 Phase II in EPAS 2019-2023, this Notice of Proposed Amendment (NPA) proposes amendments to Annex I (Part 21) to Regulation (EU) No 748/2012 and Annex II (Part-145) to Regulation (EU) No 1321/2014, in order to:

- introduce safety management principles that implement ICAO Annex 19; and
- foster an organisational culture for effective safety management and effective occurrence reporting in accordance with Commission Regulation (EU) No 376/2014.

Note 1: Phase I of RMT.0251 was limited to the introduction of safety management requirements into Part-CAMO (see Opinion No 06/2016).

Note 2: The review of the occurrence reporting system was governed by RMT.0681, but certain additional changes are proposed through this RMT, in light of the principles of ICAO Annex 19, Chapter 5.

This NPA proposes to consider the applicability of safety management systems (SMSs) to Part-145 approved maintenance organisations, as well as to production and design organisations that are approved in accordance with Subparts G and J of Part 21.

By doing so, safety will be enhanced through:

- the establishment of safety policies and objectives that are associated with sufficient resources;
- the systematic identification of hazards, and a risk management system;
- the safety assurance system, including giving consideration to safety performance; and
- safety promotion.

This RMT also aims to streamline the procedures for oversight, and introduce a set of new, common management system requirements for competent authorities to increase their efficiency.

NPA 2019-05 is divided into three parts. The present NPA 2019-05 (B) includes the draft implementing rules (IRs) as well the draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) for Part 21.

NPA 2019-05 (A) includes:

- the procedural information pertaining to the regulatory proposal;
- the explanatory note to the proposed amendments;
- the regulatory impact assessment; and
- a detailed summary of the proposed amendments (see Chapter 7 ‘Appendices’).

The draft IRs as well as the draft AMC and GM for Part-145 are proposed in NPA 2019-05 (C).

Action area:	Systemic enablers to safety — safety management		
Affected rules:	Part-145 and Part 21		
Affected stakeholders:	AMOs (Part-145); POA holders; DOA holders; ETSOA holders; competent authorities		
Driver:	Safety	Rulemaking group:	No (but Focused Consultation Group)
Impact assessment:	Full	Rulemaking Procedure:	Standard

• EASA rulemaking process milestones



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Proposed amendments to Part 21

The text of the amendment is arranged to show deleted text, new or amended text as shown below:

- deleted text is ~~struck through~~;
- new or amended text is highlighted in grey;
- text proposed to be added or amended by Opinion No 07/2016, whose adoption by the European Commission is pending, is highlighted in blue;
- an ellipsis '[...]' indicates that the rest of the text is unchanged.

Important note: 'easy-to-read document'

Under each modified requirement (i.e. implementing rules), the blue underlined [AMC or GM](#), when also modified, can be accessed through the associated hyperlinks [press Ctrl and click]. In order to return to the previous view (i.e. initial text), please use [press Alt + left arrow].



**Draft cover regulation (EU) xxx/xxx amending Regulation (EU) No 748/2012
(Draft EASA opinion)**

Article 1

Annex I (Part 21) to Commission Regulation (EU) No 748/2012 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from [2 years after the entry into force of this Regulation].

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

Done at Brussels,



Draft Annex (Draft EASA opinion)

[Note: related AMC/GM:

- [GM1 Annex I Definitions](#)
- [GM2 Annex I Acronyms](#)]

21.1 General Competent authority

For the purpose of this Annex I (Part 21), the 'competent authority' shall be:

- (a) for Section A, Subparts B, D, E, J, K, M, O, and Q, EASA;
- (b) for Section A, Subparts F, G, H, and I:
 - (a1) for organisations having that have their principal place of business in a Member State, the authority designated by that Member State; or the Agency EASA if so requested by that Member State; or
 - (b2) for organisations having that have their principal place of business in a non-member State third country, the Agency EASA.
- (c) for Section A, Subpart P:
 - (1) for registered aircraft, 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.

[Note: related AMC/GM:

- [GM1 21.1 Competent authority](#)
- [GM1 21.1\(c\) Competent authority](#)]



SECTION A TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

21.A.1 Scope

This Section Subpart establishes general provisions governing the rights and obligations of the applicant for, and holder of, any certificate issued or to be issued in accordance with this Section Annex.

21.A.3A Failures, malfunctions and defects Occurrence reporting

(a) ~~System for Collection, Investigation and Analysis of Data~~

~~The holder of~~ Without prejudice to Regulation (EU) No 376/2014, all natural or legal persons who hold or who have applied for a ~~type certificate~~ type certificate, restricted type certificate ~~type certificate~~, supplemental type certificate ~~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~~ Annex shall:

- (1) ~~have~~ establish and maintain a system for collecting, investigating and analysing mandatory and voluntary occurrence reports in order to identify any adverse trends or to address any deficiencies, and to extract reportable occurrences. The 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~~ type certificate, restricted type certificate ~~type certificate~~, supplemental type certificate ~~type certificate~~, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this ~~Annex Regulation~~; and
 - (ii) internal errors, near misses, and hazards that do not fall under point (i).
- (2) ~~Information about this system shall be made available to all~~ make available to known operators of the product, part or appliance and, on request, to any person authorised under other associated implementing Regulations, 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 occurrences.

(b3) Reporting to the Agency

~~The holder of a type certificate, restricted type certificate, supplemental type certificate, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall report to the Agency~~ EASA any failure, malfunction, defect or other occurrence of which it is aware related to a product, part, or appliance covered by the ~~type certificate~~ type certificate, restricted type certificate ~~type certificate~~, supplemental type certificate ~~type certificate~~, ETSO

authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Annex Regulation, and which has resulted in or may result in an unsafe condition, in accordance with Commission Implementing Regulation (EU) 2015/1018.

(b) Without prejudice to Regulation (EU) No 376/2014, all natural or legal persons who hold or have applied for a production approval under Subpart G, or who produce a product, part or appliance under Subpart F, shall:

(1) establish and maintain a system for collecting and assessing internal mandatory and voluntary occurrence reports, including reports on internal errors, near misses, and hazards, in order to identify any adverse trends or to address any deficiencies, and extract reportable occurrences. This system shall include the evaluation of relevant information related to occurrences, and the promulgation of the related information;

(2) report to the holder of the type certificate, restricted type certificate or design approval, all cases in which products, parts or appliances have been released by the production organisation and subsequently identified to have deviations from the applicable design data, and investigate with the holder of the type certificate, restricted type certificate or design approval to identify those deviations which could lead to an unsafe condition, in accordance with Commission Implementing Regulation (EU) 2015/1018;

(3) report to EASA and the competent authority of the Member State the deviations which could lead to an unsafe condition that were identified according to point (2);

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

(2c) The These reports defined in points (a) and (b) shall appropriately safeguard the confidentiality of the reporter and of the persons mentioned in the report and be made in a form and manner established by the competent authority Agency, as soon as practicable and in any case dispatched not later than 72 hours after the identification of the possible unsafe condition, unless exceptional circumstances prevent this.

(c) ~~Investigation of Reported Occurrences~~

(d1-) Without prejudice to Regulation (EU) No 376/2014, if ~~When~~ an occurrence reported under ~~point (b)~~ point (a)(3), or under point (b)(3) ~~points 21.A.129(f)(2) or 21.A.165(f)(2)~~ results from a deficiency in the design, or a manufacturing production deficiency, the holder of the type certificate ~~type certificate~~, restricted type certificate ~~type certificate~~, supplemental type certificate ~~type certificate~~, major repair design approval, ETSO authorisation, or any other relevant approval deemed to have been issued under this Annex Regulation, or the production organisation ~~manufacturer~~ as appropriate, shall investigate the reason for the deficiency and report to the Agency EASA and to the competent authority of the Member State the results of its investigation and any action it is taking or proposes to take to correct that deficiency.



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

[Note: related AMC/GM:

- [AMC1 21.A.3A\(a\)\(1\) Occurrence reporting](#)
- [AMC2 21.A.3A\(a\)\(1\) Occurrence reporting](#)
- [GM1 21.A.3A\(a\) and 21.A.3A\(b\) Occurrence reporting](#)
- [GM2 21.A.3A\(b\)\(a\) and \(b\) Occurrence reporting](#)
- [GM1 21.A.3A\(a\)\(1\) and \(b\)\(1\) Occurrence reporting](#)
- [GM1 21.A.3A\(a\)\(1\)\(ii\) and \(b\)\(1\)\(i\) Occurrence reporting](#)
- [AMC1 21.A.3A\(b\)\(2\)\(d\) Occurrence reporting](#)

21.A.5 Record-keeping

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

- (a) when designing a product, part or appliance or changes or repairs to them, maintain relevant design information/data, and retain them at the disposal of EASA in order to provide the information necessary to ensure their continued airworthiness, the continued validity of the operational suitability data, and continued compliance with the applicable environmental protection requirements;
- (b) when producing a product, part or appliance:
- (1) maintain the relevant records produced under the production system that was used to justify the conformity of the products, parts or appliances, and retain them in order to provide the information necessary to ensure the continued airworthiness of the product, part or appliance;
 - (2) for production organisations approved in accordance with Subpart G, record all details of the work carried out and establish a record-keeping system that incorporates the requirements imposed on its partners, suppliers and subcontractors, and ensures the conservation of the data used to justify the conformity of the products, parts or appliances. This data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances; and
- (c) with regard to permits to fly:
- (1) maintain documents produced to establish and justify the flight conditions, and retain them at the disposal of EASA and the competent authority in order to provide the information necessary to ensure the continued airworthiness of the aircraft;

- (2) when issuing a permit to fly under the privilege of approved organisations, maintain the documents associated with it, including inspection records, documents that support the approval of flight conditions and the permit to fly itself, retain them at the disposal of EASA or the competent authority, and in order to provide the information necessary to ensure the continued airworthiness of the aircraft;
- (d) retain records of competence and the qualifications of personnel who are involved in design or production, in independent monitoring of compliance and adequacy, and in safety management if required by points 21.A.139, 21.A.145, 21.A.239 or 21.A.245; and
- (e) when employing personnel who exercise the privileges of the approved organisation according to points 21.A.163 or 21.A.263, or who carry out the independent monitoring of compliance and adequacy according to points 21.A.139(f) and 21.A.239(f), retain the records of their authorisation.

[Note: related AMC/GM:

- [AMC1 21.A.5 Record-keeping](#)
- [GM1 21.A.5 Record-keeping](#)
- [AMC1 21.A.5\(a\) and 21.A.433\(a\) Record-keeping](#)
- [GM1 21.A.5\(a\) and \(b\) Record-keeping](#)
- [AMC1 21.A.5\(e\) Record-keeping](#)

21.A.9 Investigations

- (a) All organisations who hold or who have applied for a type certificate, restricted type certificate, supplemental type certificate, ETSO authorisation, major repair design approval, permit to fly, design organisation approval, production organisation approval or letter of agreement under this Annex, shall make arrangements that allow the competent authority to make any investigations, including investigations of partners, supplier and subcontractors, that are necessary to determine the compliance and the continued compliance of the organisation with the applicable requirements of this Annex.
- (b) Design and production organisations and applicants for, or holders of, permits to fly or ETSO authorisations shall allow the competent authority to review any report and make any inspection and perform or witness any test that is necessary to check the compliance of the organisation with this Annex, and to inspect the technical data files.

[Note: related AMC/GM:

- [GM1 21.A.9 Investigations](#)



SUBPART B — TYPE CERTIFICATES AND RESTRICTED TYPE CERTIFICATES

21.A.44 Obligations of the holder

Each holder of a ~~type certificate~~ type certificate or restricted type certificate ~~type certificate~~ shall:

- (a) undertake the obligations laid down in points 21.A.3A, 21.A.3B, 21.A.4, ~~21.A.55~~, 21.A.5, 21.A.9, 21.A.57, 21.A.61 and 21.A.62; and, for this purpose, shall continue to meet the qualification requirements for eligibility under point 21.A.14; and
- (b) specify the marking in accordance with Subpart Q.

21.A.55 Record-keeping

~~All relevant design information, drawings and test reports, including inspection records for the product tested, shall be held by the type certificate or restricted type certificate holder at the disposal of the Agency and shall be retained in order to provide the information necessary to ensure the continued airworthiness, continued validity of the operational suitability data and compliance with applicable environmental protection requirements of the product.~~



SUBPART D — CHANGES TO TYPE CERTIFICATES AND RESTRICTED TYPE CERTIFICATES

21.A.105 Record-keeping

~~For each change, all relevant design information, drawings and test reports, including inspection records for the changed product tested, shall be held by the applicant at the disposal of the Agency and shall be retained in order to provide the information necessary to ensure the continued airworthiness, continued validity of the operational suitability data and compliance with applicable environmental protection requirements of the changed product.~~

21.A.109 Obligations and EPA marking

The holder of a minor change approval to a type certificate ~~type certificate~~ shall:

- (a) undertake the obligations laid down in points 21.A.4, 21.A.105, 21.A.5, 21.A.9, 21.A.107 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.118A Obligations and EPA marking

Each holder of a supplemental ~~type certificate~~ ~~type-certificate~~ shall:

- (a) undertake the obligations:
 - (1)- laid down in points 21.A.3A, 21.A.3B, 21.A.4, ~~21.A.105~~, 21.A.5, 21.A.9, 21.A.119, 21.A.120A and 21.A.120B;
 - (2)- implicit in the collaboration with the ~~type certificate~~ ~~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).



SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

21.A.124A Alternative means of compliance

- (a) Alternative means of compliance to the AMC adopted by EASA may be used by an organisation to establish compliance with Regulation (EU) 2018/1139¹ and the delegated and implementing acts adopted on the basis thereof.
- (b) If an organisation wishes to use an alternative means of compliance, it shall, prior to implementing it, provide the competent authority with a full description of the alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.

The organisation may implement these alternative means of compliance subject to prior approval by the competent authority, and upon receipt of the notification.

[Note: related AMC/GM:

- [AMC1 21.A.124A Alternative means of compliance](#)]

21.A.125B Findings

- ~~(a) When objective evidence is found showing non-compliance of the holder of a letter of agreement with the applicable requirements of this [Annex I](#) (Part 21), the finding shall be classified as follows:~~
- ~~1. a level one finding is any non-compliance with this [Annex I](#) (Part 21) which could lead to uncontrolled non-compliances with applicable design data and which could affect the safety of the aircraft;~~
 - ~~2. a level two finding is any non-compliance with this [Annex I](#) (Part 21) which is not classified as level one.~~
- ~~(b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).~~
- (ea) After receipt of notification of findings issued by the competent authority according to point 21.B.125:
- ~~(1)~~ in case of a level 1 ~~one~~ or level 2 finding, the holder of the letter of agreement shall demonstrate ~~corrective action~~ to the satisfaction of the competent authority that it has taken adequate corrective action within the time period set by the competent authority in accordance with point 21.B.125 within a period of no more than 21 working days after written confirmation of the finding;
 2. in case of level two findings, the corrective action period granted by the competent authority shall be appropriate to the nature of the finding but in any case initially shall

¹ Or EASA if EASA is the competent authority.

~~not be more than three months. In certain circumstances and subject to the nature of the finding, the competent authority may extend the three months period subject to the provision of a satisfactory corrective action plan agreed by the competent authority;~~

- ~~(2)-~~ a level ~~3~~ three finding shall not require immediate action by the holder of the letter of agreement.
- (db) In case of level ~~1~~ one or level ~~2~~ two findings, the letter of agreement may be subject to a partial or full limitation, suspension and revocation under point ~~21.B.65~~ ~~21.B.145~~. ~~The~~ In that case, the holder of the letter of agreement shall provide confirmation of the receipt of the notice of limitation, suspension or revocation of the letter of agreement in a timely manner.

[Note: related AMC/GM:

- [GM1 21.A.125B\(a\), 21.A.158\(a\) and 21.A.258\(a\) Findings](#)]

21.A.125C Duration and continued validity

- (a) The letter of agreement shall be issued for a limited duration not exceeding one year. It shall remain valid unless:
- ~~(1)-~~ the holder of the letter of agreement fails to demonstrate compliance with the applicable requirements of this ~~Annex~~ ~~Subpart~~; or
 - ~~(2)~~ the competent authority is prevented by the holder or any of its partners or subcontractors from performing the investigations in accordance with point 21.A.9;
 - ~~(3)-~~ there is evidence that the ~~production organisation~~ ~~manufacturer~~ cannot maintain satisfactory control of the manufacture of products, parts, or appliances under the agreement; or
 - ~~(4)-~~ the ~~production organisation~~ ~~manufacturer~~ no longer meets the requirements of point 21.A.122; or
 - ~~(5)-~~ the letter of agreement has been ~~surrendered~~, revoked under point ~~21.B.145~~, ~~21.B.65~~, ~~surrendered~~ or has expired.
- (b) Upon surrender, revocation or expiry, the letter of agreement shall be returned to the competent authority.

21.A.126 Production inspection system

- (a) The production inspection system required under point 21.A.125A(a) shall provide a means for determining whether:
- ~~(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; ~~and~~

- (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; and
- (5)- materials and parts that are withheld because of departures from design data or 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 determined by this procedure to be serviceable shall be properly identified and reinspected if rework or repair is necessary. Materials and parts rejected by this procedure shall be marked and disposed of to ensure that they are not incorporated in the final product.;
- ~~6. records produced under the production inspection system are maintained, identified with the completed product or part where practicable, and retained by the manufacturer in order to provide the information necessary to ensure the continued airworthiness of the product.~~

[Note: related AMC/GM:

- **GM 21.A.126 Production inspection system** (unchanged)
- **GM 21.A.126(a)(1) Production inspection system —Conformity of supplied parts, appliances and material** (unchanged)
- **GM 21.A.126(a)(2) Production inspection system — Identification of incoming materials and parts** (unchanged)
- **GM No 1 to 21.A.126(a)(3) Production inspection system — List of specifications** (unchanged)
- **GM No 2 to 21.A.126(a)(3) Production inspection system — Means of checking of the production processes** (unchanged)
- **GM 21.A.126(a)(4) Production inspection system — Applicable design/production data procedures** (unchanged)
- **GM 21.A.126(b)(1) Production inspection system — Inspection of parts in process** (unchanged)



- **GM 21.A.126(b)(2) Production inspection system — Suitable storage and protection** (unchanged)
- **GM 21.A.126(b)(3) Production inspection system — Use of derived data instead of original design data** (unchanged)
- **GM 21.A.126(b)(4) Production inspection system — Segregation of rejected material** (unchanged)
- **GM 21.A.126(b)(5) Production inspection system — Engineering and manufacturing review procedure** (unchanged)
- **GM 21.A.126(b)(6) Production inspection system — Recording and record keeping** (moved to GM1 21.A.5(a) and (b))]

21.A.129 Obligations of the manufacturer

Each organisation producing 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 type-certificate, restricted type certificate 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; and
- (e) comply with Subpart A of this Annex. ~~establish and maintain an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of occurrence reports in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include evaluation of relevant information relating to occurrences and the promulgation of related information;~~
- (f) ~~1. report to the holder of the type-certificate, restricted type-certificate or design approval, all cases where products, parts or appliances have been released by the manufacturer and subsequently identified to have deviations from the applicable design data, and investigate with the holder of the type-certificate, restricted type-certificate or design approval to identify those deviations which could lead to an unsafe condition;~~
 - 2. ~~report to the Agency and the competent authority of the Member State the deviations which could lead to an unsafe condition identified according to point (1). Such reports shall be made in a form and manner established by the Agency under point 21.A.3A(b)(2) or accepted by the competent authority of the Member State;~~
 - 3. ~~where the manufacturer acts as supplier to another production organisation, report also to that other organisation all cases where it has released products, parts or~~

~~appliances to that organisation and subsequently identified them to have possible deviations from the applicable design data.~~

[Note: related AMC/GM:

- **GM 21.A.129(a) Availability for inspection by the competent authority** (unchanged)
- **AMC No 1 to 21.A.129(c) Obligations of the manufacturer — Conformity of prototype models and test specimens** (unchanged)
- **AMC No 2 to 21.A.129(c) Obligations of the manufacturer — Conformity with Applicable Design Data** (unchanged)
- **AMC No 3 to 21.A.129(c) Obligations of the manufacturer condition for safe operation** (unchanged)]

SUBPART G — PRODUCTION ORGANISATION APPROVAL

21.A.134A Alternative means of compliance

- (a) Alternative means of compliance to the AMC adopted by EASA may be used by an organisation to establish compliance with Regulation (EU) 2018/1139¹ and the delegated and implementing acts adopted on the basis thereof.
- (b) If an organisation wishes to use an alternative means of compliance, it shall, prior to implementing it, provide the competent authority with a full description of the alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.

The organisation may implement these alternative means of compliance subject to prior approval by the competent authority, and upon receipt of the notification.

[Note: related AMC/GM:

- [AMC1 21.A.134A Alternative means of compliance](#)

21.A.139 Quality Production management System

- (a) The production organisation shall establish, implement, and maintain a production management system that includes a safety management system and a quality system with clear lines of responsibility and accountability throughout the organisation ~~demonstrate that it has established and is able to maintain a quality system.~~
- (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; and

¹ Or EASA if EASA is the competent authority.

- (2) be established under the direct accountability of a single accountable manager according 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 to execute the safety policy in accordance with point 21.A.145(c)(2);
 - (3) establish, implement and maintain a safety risk management process that includes:
 - (i) hazard identification in all domains of the organisation and its production activities, resulting from analysis of the occurrences collected according to point 21.A.3A; and
 - (ii) safety risk assessment and mitigation;
 - (4) establish, implement and maintain a safety assurance process that includes:
 - (i) the measurement and monitoring of safety performance;
 - (ii) the management of changes in accordance with points 21.A.143(b) and 21.A.147; and
 - (iii) principles for continuous improvement of the safety management system;
 - (5) promote safety in the organisation through:
 - (i) training and education; and
 - (ii) communication.
- (d) As part of the quality management element of the production management system, the production organisation shall:
- (1) ~~The quality system shall be documented. This quality system shall be such as to enable the organisation to 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, and thus exercise the privileges set forth as defined in point 21.A.163.~~
 - (2b) ~~The quality system shall contain~~ establish, implement, and maintain, as applicable, within the scope of approval, 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) airworthiness coordination with the applicant for, or holder of, the design approval;
 - (x) ~~records~~ the completion and retention of records;
 - (xi) ~~personnel~~ the competence and ~~qualification~~ 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 carried out after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;
 - (xvii) ~~issue~~ issuance of permit to fly and approval of associated flight conditions.
- (3) ~~The control procedures need to include specific provisions for any critical parts in the control procedures for any critical parts.~~
- (e) The production organisation shall document, in accordance with point 21.A.143, all the key processes of the production management system, and maintain a process for:
- (1) amending that documentation; and
 - (2) making personnel aware of their responsibilities under the production management system.
- (f) The production organisation shall include in the production management system ~~An independent quality assurance function to monitor~~ monitoring of compliance with, and the adequacy of, the production management system and its documented procedures ~~of the quality system~~. This monitoring shall include a feedback system to the person or group of persons referred to in point 21.A.145(c)(2) and ultimately to the manager referred to in point 21.A.145(c)(1) to ensure, as necessary, corrective action.
- (g) If the organisation holds other organisation certificates 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).

[Note: related AMC/GM:

- [GM1 21.A.139\(c\) Production management system](#)
- [AMC1 21.A.139\(c\) Production management system](#)
- [AMC1 21.A.139\(c\)\(1\) Production management system](#)
- [GM1 21.A.139\(c\)\(1\) Production management system](#)
- [AMC1 21.A.139\(c\)\(2\) Production management system](#)



- [GM1 21.A.139\(c\)\(2\) Production management system](#)
- [AMC1 21.A.139\(c\)\(3\) and \(4\) Production management system](#)
- [AMC1 21.A.139\(c\)\(3\) Production management system](#)
- [GM1 21.A.139\(c\)\(4\)\(ii\) Production management system](#)
- [AMC1 21.A.139\(c\)\(4\)\(ii\) Production management system](#)
- [AMC1 21.A.139\(c\)\(5\) Production management system](#)
- [GM1 21.A.139\(c\)\(5\) Production management system](#)
- [AMC1 21.A.139\(c\)\(5\)\(i\) Production management system](#)
- [GM1 21.A.139\(c\)\(5\)\(i\) Production management system](#)
- [AMC1 21.A.139\(d\) Production management system](#)
- [AMC1 21.A.139\(d\)\(2\) Production management system](#)
- [GM1 21.A.139\(d\)\(1\) Production management system](#)
- [AMC1 21.A.139\(d\)\(2\)\(ii\) Production management system](#)
- [AMC2 21.A.139\(d\)\(2\)\(ii\) Production management system](#)
- [GM1 21.A.139\(d\)\(2\)\(ii\) Production management system](#)
- [AMC1 21.A.139\(e\) Production management system](#)
- [AMC1 21.A.139\(f\) Production management system](#)

21.A.143 Exposition

- (a) As part of the production management system, the ~~The~~ organisation shall ~~establish~~ ~~submit to the competent authority~~ a production organisation exposition ~~that provides~~ ~~providing~~ directly or by cross reference the following information:
- (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 ~~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~~ ~~accountabilities~~ 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 point 21.A.145(c)(1) and (2);
 - (5)- a list of the certifying staff as referred to in point 21.A.145(d);
 - (6)- a general description of the 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 ~~quality~~ production management system, the policy, processes and the procedures as required by point 21.A.139(b)(1);

- (12) a list of those outside parties referred to in point 21.A.139(a), 21.A.139(d)(1); and
- (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; and
 - (vi) a list of documents that need to be produced for flight test.
- (b) The production organisation exposition shall be amended as necessary to remain an up-to-date description of the organisation, and copies of any amendments shall be supplied to the competent authority.

[Note: related AMC/GM:

- **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)** (unchanged);
- [GM1 21.A.143 Exposition](#)
- [AMC1 21.A.143\(a\)\(1\) Exposition](#)

21.A.145 Approval requirements Resources

The production organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.143 that:

- (a) with regard to general approval requirements, facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and general organisation are adequate to discharge the obligations under point 21.A.165;
- (b) with regard to all necessary airworthiness and environmental, noise, fuel venting and exhaust emissions data:
 - (1) the production organisation is in receipt of such data from the Agency EASA, and from the holder of, or applicant for, the type certificate type certificate, restricted type certificate type certificate or design approval, including any exemption granted against the CO2 production cut-off requirements, to determine conformity with the applicable design data;



- (2)- the production organisation has established a procedure to ensure that airworthiness and environmental noise, fuel venting and exhaust emissions data are correctly incorporated in its production data;
- (3)- such data are 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)- a an accountable manager has been nominated by the production organisation, and is accountable to the competent with authority to ensure that, His or her responsibility within the organisation, shall consist of ensuring that all production is performed to the required standards and that the production organisation is continuously in compliance with the requirements of the management system referred to in point 21.A.139, and the data and the procedures identified in the exposition referred to in point 21.A.143;
- (2)- the accountable manager shall nominate a person or group of persons have been nominated by the production organisation to ensure that the organisation is in compliance with the requirements of this Annex I (Part 21), and are identified, together with the extent of their authority. Such person(s) shall act under the direct authority of the accountable manager referred to in point (1). The persons nominated shall be able to show 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 production organisation in respect of airworthiness, noise, fuel venting and exhaust emission data matters;
- (d) with regard to certifying staff, authorised by the production organisation to sign the documents issued under point 21.A.163 under the scope or terms of approval:
- (1)- the knowledge, background (including other functions in the organisation), and experience of the certifying staff are appropriate to discharge their allocated responsibilities;
2. — the production organisation maintains a record of all certifying staff which shall include details of the scope of their authorisation;
- (2)- certifying staff are provided with evidence of the scope of their authorisation.

[Note: related AMC/GM:

- [AMC1 21.A.145\(a\) Resources](#)
- [GM1 21.A.145\(a\) Resources](#)
- [GM1 21.A.145\(b\)\(2\) Resources](#)
- [AMC1 21.A.145\(c\)\(1\) Resources](#)
- [GM1 21.A.145\(c\)\(1\) Resources](#)
- [AMC1 21.A.145\(c\)\(2\) Resources](#)
- [AMC2 21.A.145\(c\)\(2\) Resources](#)
- [AMC1 21.A.145\(d\)\(1\) Resources](#)
- [AMC1 21.A.145\(d\)\(2\)Resources](#)



21.A.147 Changes to the approved production management system organisation

- (a) After the issue of a production organisation approval, each change to the approved production management system organisation that is significant to the showing demonstration of conformity or to the airworthiness and environmental characteristics of noise, fuel venting and exhaust emissions of the product, part or appliance, particularly changes to the quality system, shall be approved by the competent authority before being implemented. Before the implementation of the change, an application for approval shall be submitted in writing to the competent authority, and the organisation shall demonstrate, to the competent authority before implementation of the change, that it will continue to comply with this Subpart Annex after the implementation.
- (b) The competent authority shall establish the conditions under which a production organisation approved under this Subpart may operate during such changes unless the competent authority determines that the approval should be suspended.

[Note: related AMC/GM:

- [AMC1 21.A.147 Changes to the production management system](#)
- [GM1 21.A.147 Changes to the production management system](#)

21.A.157 Investigations

A production organisation shall make arrangements that allow the competent authority to make any investigations, including investigations of partners and subcontractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.

21.A.158 Findings

- (a) When objective evidence is found showing non-compliance of the holder of a production organisation approval with the applicable requirements of this Annex I (Part 21), the finding shall be classified as follows:
1. a level one finding is any non-compliance with this Annex I (Part 21) which could lead to uncontrolled non-compliances with applicable design data and which could affect the safety of the aircraft;
 2. a level two finding is any non-compliance with this Annex I (Part 21) which is not classified as level one.
- (b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).
- (ea) After receipt of notification of findings issued by the competent authority according to point [21.B.225](#),
- (1) in case of a level 1 or level 2 one findings, the holder of the production organisation approval shall demonstrate corrective action to the satisfaction of the competent authority that it has taken adequate corrective action within a the time period set by



the competent authority in accordance with point 21.B.225 of no more than 21 working days after written confirmation of the finding;

~~2. in case of level two findings, the corrective action period granted by the competent authority shall be appropriate to the nature of the finding but in any case initially shall not be more than three months. In certain circumstances and subject to the nature of the finding the competent authority may extend the three months period subject to the provision of a satisfactory corrective action plan agreed by the competent authority;~~

~~(2)3. a level 3 three finding shall not require immediate action by the holder of the production organisation approval.~~

(db) In case of level 1 one or level 2 two findings, the production organisation approval may be subject to a partial or full limitation, suspension or revocation under point 21.B.245 21.B.65. In that case, the The holder of the production organisation approval shall provide confirmation of receipt of the notice of limitation, suspension or revocation of the production organisation approval in a timely manner.

[Note: related AMC/GM:

— [GM1 21.A.125B\(a\), 21.A.158\(a\) and 21.A.258\(a\) Findings](#)]

21.A.159 Duration and continued validity

(a) A production organisation approval shall be issued for an unlimited duration. It shall remain valid unless:

~~(1). the production organisation fails to demonstrate compliance with the applicable requirements of this Subpart Annex; or~~

~~(2). the competent authority is prevented by the holder or any of its partners or subcontractors to perform the investigations in accordance with point 21.A.9 21.A.157; or~~

~~(3). there is evidence that the production organisation cannot maintain satisfactory control of the manufacture of products, parts or appliances under the approval; or~~

~~(4). the production organisation no longer meets the eligibility requirements of point 21.A.133; or~~

~~(5). the certificate has been surrendered or revoked under point 21.B.65 21.B.245 or surrendered.~~

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority.

[Note: related AMC/GM:

— **GM 21.A.159(a)(3) Evidence of a lack of satisfactory control** (unchanged)]

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 engines, determine that the completed engine is in compliance with the applicable emissions requirements on the date of manufacture of the engine;
 - ~~(4)-~~ determine that other products, parts or appliances conform to the applicable data before issuing an EASA Form 1 as a conformity certificate.
- ~~(d) — record all details of work carried out;~~
- ~~(e) — establish and maintain an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of occurrence reports in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include evaluation of relevant information relating to occurrences and the promulgation of related information;~~
- ~~(f) — 1. — report to the holder of the type certificate or design approval, all cases where products, parts or appliances have been released by the production organisation and subsequently identified to have possible deviations from the applicable design data, and investigate with the holder of the type certificate or design approval in order to identify those deviations which could lead to an unsafe condition;~~
 - ~~2. — report to the Agency and the competent authority of the Member State the deviations which could lead to an unsafe condition identified according to point (1). Such reports shall be made in a form and manner established by the Agency under point 21.A.3A(b)(2) or accepted by the competent authority of the Member State;~~
 - ~~3. — where the holder of the production organisation approval is acting as a supplier to another production organisation, report also to that other organisation all cases where it has released products, parts or appliances to that organisation and subsequently identified them to have possible deviations from the applicable design data;~~
- (dg) provide assistance to the holder of the **type certificate** ~~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;



- (h) ~~establish an archiving system incorporating requirements imposed on its partners, suppliers and subcontractors, ensuring conservation of the data used to justify conformity of the products, parts or appliances. Such data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances;~~
- (ei) where, under its terms of approval, the holder issues a certificate of release to service, determine that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation, prior to issuing the certificate;
- (fj) where applicable, under the privilege of point 21.A.163(e), determine the conditions under which a permit to fly can be issued;
- (gk) where applicable, under the privilege of point 21.A.163(e), establish compliance with points 21.A.711(c) and (e) before issuing a permit to fly to an aircraft;
- (h) comply with Subpart A of this Annex.

[Note: related AMC/GM:

- **GM 21.A.165(a) Obligations of the holder — Basic working document** (unchanged);
- **GM No 1 to 21.A.165(c) Obligations of the holder — Conformity of prototype models and test specimens** (unchanged);
- **GM No 2 to 21.A.165(c) Obligations of holder — Conformity with type design** (unchanged);
- **GM No 3 to 21.A.165(c) Obligations of the holder — Condition for safe operation** (unchanged);
- **GM No 4 to 21.A.165(c) Airworthiness Release or Conformity Certificate** (unchanged);
- **AMC 21.A.165(c)(3) Applicable emissions requirements** (unchanged);
- **GM 21.A.165(c)(3) Definitions of engine type certification date and production date** (unchanged);
- **GM 21.A.165(d) and (h) Obligations of the holder — Recording and archiving system** (moved to — GM1 21.A.5(a) and (b))]

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

21.A.180 Inspections

The holder of the airworthiness certificate shall provide access to the aircraft for which that airworthiness certificate has been issued upon request by the competent authority of the Member State of registry.

21.A.181 Duration and continued validity

- (a) An airworthiness certificate shall be issued for an unlimited duration. It shall remain valid subject to:
- (1) compliance with the applicable type-design and continuing airworthiness requirements; and
 - (2) the aircraft remaining on the same register; and
 - (3) the type certificate type certificate or restricted type certificate type certificate under which it is issued not being previously invalidated under point 21.A.51;
 - (4) the certificate not being surrendered or revoked under point 21.B.65 21.B.330 or surrendered.
- (b) Upon surrender or revocation, the certificate shall be returned to the competent authority of the Member State of registry.



SUBPART I — NOISE CERTIFICATES

21.A.210 Inspections

The holder of the noise certificate shall provide access to the aircraft for which that noise certificate has been issued upon request by the competent authority of the Member State of registry or by the Agency for inspection.

21.A.211 Duration and continued validity

- (a) A noise certificate shall be issued for an unlimited duration. It shall remain valid subject to:
- (1) compliance with the applicable type-design, environmental protection and continuing airworthiness requirements; and
 - (2) the aircraft remaining on the same register; and
 - (3) the type certificate type certificate or restricted type certificate type certificate under which it is issued not being previously invalidated under point 21.A.51;
 - (4) the certificate not being surrendered or revoked under point 21.B.430 21.B.65 or surrendered.
- (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.239 Design assurance management system

- (a) The design organisation shall establish, implement, and maintain a design management system that includes a safety management system and a design assurance system with clear lines of responsibility and accountability throughout the organisation.
- (b) The design management system shall:
- (1) correspond to the size of the organisation and the nature and complexity of its activities, taking into account the hazards and the associated risks that are inherent in these activities; and
 - (2) be established under the direct accountability of a single manager according 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 to execute the safety policy in accordance with point 21.A.245(b);
 - (3) establish, implement and maintain a safety risk management process that includes:
 - (i) hazard identification in all domains of the organisation and its design activities, resulting from analysis of the occurrences collected according to point 21.A.3A; and
 - (ii) safety risk assessment and mitigation;
 - (4) establish, implement and maintain a safety assurance process that includes:
 - (i) measurement and monitoring of safety performance;
 - (ii) management of changes in accordance with points 21.A.243(c) and 21.A.247; and
 - (iii) principles for continuous improvement of the safety management system; and
 - (5) promote safety in the organisation through:
 - (i) training and education; and
 - (ii) communication.
- (d) As part of the design assurance element of the design management system, the design organisation shall:
- (a1) ~~The design organisation shall demonstrate that it has established and is able to maintain a design assurance system for~~ establish, implement and maintain a system for the control and supervision of the design, and of design changes, of products, parts and appliances covered by the application. This ~~design assurance system shall be such as to~~ enable the organisation to ensure that:

- (i)1. ~~to ensure that~~ the design of the products, parts and appliances or the design change thereof, comply with the applicable type-certification basis, the applicable operational suitability data certification basis and ~~the~~ environmental protection requirements; and
- (ii)2. ~~to ensure that its responsibilities are properly~~ discharge its responsibilities ~~discharged~~ in accordance with ~~the appropriate provisions of~~ this Annex I (~~Part 21~~); and 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 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 partners or subcontractors according to methods which are the subjects of written procedures.
- (e) The design organisation shall document, in accordance with point 21.A.243, all the key processes of the design management system, and maintain a process for:
- (1) amending that documentation;
- (2) making personnel aware of their responsibilities under the design management system;
- (f) Include in the design management system independent monitoring of ~~to independently monitor~~ the compliance with, and the adequacy of, the design management system and its documented procedures ~~of the system~~. This monitoring shall include a feed-back system to ~~the~~ a person or a group of persons referred to in point 21.A.245(b), and ultimately to the manager referred to in point 21.A.245(a) to ensure, as necessary, that corrective action takes place. ~~having the responsibility to ensure corrective actions.~~
- (g) If the organisation holds other organisation certificates that were issued on the basis of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, the design organisation may integrate the design management system with the management system that is required for the issuance of the other certificate(s).
- ~~(b) The design assurance system shall include an independent checking function of the showings of compliance on the basis of which the organisation submits compliance statements and associated documentation to the Agency.~~
- ~~(c) The design organisation shall specify the manner in which the design assurance system accounts for the acceptability of the parts or appliances designed or the tasks performed by partners or subcontractors according to methods which are the subject of written procedures.~~

[Note: related AMC/GM:

- [GM1 21.A.239\(c\) Design management system](#)
- [AMC1 21.A.239\(c\) Design management system](#)
- [AMC1 21.A.239\(c\)\(1\) Design management system](#)
- [GM1 21.A.239\(c\)\(1\) Design management system](#)
- [AMC1 21.A.239\(c\)\(2\) Design management system](#)
- [GM1 21.A.239\(c\)\(2\) Design management system](#)



- [AMC1 21.A.239\(c\)\(3\) and \(4\) Design management system](#)
- [AMC1 21.A.239\(c\)\(3\) Design management system](#)
- [AMC1 21.A.239\(c\)\(4\)\(ii\) Design management system](#)
- [GM1 21.A.239\(c\)\(4\)\(ii\) Design management system](#)
- [AMC1 21.A.239\(c\)\(5\) Design management system](#)
- [GM1 21.A.239\(c\)\(5\) Design management system](#)
- [AMC1 21.A.239\(c\)\(5\)\(i\) Design management system](#)
- [GM1 21.A.239\(c\)\(5\)\(i\) Design management system](#)
- [GM1 21.A.239\(d\) Design management system](#)
- [AMC1 21.A.239\(d\) Design management system](#)
- [AMC2 21.A.239\(d\) Design management system](#)
- [AMC1 21.A.239\(d\)\(2\) Design management system](#)
- [GM1 21.A.239\(d\)\(3\) Design management system](#)
- [AMC1 21.A.239\(e\) Design management system](#)
- [AMC1 21.A.239\(f\) Design management system](#)

21.A.243 Data Handbook

- (a) The As part of the design management system, the design organisation shall furnish establish a handbook to the Agency describing, directly or by cross-reference, the organisation, the relevant procedures and the products or changes to products to be designed and, where relevant, the interfaces with and the control of partners or subcontractors. If flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test shall be furnished established. The flight test operations manual shall include:
- (1i) a description of the organisation's processes for flight test, including the flight test organisation involvement into the permit to fly issuance process;
 - (2ii) crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex I (Part 21), where applicable;
 - (3iii) procedures for the carriage of persons other than crew members and for flight test training, when applicable;
 - (4iv) a policy for risk and safety management and associated methodologies;
 - (5v) procedures to identify the instruments and equipment to be carried;
 - (6vi) a list of documents that need to be produced for 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 give, for all parts and appliances, the assurance of compliance required by point 21.A.239(b), and shall contain, directly or by cross-reference, descriptions and information on the design activities and organisation of those partners or subcontractors, as necessary to establish this statement.
- (c) The handbook shall be amended as necessary to remain an up-to-date description of the organisation, and copies of amendments shall be supplied to the Agency EASA.
- (d) The design organisation shall furnish establish and maintain a statement of the qualifications and experience of the management staff and other persons in the organisation responsible for

making decisions affecting airworthiness, operational suitability data and environmental protection in the organisation.

[Note: related AMC/GM:

- **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)** (unchanged);
- [AMC1 21.A.243\(a\) Handbook](#)
- [AMC2 21.A.243\(a\) Handbook](#)
- [AMC1 21.A.243\(d\) Handbook](#)
- [GM1 21.A.243\(d\) Handbook](#)
- [AMC2 21.A.243\(d\) Handbook](#)

21.A.245 Resources Approval requirements

~~The design organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.243 that, in addition to complying with point 21.A.239:~~

- (a) The organisation shall nominate a head of the design organisation with authority for ensuring 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 management system referred to in point 21.A.239 and the procedures identified in the handbook referred to in point 21.A.243.
- (b) Depending on the size of the organisation and on the nature and complexity of its activities, the head of the design organisation shall nominate and identify, together with the extent of their authority:
 - (1) a chief of the office of airworthiness;
 - (2) a chief of the independent monitoring of compliance and adequacy function; and
 - (3) any other person or group of persons who are needed to ensure that the organisation is in compliance with the requirements of this Annex.
- (c) The person or group of persons identified in point (b) shall:
 - (1) act under the direct authority of the head of the design organisation; and
 - (2) be able to show the appropriate knowledge, background and experience to discharge their responsibilities.
- (d) The design organisation shall ensure that:
 - (a1) the staff in all technical departments are of sufficient numbers and experience and have been given appropriate authority to be able to discharge their allocated responsibilities and these, together with the accommodation, facilities and equipment, are adequate to enable the staff to achieve the airworthiness, operational suitability and environmental protection objectives for the product;
 - (b2) there is full and efficient coordination between departments and within departments in respect of airworthiness, operational suitability and environmental protection matters.

[Note: related AMC/GM:

- [AMC1 21.A.245 Resources](#)
- [AMC2 21.A.245 Resources](#)
- [AMC1 21.A.245\(a\) Resources](#)
- [AMC1 21.A.245\(b\) Resources](#)
- [AMC2 21.A.245\(b\) Resources](#)

21.A.247 Changes in to the design management assurance system

After the issue of a design organisation approval, each change to the design management assurance system that is significant to the showing demonstration of compliance or to the airworthiness, operational suitability and environmental protection of the product, part or appliance shall be approved by the Agency EASA. Before the implementation of the change, an An application for approval shall be submitted in writing to the Agency EASA, and the design organisation shall demonstrate to the Agency, on the basis of the submission of the proposed changes to the handbook, and before implementation of the change, that it will continue to comply with this Subpart Annex after the implementation.

[Note: related AMC/GM:

- [AMC1 21.A.247 Changes to the design management system](#)
- [GM1 21.A.247 Changes to in the design management assurance system](#)

21.A.257 Investigations

- ~~(a) The design organisation shall make arrangements that allow the Agency to make any investigations, including investigations of partners and subcontractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.~~
- ~~(b) The design organisation shall allow the Agency to review any report and make any inspection and perform or witness any flight and ground test necessary to check the validity of the compliance statements submitted by the applicant under point 21.A.239(b).~~

21.A.258 Findings

- ~~(a) When objective evidence is found showing non-compliance of the holder of a design organisation approval with the applicable requirements of this Annex I (Part 21), the finding shall be classified as follows:
 - ~~1. a level one finding is any non-compliance with this Annex I (Part 21) which could lead to uncontrolled non-compliances with applicable requirements and which could affect the safety of the aircraft;~~
 - ~~2. a level two finding is any non-compliance with this Annex I (Part 21) which is not classified as level one.~~~~
- ~~(b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).~~

- (ae) After receipt of notification of findings issued by EASA according to point 21.B.433 under the applicable administrative procedures established by the Agency,
- (1) ~~1.~~ in case of a level 1 or level 2 ~~one~~ findings, the holder of the design organisation approval shall demonstrate to the satisfaction of EASA that it has taken adequate corrective action within the time period set by EASA in accordance with 21.B.433 ~~to the satisfaction of the Agency within a period of no more than 21 working days after written confirmation of the finding;~~
 2. ~~in case of level two findings, the corrective action period granted by the Agency shall be appropriate to the nature of the finding but in any case initially shall not be more than three months. In certain circumstances and subject to the nature of the finding the Agency may extend the three months period subject to the provision of a satisfactory corrective action plan agreed by the Agency;~~
 - (2) ~~3.~~ a level 3 ~~three~~ finding shall not require immediate action by the holder of the design organisation approval.
- (bd) In case of level 1 ~~one~~ or level 2 ~~two~~ findings, the design organisation approval may be subject to a partial or full limitation, suspension or revocation under the applicable administrative procedures established by the Agency point 21.B.65. In that case, the holder of the design organisation approval shall provide confirmation of the receipt of the notice of limitation, suspension or revocation of the design organisation approval in a timely manner.

[Note: related AMC/GM:

- [GM1 21.A.125B\(a\), 21.A.158\(a\) and 21.A.258\(a\) Findings](#)]

21.A.259 Duration and continued validity

- (a) A design organisation approval shall be issued for an unlimited duration. It shall remain valid unless:
- (1) ~~1.~~ the design organisation fails to demonstrate compliance with the applicable requirements of this Subpart Annex; or
 - (2) ~~2.~~ the Agency EASA is prevented by the holder or any of its partners or subcontractors ~~to from performing perform~~ the investigations in accordance with point 21.A.9 ~~21.A.257;~~ or
 - (3) ~~3.~~ there is evidence that the design management assurance system cannot maintain satisfactory control and supervision of the design of products or changes thereof under the approval; or
 - (4) ~~4.~~ the design organisation no longer meets the eligibility requirements of point 21.A.233; or
 - (5) ~~5.~~ the certificate has been surrendered or revoked under point 21.B.65 or surrendered the applicable administrative procedures established by the Agency.
- (b) Upon surrender or revocation, the certificate shall be returned to the Agency EASA.



21.A.263 Privileges

- (a) ~~(Reserved) The holder of a design organisation approval shall be entitled to perform design activities under this Annex I (Part 21) and within its scope of approval.~~
- (b) ~~(Reserved) Subject to point 21.A.257(b), the Agency shall accept without further verification the following compliance documents submitted by the applicant for the purpose of obtaining:~~
- ~~1. the approval of flight conditions required for a permit to fly; or~~
 - ~~2. a type certificate or approval of a major change to a type certificate; or~~
 - ~~3. a supplemental type certificate; or~~
 - ~~4. an ETSO authorisation under point 21.A.602B(b)(1); or~~
 - ~~5. a major repair design approval.~~
- (c) ~~The A~~ holder of a design organisation approval shall be entitled, within ~~the scope of~~ its terms of approval ~~as established by EASA~~ and under the relevant procedures of the design management assurance system:
- ~~(1)1.~~ to classify changes to the ~~type certificate~~ ~~type certificate~~ or to a supplemental ~~type certificate~~ ~~type certificate~~ and repair ~~designs~~ as 'major' or 'minor';
 - ~~(2)2.~~ to approve minor changes to ~~type certificate~~ ~~type certificate~~ or to a ~~type certificate~~ ~~supplemental type certificate~~ and minor repair ~~designs~~;
 - ~~(3)3.~~ ~~(Reserved) to issue information or instructions containing the following statement: 'The technical content of this document is approved under the authority of DOA ref. EASA. 21J. [XXXX].';~~
 - ~~(4)4.~~ ~~(Reserved) to approve minor revisions to the aircraft flight manual and supplements, and issue such revisions containing the following statement: 'Revision No [YY] to AFM (or supplement) ref. [ZZ] is approved under the authority of DOA ref. EASA. 21J. [XXXX].';~~
 - ~~(5)5.~~ to approve ~~the design of~~ ~~certain~~ major repair ~~designs under Subpart M~~ to products or Auxiliary Power Units (APUs) ~~for which it holds the type certificate or the supplemental type certificate or ETSO authorisation;~~
 - ~~(6)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)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~~ ~~under~~ point 21.A.263(c)(6) the ~~flight~~ conditions under which the permit to fly can be issued, and ~~when~~ ~~where~~ the design organisation itself:
 - ~~(i)~~ ~~is controlling controls~~ ~~under its Design Organisation Approval~~ the configuration of the aircraft and
 - ~~(ii)~~ ~~is attesting~~ ~~attests~~ conformity with the design conditions approved for the flight.

- (7) ~~to approve certain major changes to a type certificate~~ ~~type-certificate~~ under Subpart D;
and
- (8) ~~to issue certain supplemental type certificate~~ ~~type-certificates~~ under Subpart E and
approve certain major changes to those certificates.

[Note: related AMC/GM:

- **GM 21.A.263(b) DOA privilege related to compliance documents** (unchanged)
- **AMC 21.A.263(b)(1) Compliance documents with conditions related to engine or propeller without a type-certificate or with unapproved changes and fitted on aircraft for which a permit to fly is requested** (unchanged)
- **AMC No 1 to 21.A.263(c)(1) Procedure for the classification of changes to type certificate (TC) and repairs as minor or major** (unchanged)
- **AMC No 2 to 21.A.263(c)(1) Privileges —Organisations designing minor changes to a type certificate (TC) or minor repairs to products: classification procedure** (unchanged)
- **AMC No 1 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (TC) or minor repairs** (unchanged)
- **AMC No 2 to 21.A.263(c)(2) Privileges —Organisations designing minor changes to a type certificate (TC) or minor repairs to products: procedure for the approval of minor changes to a TC or minor repairs** (unchanged)
- **GM 21.A.263(c)(3) Issue of information or instructions** (unchanged)
- **GM 21.A.263(c)(4) Procedure for the approval of minor revisions to the aircraft flight manual** (unchanged)
- **AMC 21.A.263(c)(6) Procedure for the approval of the conditions for issue of a permit to fly** (unchanged)
- **AMC 21.A.263(c)(7) Procedure for the issue of a permit to fly** (unchanged)]

21.A.265 Obligations of the holder

The holder of a design organisation approval shall ~~within the scope of its terms of approval, as established by the Agency~~ EASA:

- (a) maintain the handbook ~~required under point 21.A.243~~ in conformity with the design management assurance system;
- (b) ensure that this handbook ~~or the relevant procedures included by cross-reference are~~ is used as a basic working document within the organisation;
- (c) determine that the design of products, or changes or repairs ~~thereto thereof, as applicable,~~ comply with applicable ~~specifications and~~ requirements and have no unsafe ~~feature~~ features;
- (d) ~~except for minor changes or repairs approved under the privilege of point 21.A.263,~~ provide to the Agency EASA ~~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 EASA data and information or instructions related to required actions under point 21.A.3B;
- (f) where applicable, under the privilege of point 21.A.263(c)(6), determine in accordance with point 21.A.263(c)(6), the flight conditions under which a permit to fly can be issued;
- (g) where applicable, under the privilege of point 21.A.263(c)(7), establish in accordance with point 21.A.263(c)(7), compliance with points (b) and (e) of point 21.A.711(b) and (e) 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 EASA with the following statement: 'The technical content of this document is approved under the authority of the DOA ref. EASA. 21J.[XXXX]'; and
- (i) comply with Subpart A of this Annex.

[Note: related AMC/GM:

- **AMC 21.A.265(a) Administration of the Handbook** (unchanged)
- **GM 21.A.265(b) Use of the Handbook** (unchanged)]



SUBPART M — REPAIRS

21.A.447 Record keeping

For each repair, all relevant design information, drawings, test reports, instructions and limitations possibly issued in accordance with point 21.A.443, justification for classification and evidence of the design approval, shall:

- (a) ~~be held by the repair design approval holder at the disposal of the Agency; and~~
- (b) ~~be retained by the repair design approval holder in order to provide the information necessary to ensure the continued airworthiness of the repaired products, parts or appliances.~~

[Note: related AMC/GM:

- **AMC 21.A.433(a) and 21.A.447 Repair design and record-keeping** (moved to AMC1 21.A.5(a) and 21.A.433(a))]

21.A.451 Obligations and EPA marking

- (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.9**, 21.A.439, 21.A.441, 21.A.443, ~~21.A.447~~ and 21.A.449;
 - (ii) implicit in the collaboration with the **type certificate** ~~type certificate~~, supplemental **type certificate** ~~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** ~~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.447 and 21.A.449; and
 - ~~(2)-~~ specify the marking, including EPA letters, in accordance with point 21.A.804(a).

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.A.604 ETSO Authorisation for an Auxiliary Power Unit (APU)

With regard to ETSO authorisation for an APU-auxiliary power unit:

- (a) by way of derogation from points 21.A.603, 21.A.610 and 21.A.615 21.A.9, the following points shall apply: points 21.A.15, 21.A.16B, 21.A.17A, 21.A.17B, 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44 21.B.75 and 21.B.80. shall apply by way of derogation from points 21.A.603, 21.A.606(c), 21.A.610 and 21.A.9 21.A.615, except that However an ETSO Authorisation shall be issued in accordance with point 21.A.606 instead of the type certificate 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 the requirements of ~~of~~ Subpart E shall apply to ~~is applicable for~~ the approval of design changes by other applicants ~~way of derogation from point 21.A.611~~. When Subpart E is used, a separate ETSO authorisation shall be issued instead of a supplemental type certificate type-certificate.
- (c) the requirements of Subpart M shall apply ~~is applicable~~ to the approval of repair designs.

21.A.609 Obligations of holders of ETSO authorisations

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, a current file of complete technical data and records in accordance with point 21.A.5 21.A.613;
- (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 EASA 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, and 21.A.4 and 21.A.9;
- (g) continue to meet the qualification requirements of point 21.A.602B.

21.A.613 Record-keeping

~~Further to the record-keeping requirements appropriate to or associated with the quality system, all relevant design information, drawings and test reports, including inspection records for the article tested, shall be held at the disposal of the Agency and shall be retained in order to provide the~~

information necessary to ensure the continued airworthiness of the article and of the type-certificated product in which it is fitted.

21.A.615 Inspection by the Agency

Upon a request of the Agency, each applicant for, or holder of an ETSO authorisation for an article shall allow the Agency to:

- (a) witness any tests;
- (b) inspect the technical data files on that article.

21.A.619 Duration and continued validity

- (a) An ETSO authorisation shall be issued for an unlimited duration. It shall remain valid unless:
 - (1) the conditions required when the ETSO authorisation was granted are no longer being observed; or
 - (2) the obligations of the holder specified in point 21.A.609 are no longer being discharged; or
 - (3) the competent authority is prevented by the holder or any of its partners or subcontractors from performing the investigations in accordance with point 21.A.9; or
 - (4) the article has proved to give rise to unacceptable hazards in service; or
 - (5) the authorisation has been surrendered or revoked under point 21.B.65, or surrendered the applicable administrative procedures established by the Agency.
- (b) Upon surrender or revocation, the certificate shall be returned to the Agency EASA.

SUBPART P — PERMIT TO FLY

~~21.A.705 Competent authority~~

~~Notwithstanding point 21.1 of this Annex I (Part 21) for the purpose of this Subpart, the 'competent authority' shall be:~~

- ~~(a) — the authority designated by the Member State of registry; or~~
- ~~(b) — for unregistered aircraft, the authority designated by the Member State which prescribed the identification marks.~~

[Note: related AMC/GM:

- **GM 21.A.705 Competent authority** (moved to GM1 21.1(c))]

~~21.A.721 Inspections~~

~~The holder of, or the applicant for, a permit to fly shall provide access to the aircraft concerned at the request of the competent authority.~~

~~21.A.723 Duration and continued validity~~

- (a) A permit to fly shall be issued for a maximum of 12 months and shall remain valid subject to:
 - ~~(1)-~~ compliance with the conditions and restrictions of point 21.A.711(e) associated with the permit to fly;
 - (2) the competent authority is permitted by the holder or any of its partners or subcontractors to perform the investigations in accordance with point 21.A.9;
 - ~~(3)2-~~ the permit to fly not being surrendered or revoked under point 21.B.65 or surrendered; or
 - ~~(4)3-~~ the aircraft remaining 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.729 Record-keeping~~

- ~~(a) — All documents produced to establish and justify the flight conditions shall be held by the holder of the approval of the flight conditions at the disposal of the Agency and competent authority and shall be retained in order to provide the information necessary to ensure the continued airworthiness of the aircraft.~~
- ~~(b) — All documents associated with the issue of permits to fly under the privilege of approved organisations, including inspection records, documents supporting the approval of flight conditions and the permit to fly itself, shall be held by the related approved organisation at~~

~~the disposal of the Agency or the competent authority and shall be retained in order to provide the information necessary to ensure the continued airworthiness of the aircraft.~~



SECTION B PROCEDURES FOR COMPETENT AUTHORITIES

SUBPART A — GENERAL PROVISIONS

21.B.5 Scope

- ~~(a) This Section establishes the procedure for the competent authority of the Member State when exercising its tasks and responsibilities concerned with the issuance, maintenance, amendment, suspension and revocation of certificates, approvals and authorisations referred to in this Annex I (Part 21).~~
- ~~(b) The Agency shall develop in accordance with Article 19 of Regulation (EC) No 216/2008 certification specifications and guidance material to assist Member States in the implementation of this Section.~~

This section establishes the administrative and management system requirements to be followed by the competent authority that is in charge of the implementation and enforcement of Section A of this Annex.

21.B.10 Oversight documentation

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 EASA

- (a) The competent authority of the Member State shall notify EASA without undue delay if there are any significant problems with the implementation of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (b) The competent authority of the Member State shall provide EASA with any safety-significant information stemming from the occurrence reports it has received, pursuant to 21.A.3A.

21.B.20 Obligations of the competent authority

~~Each competent authority of the Member State is responsible for the implementation of Section A, Subparts F, G, H, I and P only for applicants, or holders, whose principal place of business is in its territory.~~

21.B.20 Immediate reaction to a safety problem

- (a) Without prejudice to Regulation (EU) No 376/2014 and its implementing acts, the competent authority of the Member State shall implement a system to appropriately collect, analyse, and disseminate safety information.

- (b) EASA shall implement a system to appropriately analyse any relevant safety information received, and without undue delay, provide to Member States and the Commission 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 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) shall immediately be notified to all persons or organisations which 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 EASA and, when combined action is required, to the other Member States concerned.

[Note: related AMC/GM:

- **GM 21.B.20 Responsibility for implementation** (moved to 21.1(a)(2) and (3))]

21.B.25 Requirements for the organisation of the competent authority

(a) ~~General:~~

~~The Member State shall designate a competent authority with allocated responsibilities for the implementation of Section A, Subparts F, G, H, I and P with documented procedures, organisation structure and staff.~~

(b) ~~Resources:~~

- ~~1. the number of staff shall be sufficient to perform the allocated tasks;~~
- ~~2. the competent authority of the Member State shall appoint a manager, or managers, who are responsible for the execution of the related task(s) within the authority, including the communication with the Agency and the other national authorities as appropriate.~~

(c) ~~Qualification and training:~~

~~All staff shall be appropriately qualified and have sufficient knowledge, experience and training to perform their allocated task.~~

21.B.25 Management system

- (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 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. Compliance monitoring shall include a system to feed back audit findings to the senior management of the competent authority to ensure the implementation of corrective actions as necessary; and
 - (6) a person or group of persons ultimately responsible 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 necessary information and assistance with any other competent authorities concerned, including 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 EASA.
- (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 EASA for the purpose of standardisation.

[Note: related AMC/GM:

- [AMC1 21.B.25 Management system](#)
- [AMC2 21.B.25 Management system](#)
- [AMC1 21.B.25\(a\)\(1\) Management system](#)
- [GM1 21.B.25\(a\)\(2\) Management system](#)
- [AMC1 21.B.25\(a\)\(3\) Management system](#)
- [AMC2 21.B.25\(a\)\(3\) Management system](#)
- [AMC3 21.B.25\(a\)\(3\) Management system](#)
- [AMC1 21.B.25\(a\)\(5\) Management system](#)
- [GM1 21.B.25\(a\)\(5\) Management system](#)
- [AMC1 21.B.25\(d\) Management system](#)

21.B.30 Documented procedures

- (a) ~~The competent authority of the Member State shall establish documented procedures to describe its organisation, means and methods to fulfil the requirements of this Annex I (Part 21). The procedures shall be kept up to date and serve as the basic working documents within that authority for all related activities.~~
- (b) ~~A copy of the procedures and their amendments shall be available to the Agency.~~

21.B.30 Allocation of tasks to qualified entities

- (a) Tasks related to the initial certification, or to the continuing oversight of persons, or organisations subject to Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, may be allocated only 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' referred to in Article 69 of 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 clearly 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; and
 - (v) the protection given to information acquired in carrying out such tasks.
- (b) The competent authority shall ensure that the internal audit process and safety risk management process required by point 21.B.25(a)(5) cover all the certification and continuing oversight tasks performed on its behalf.

[Note: related AMC/GM:

- [GM1 21.B.30 Allocation of tasks to qualified entities](#)]

21.B.35 Changes in the management system ~~organisation and~~ procedures

- (a) ~~The competent authority of the Member State shall notify any significant change in its organisation and documented procedures to the Agency.~~
- (b) ~~The competent authority of the Member State shall update its documented procedures relating to any change to regulations in a timely manner to ensure effective implementation.~~
- (a) The competent authority shall have a system in place to identify any changes that affect its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU)



2018/1139 and the delegated and implementing acts adopted on the basis thereof. This system shall enable it to take action as appropriate 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 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 EASA of any changes affecting its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.

21.B.40 Resolution of disputes

- ~~(a) The competent authority of the Member State shall establish a process for the resolution of disputes within its organisation documented procedures.~~
- ~~(b) Where a dispute, which cannot be resolved, exists between the competent authorities of the Member States, the competent authorities shall it is the responsibility of the managers as defined in point 21.B.25(b)(2) to raise the issue with the Agency for mediation.~~

[Note: related AMC/GM:

- **GM 21.B.40 Principles for the resolution of disputes** (unchanged)]

21.B.45 Reporting/coordination

- ~~(a) The competent authority of the Member State shall ensure coordination as applicable with other related certification, investigation, approval or authorisation teams of that authority, other Member States and the Agency to ensure efficient exchange of information relevant for safety of the products, parts and appliances.~~
- ~~(b) The competent authority of the Member State shall notify any difficulty in the implementation of this Annex I (Part 21) to the Agency.~~

[Note: related AMC/GM:

- **GM No 1 to 21.B.45 Co-ordination with other related activities** (deleted);
- **GM No 2 to 21.B.45 Co-ordination** (deleted);
- **GM No 3 to 21.B.45 Reporting – Information relevant to registers established by EASA** (deleted)]

21.B.55 Record-keeping

~~The competent authority of the Member State shall keep, or maintain access to, the appropriate records related to the certificates, approvals and authorisations it has granted in accordance with the respective national regulations, and for which responsibility is transferred to the Agency, as long as these records have not been transferred to the Agency.~~

- (a) The competent authority shall establish a system of record-keeping that allows 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 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) details of findings, corrective actions, dates of action closures, any exemptions and enforcement actions;
 - (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 organisation expositions, handbooks or manuals and amendments to them; and
 - (ix) copies of any other document approved by the competent authority; and
 - (5) the evaluation and notification to EASA of any alternative means of compliance proposed by organisations, and the assessment of any alternative means of compliance used by the competent authority itself;
 - (6) safety information and follow-up measures in accordance with point 21.B.15; and
 - (7) the use of flexibility provisions in accordance with Article 71 of Regulation (EU) 2018/1139.
- (b) The competent authority shall maintain a list of all certificates, approvals, authorisations and letters of agreement that it has issued.
- (c) All records referred to in points (a) and (b) shall be kept for a minimum period of 5 years, subject to applicable data protection law.
- (d) All the records referred to in points (a) and (b) shall be made available upon request to a competent authorities of another Member State or EASA.
- (e) For organisations that produce products, parts or appliances without a production organisation approval according to Subpart F of Section A of this Annex, the competent authority shall also maintain records of all Statements of Conformity (EASA Form 52, see

Appendix VIII) and Authorised Release Certificates (EASA Form 1, see Appendix I) that it has validated.

[Note: related AMC/GM:

- [AMC1 21.B.55\(a\) Record-keeping](#)
- [AMC1 21.B.55\(a\)\(1\) Record-keeping](#)
- [GM1 21.B.55 Record-keeping](#)
- [GM1 21.B.55\(e\) Record-keeping](#)

21.B.65 Suspension, limitation and revocation

The competent authority shall:

- (a) suspend a certificate, approval, permit to fly, authorisation or letter of agreement on reasonable grounds in the case of a potential safety threat or if there is evidence that any of the conditions specified in points 21.A.51(a), 21.A.118B(a) 21.A.181(a) or 21.A.211(a), 21.A.619(a), 21A.723(a) is not met;
- (b) suspend, revoke or limit a certificate, approval, authorisation or letter of agreement pursuant to points 21.B.125, 21.B.225 or 21.B.433; or
- (c) suspend a certificate, approval, authorisation or letter of agreement if the competent authority's inspectors are unable over a period of 24 months to discharge their oversight responsibilities through on-site audit(s) due to the security situation in the State where the facilities are located.

[Note: related AMC/GM:

- [AMC1 21.B.65 Suspension, limitation and revocation](#)
- [AMC1 21.B.65\(c\) Suspension, limitation and revocation](#)
- [GM1 21.B.65 Suspension, limitation and revocation](#)

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

21.B.115 Alternative means of compliance

- (a) Alternative means of compliance may be used to establish compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (b) The competent authority shall establish a system to consistently evaluate that all alternative means of compliance used by itself or by organisations under its oversight, allow the establishment of compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (c) The competent authority shall evaluate all the alternative means of compliance proposed by an organisation in accordance with point 21.A.124A by analysing the documentation provided and, if considered necessary, by conducting an inspection of the organisation.

When the competent authority finds that the alternative means of compliance are in accordance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, it shall without undue delay:

- (1) notify the applicant that the alternative means of compliance may be implemented and, if applicable, amend the letter of agreement of the applicant accordingly;
 - (2) notify EASA of their content, and include copies of all the relevant documentation.
- (d) If the competent authority itself uses alternative means of compliance to achieve compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, it shall:
 - (1) make them available to all the organisations and persons under its oversight;
 - (2) notify EASA without undue delay; and
 - (3) provide EASA with a full description of the alternative means of compliance, including any revisions to procedures that may be relevant, as well as an assessment demonstrating that the requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof have been met.

[Note: related AMC/GM:

- [GM1 21.B.115 and 21.B.215 Alternative means of compliance](#)
- [AMC1 21.B.115\(d\) and 21.B.215\(d\) Alternative means of compliance](#)

21.B.120 Investigation

- ~~(a) The competent authority shall appoint an investigation team for each applicant for, or holder of, a letter of agreement to conduct all relevant tasks related to this letter of agreement, consisting of a team leader to manage and lead the investigation team and, if required, one or more team members. The team leader shall report to the manager responsible for the activity, as defined in point 21.B.25(b)(2).~~



- (b) ~~The competent authority shall perform sufficient investigation activities for an applicant for, or holder of, a letter of agreement to justify recommendations for the issuance, maintenance, amendment, suspension or revocation of the letter of agreement.~~
- (c) ~~The competent authority shall prepare procedures for the investigation of applicants for, or holders of, a letter of agreement as part of the documented procedures covering at least the following elements:~~
- ~~1. evaluation of applications received;~~
 - ~~2. determination of investigation team;~~
 - ~~3. investigation preparation and planning;~~
 - ~~4. evaluation of the documentation (manual, procedures, etc.);~~
 - ~~5. auditing and inspection;~~
 - ~~6. follow up of corrective actions; and~~
 - ~~7. recommendation for issuance, amendment, suspension or revocation of the letter of agreement.~~

21.B.120 Initial certification procedure

- (a) Upon receiving an application for the initial issue of a letter of agreement, the competent authority shall verify the organisation's compliance with the applicable requirements.
- (b) The competent authority shall record all findings, actions (i.e. actions required to close a finding), and recommendations.
- (c) The competent authority shall confirm to the organisation 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.
- (d) When satisfied that the organisation complies with the applicable requirements and has corrected all the findings to its satisfaction, the competent authority shall issue a letter of agreement (EASA Form 65, see Appendix XI) without undue delay.
- (e) The letter of agreement shall contain the scope of the agreement, a termination date and, where applicable, the appropriate limitations related to the authorisation.
- (f) The duration of the letter of agreement shall not exceed one year.

[Note: related AMC/GM:

- [AMC1 21.B.120\(a\) Initial certification procedure](#)
- [AMC2 21.B.120\(a\) Initial certification procedure](#)
- [AMC3 21.B.120\(a\) Initial certification procedure](#)
- [AMC4 21.B.120\(a\) Initial certification procedure](#)
- [GM1 21.B.120\(c\) Initial certification procedure](#)
- [AMC1 21.B.120\(d\) Initial certification procedure](#)



21.B.125 Findings and corrective actions

~~(a) When during audits or by other means objective evidence is found by the competent authority, showing non-compliance of the holder of a letter of agreement with the applicable requirements of Section A of this Annex, the competent authority shall issue a finding. The competent authority this finding shall be classified in accordance with point 21.A.125B(a) classify the findings as follows:~~

- (a) The competent authority shall have a system to analyse findings for their safety significance.
- (b) A level 1 finding shall be issued by the competent authority when it detects a non-compliance that may lead to uncontrolled non-compliances with the applicable design data which lowers safety or seriously endangers flight safety.

The level 1 findings shall also include:

- (1) any failure to give the competent authority access to the organisation's facilities as defined in point 21.A.9 during normal operating hours and after two written requests;
 - (2) obtaining or maintaining the validity of a letter of agreement by falsification the submitted documentary evidence; and
 - (3) any evidence of malpractice or of fraudulent use of the letter of agreement.
- (c) A level 2 finding shall be issued by the competent authority when any other non-compliance with the applicable requirements of this Annex which could lower the level of safety or endanger flight safety, is detected.
- (d) A level 3 finding shall be issued by the competent authority when there is objective evidence that it could lead to a non-compliance under points (b) or (c).
- (e) 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 the delegated and implementing acts adopted on the basis thereof, communicate the finding to the organisation in writing, and request corrective action to address the non-compliance(s) identified. If a finding directly relates to an aircraft, the competent authority shall inform the State in which the aircraft is registered.

~~(f)~~ The competent authority shall take the following actions:

~~(1-)~~ in the case of ~~for~~ level 1 findings:

- (i) take immediate and appropriate action shall be taken by the competent authority to prohibit or limit the activities of the organisation involved, and, if appropriate, it shall take action to limit, suspend or revoke the letter of agreement 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 completed by the organisation;
- (ii) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, which shall not in any case be more than 21 working days. It shall commence from the date of the written communication



of the finding to the organisation, requesting corrective action to address the non-compliance identified.

(2-) in the case of ~~for~~ level 2 findings:

- (i) ~~, the competent authority shall grant a corrective action implementation period that is appropriate to the nature of the finding, which in any case that 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. In certain circumstances, at~~ At the end of this period, and subject to the nature of the finding and the past safety performance of the organisation, the competent authority ~~can~~ may extend the 3-month period provided that a satisfactory corrective action plan ~~provided by the organisation~~ 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(s), accept them.

(3) in the case of level 3 findings, recommend to the organisation to take action so that the item identified does not result in a non-compliance with this Annex;

(4) if an 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 a level 1 finding, and action shall be taken as laid down in point (d)(1)(i); and

(5) record all the findings that it has raised or that have been communicated to it in accordance with point (d) and, where applicable, the enforcement measures it has applied, as well as all the corrective actions and the dates of action closures for findings.

~~(c) Action shall be taken by the competent authority to suspend the letter of agreement in whole or in part in case of failure to comply within the timescale granted by the competent authority.~~

[Note: related AMC/GM:

- [GM1 21.B.125\(b\), 21.B.225\(b\) and 21.B.430\(b\) Findings and corrective actions](#)
- [GM1 21.B.125\(b\) Findings and corrective actions](#)
- [GM1 21.B.125\(b\)\(1\) and 21.B.225\(b\)\(1\) Findings and corrective actions](#)
- [AMC1 21.B.125\(d\) Findings and corrective actions](#)

21.B.130 Issue of letter of agreement

~~(a) When satisfied that the manufacturer is in compliance with the applicable requirements of Section A, Subpart F the competent authority shall issue a letter of agreement to the showing of conformity of individual products, parts or appliances (EASA Form 65, see Appendix XI) without undue delay.~~

~~(b) The letter of agreement shall contain the scope of the agreement, a termination date and, where applicable, the appropriate limitations relating to the authorisation.~~



(c) ~~The duration of the letter of agreement shall not exceed one year.~~

[Note: related AMC/GM:

- **AMC 21.B.130 Issue of the letter of agreement** (moved to AMC1 21.B.120(d))
- **GM 21.B.130(b) Issue of the letter of agreement** (moved to AMC1 21.B.120(d))

21.B.145 Limitation, suspension and revocation of a letter of agreement

- ~~(a) The limitation, suspension or revocation of the letter of agreement shall be communicated in writing to the holder of the letter of agreement. The competent authority shall state the reasons for the limitation, suspension or revocation and inform the holder of the letter of agreement on its right to appeal.~~
- ~~(b) When a letter of agreement has been suspended it shall only be reinstated after compliance with Section A Subpart F has been re-established.~~

21.B.150 Record-keeping

- ~~(a) The competent authority shall establish a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual letter of agreement.~~
- ~~(b) The records shall at least contain:~~
- ~~1. the documents provided by the applicant for, or holder of, a letter of agreement;~~
 - ~~2. documents established during investigation and inspection, in which the activities and the final results of the elements defined in point 21.B.120 are stated;~~
 - ~~3. the letter of agreement, including changes; and~~
 - ~~4. minutes of the meetings with the manufacturer.~~
- ~~(c) The records shall be archived for a minimum retention period of six years after termination of the letter of agreement.~~
- ~~(d) The competent authority shall also maintain records of all Statements of Conformity (EASA Form 52, see Appendix VIII) and Authorised Release Certificates (EASA Form 1, see Appendix I) that it has validated.~~

[Note: related AMC/GM:

- **GM 21.B.150(d) Record-keeping – Traceability of release certificates** (moved to GM1 21.B.55(e))

SUBPART G — PRODUCTION ORGANISATION APPROVAL

21.B.215 Alternative means of compliance

- (a) Alternative means of compliance may be used to establish compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (b) The competent authority shall establish a system to consistently evaluate that all alternative means of compliance used by itself or by organisations under its oversight, allow the establishment of compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (c) The competent authority shall evaluate all the alternative means of compliance proposed by an organisation in accordance with point 21.A.134A by analysing the documentation provided and, if considered necessary, conducting an inspection of the organisation.

When the competent authority finds that the alternative means of compliance are in accordance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, it shall without undue delay:

- (1) notify the applicant that the alternative means of compliance may be implemented and, if applicable, amend the approval of the applicant accordingly;
 - (2) notify EASA of their content, including copies of all relevant documentation.
- (d) If the competent authority itself uses alternative means of compliance to achieve compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, it shall:
 - (1) make them available to all the organisations and persons under its oversight;
 - (2) notify EASA without undue delay.
 - (3) provide EASA with a full description of the alternative means of compliance, including any revisions to procedures that may be relevant, as well as an assessment demonstrating that the implementing rules have been met.

[Note: related AMC/GM:

- [GM1 21.B.115 and 21.B.215 Alternative means of compliance](#)
- [AMC1 21.B.115\(d\) and 21.B.215\(d\) Alternative means of compliance](#)

21.B.220 Investigation

- ~~(a) The competent authority shall appoint a production organisation approval team for each applicant, or holder of, a production organisation approval to conduct all relevant tasks related to this production organisation approval, consisting of a team leader to manage and lead the approval team and, if required, one or more team members. The team leader shall report to the manager responsible for the activity as defined in point 21.B.25(b)(2).~~



- (b) ~~The competent authority shall perform sufficient investigation activities for an applicant for, or holder of, a production organisation approval to justify recommendations for the issuance, maintenance, amendment, suspension or revocation of the approval.~~
- (c) ~~The competent authority shall prepare procedures for the investigation of a production organisation approval as part of the documented procedures covering at least the following elements:~~
- ~~1. evaluation of applications received;~~
 - ~~2. determination of production organisation approval team;~~
 - ~~3. investigation preparation and planning;~~
 - ~~4. evaluation of the documentation (production organisation exposition, procedures, etc.);~~
 - ~~5. auditing;~~
 - ~~6. follow up of corrective actions;~~
 - ~~7. recommendation for issuance, amendment, suspension or revocation of production organisation approval;~~
 - ~~8. continued surveillance.~~

21.B.220 Initial certification procedure

- (a) Upon receiving an application for the initial issue of a production organisation approval certificate, the competent authority shall verify the organisation's compliance with the applicable requirements.
- (b) A meeting with the accountable manager of the organisation shall be convened at least once during the investigation for initial certification to ensure that he or she fully understands the significance of the certification process, and the reason for signing the statement specified in point 21.A.143(a)(1).
- (c) The competent authority shall record all findings, closure actions (i.e. actions required to close a finding), and recommendations.
- (d) The competent authority shall confirm to the organisation 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 organisation complies with the applicable requirements and has corrected all the findings to its satisfaction, the competent authority shall issue a production organisation approval (EASA Form 55, see Appendix X) without undue delay.
- (f) The certificate reference number shall be included on the EASA Form 55 in a manner specified by EASA.
- (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.

[Note: related AMC/GM:



- [AMC1 21.B.220 and 21.B.221 Initial certification procedure](#)
- [AMC1 21.B.220 and 21.B.430 Initial certification procedure](#)
- [AMC1 21.B.220 Initial certification procedure](#)
- [AMC1 21.B.220 Initial certification procedure](#)
- [GM1 21.B.220 Initial certification procedure](#)
- [GM2 21.B.220 Initial certification procedure](#)
- [GM3 21.B.220 Initial certification procedure](#)
- [AMC1 21.B.220\(d\)\(1\) Initial certification procedure](#)

21.B.221 Oversight principles

- (a) The competent authority shall verify:
- (1) compliance with the requirements that are applicable to organisations prior to issuing of an organisation certificate;
 - (2) continued compliance with the applicable requirements of the organisations that it has certified; and
 - (3) the implementation of appropriate safety measures mandated by the competent authority as defined in points 21.B.20(c) and (d).
- (b) This verification shall:
- (1) be supported by documentation specifically intended to provide personnel responsible for safety oversight with guidance to perform their functions;
 - (2) provide the organisations concerned with the results of safety oversight activities;
 - (3) be based on assessments, audits, inspections, and, if needed, unannounced inspections; and
 - (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 scope of the oversight defined in points (a) and (b) shall take 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 oversight tasks performed by the competent authority(ies) of the Member State(s) where the facilities are located, or by EASA for facilities that are located in a third country. 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 useful for conducting oversight activities, including unannounced inspections.

[Note: related AMC/GM:

- [AMC1 21.B.221\(a\), \(b\) and \(c\) Oversight principles](#)



21.B.222 Oversight programme

- (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 be developed taking 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 unannounced inspections and, as applicable:
 - (i) management system assessments and process audits;
 - (ii) product audits of a relevant sample of the products, parts and appliances that are under the scope of the organisation;
 - (iii) sampling of the work performed; and
 - (2) meetings convened between the accountable manager and the competent authority to ensure that they both remain informed of any significant issues.
- (c) For organisations certified by the competent authority, 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 under point 21.A.147 that it has full control over all changes;
 - (3) no level 1 findings have been issued; and
 - (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 oversight.

[Note: related AMC/GM:

- [AMC1 21.B.222 and 21.B.432 Oversight programme](#)
- [GM1 21.B.222\(a\) Oversight programme](#)
- [AMC1 21.B.222\(b\) and 21.B.432\(b\) Oversight programme](#)
- [AMC2 21.B.222\(b\) and 21.B.432\(b\) Oversight programme](#)
- [GM1 21.B.222\(b\) Oversight programme](#)
- [AMC1 21.B.222\(b\)\(1\) Oversight programme](#)
- [GM1 21.B.222\(b\)\(1\)\(ii\) Oversight programme](#)
- [AMC1 21.B.222\(c\) Oversight programme](#)
- [AMC1 21.B.222\(c\) and 21.B.432\(c\) Oversight programme](#)
- [AMC1 21.B.222\(d\) Oversight programme](#)

21.B.225 Findings and corrective actions

- (a) The competent authority shall have a system to analyse findings for their safety significance.
- (b) A level 1 finding shall be issued by the competent authority when it detects a non-compliance that may lead to uncontrolled non-compliances with the applicable design data which lowers safety or seriously endangers flight safety.

The level 1 findings shall also include:

- ~~(a) When, during audits or by other means, objective evidence is found by the competent authority, showing non-compliance of the holder of a production organisation approval with the applicable requirements of Section A of this Annex, the competent authority shall issue a finding. The competent authority this finding shall be classified in accordance with point 21.A.158(a) classify each finding as follows:~~

~~(1) level 1 finding:~~

- ~~(1) any failure to give the competent authority access to the organisation's facilities as defined in point 21.A.9 during normal operating hours and after two written requests;~~
- ~~(2) obtaining or maintaining the validity of the POA certificate by falsification of the submitted documentary evidence;~~
- ~~(3) any evidence of malpractice or of fraudulent use of the POA certificate; and~~
- ~~(4) the lack of an accountable manager.~~

- (c) A level 2 finding shall be issued by the competent authority when any other non-compliance with the applicable requirements of this Annex which could lower the level of safety or endanger flight safety, is detected.
- (d) A level 3 finding shall be issued by the competent authority when there is objective evidence that it could lead to a non-compliance under points (b) or (c).
- (e) 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 the delegated and implementing acts adopted on the basis thereof, communicate the finding

to the organisation in writing, and request corrective action to address the non-compliance(s) identified. If a finding directly relates to an aircraft, the competent authority shall inform the State in which the aircraft is registered.

- (f) The competent authority shall ~~take the following actions:~~
- (1-) ~~in the case of for level 1 findings take immediate and appropriate action shall be taken by the competent authority to prohibit or limit the activities of the organisation involved, and, if appropriate, it shall take action to limit, suspend or revoke the production 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 completed by the organisation;~~
 - (2-) ~~in the case of for level 2 findings:~~
 - (i) ~~the competent authority shall grant a corrective action implementation period that is appropriate to the nature of the finding, which in any case that 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. In certain circumstances, at~~ At the end of this period, and subject to the nature of the finding and the past safety performance of the organisation, the competent authority ~~can~~ may extend the 3-month period provided that a satisfactory corrective action plan ~~provided by the organisation~~ has been agreed by the competent authority; and
 - (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(s), accept them;~~
 - (3) ~~in case of level 3 findings, recommend to the organisation to take action so that the item identified does not result in a non-compliance with this Annex;~~
 - (4) ~~if an 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 a level 1 finding, and action shall be taken as laid down in point (d)(1)(i); and~~
 - (5) ~~record all the findings that it has raised or that have been communicated to it in accordance with point (d) and, where applicable, the enforcement measures it has applied, as well as all the corrective actions and the dates of action closures for findings.~~
- (c) ~~Action shall be taken by the competent authority to suspend the approval in whole or in part in case of failure to comply within the timescale granted by the competent authority.~~

[Note: related AMC/GM:

- [GM1 21.B.125\(b\), 21.B.225\(b\) and 21.B.430\(b\) Findings and corrective actions](#)
- [GM1 21.B.125\(b\)\(1\) and 21.B.225\(b\)\(1\) Findings and corrective actions](#)
- [AMC1 21.B.225\(d\) Findings and corrective actions](#)



21.B.230 Issue of certificate

- ~~(a) When satisfied that the production organisation is in compliance with the applicable requirements of Section A, Subpart G, the competent authority shall issue a Production Organisation Approval (EASA Form 55, see Appendix X) without undue delay.~~
- ~~(b) The reference number shall be included on the EASA Form 55 in a manner specified by the Agency.~~

[Note: related AMC/GM:

- **AMC No 1 to 21.B.230 Issue of the certificate** (deleted)]

21.B.235 Continued surveillance

- ~~(a) In order to justify the maintenance of the production organisation approval the competent authority shall perform continued surveillance:~~
- ~~1. to verify that the production organisation approval holder's quality system complies with Section A Subpart G;~~
 - ~~2. to verify that the organisation of the production organisation approval holder operates in accordance with the production organisation exposition;~~
 - ~~3. to verify the effectiveness of the production organisation exposition procedures; and~~
 - ~~4. to monitor by sample the standards of the product, part or appliance.~~
- ~~(b) Continued surveillance shall be performed in accordance with point 21.B.220.~~
- ~~(c) The competent authority shall provide through planned continued surveillance that a production organisation approval is completely reviewed for compliance with this Annex I (Part 21) during a period of 24 months. The continued surveillance may be made up of several investigation activities during this period. The number of audits may vary depending upon the complexity of the organisation, the number of sites and the criticality of the production. As a minimum the holder of a production organisation approval shall be subject to continued surveillance activity by the competent authority at least once every year.~~

[Note: related AMC/GM:

- **GM 21.B.235(a)(4) Guide to the conduct of monitoring production standards.** (moved to GM1 21.B.222(b)(1)(ii))
- **GM 21.B.235(b) Maintenance of the POA — Work allocation within the competent authority** (moved to GM1 21.B.222(a))
- **GM 21.B.235(b) and (c) Continued surveillance** (moved to GM1 21.B.222(b))
- **AMC 21.B.235(c) Continuation of POA** (moved to AMC1 21.B.222(b)(1) and 21.B.432(b)(1))

21.B.240 Amendment of a production organisation approval

- ~~(a) The competent authority shall monitor any minor change through the continued surveillance activities.~~



- (b) ~~The competent authority shall investigate as appropriate in accordance with point 21.B.220 any significant change of a production organisation approval or application by the holder of a production organisation approval for an amendment of the scope and terms of approval.~~
- (c) ~~When the competent authority is satisfied that the requirements of Section A, Subpart G continue to be complied with it shall amend the production organisation approval accordingly.~~

21.B.240 Changes to a production organisation approval

- (a) Upon receiving an application for a change that requires prior approval, the competent authority shall verify the organisation's compliance with the applicable requirements 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 production organisation approval needs to be suspended.
- (c) When satisfied that the organisation is in compliance with the applicable requirements, the competent authority shall approve the change.
- (d) Without prejudice to any additional enforcement measures, if the organisation implements changes that require prior approval without having received the approval of the competent authority pursuant to point (c), the competent authority shall suspend, limit or revoke the organisation's certificate.
- (e) For changes do not require prior approval, 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:
- (1) notify the organisation about the non-compliance and request further changes;
 - (2) in the case of level 1 or level 2 findings, act in accordance with point 21.B.225.

[Note: related AMC/GM:

- [AMC1 No 1 to 21.B.240 Changes to a production organisation approval](#)

21.B.245 Suspension and revocation of a production organisation approval

- (a) ~~In case of a level one or level two finding, the competent authority shall partly or fully limit, suspend or revoke a production organisation approval as follows:~~
1. ~~in case of a level one finding the production organisation approval shall be immediately limited or suspended. If the holder of the production organisation approval fails to comply with point 21.A.158(c)(1), the production organisation approval shall be revoked;~~
 2. ~~in case of a level two finding, the competent authority shall decide on any restriction to the scope of approval by temporary suspension of the production organisation approval or parts thereof. If the holder of a production organisation approval fails to comply with point 21.A.158(c)(2), the production organisation approval shall be revoked.~~



~~(b) The limitation, suspension or revocation of the production organisation approval shall be communicated in writing to the holder of the production organisation approval. The competent authority shall state the reasons for the suspension or revocation and inform the holder of the production organisation approval of its right to appeal.~~

~~(c) When a production organisation approval has been suspended it shall only be reinstated after compliance with Section A, Subpart G has been re-established.~~

[Note: related AMC/GM:

- **GM 21.B.245 Continued validity** (moved to GM1 21.B.65)
- **AMC 21.B.245 Corrective action plan** (moved to AMC1 21.B.65)]

21.B.260 Record-keeping

~~(a) The competent authority shall establish a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual production organisation approval.~~

~~(b) The records shall at least contain:~~

- ~~1. the documents provided by the applicant for, or holder of, a production organisation approval certificate;~~
- ~~2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.220 are stated, including findings established in accordance with point 21.B.225;~~
- ~~3. the continued surveillance programme, including records of investigations performed;~~
- ~~4. the production organisation approval certificate, including changes;~~
- ~~5. minutes of the meetings with the holder of the production organisation approval.~~

~~(c) The records shall be archived for a minimum retention period of six years.~~



SUBPART H — AIRWORTHINESS CERTIFICATES AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

~~21.B.330 Suspension and revocation of certificates of airworthiness and restricted certificates of airworthiness~~

- ~~(a) Upon evidence that any of the conditions specified in point 21.A.181(a) is not met, the competent authority of the Member State of registry shall suspend or revoke an airworthiness certificate.~~
- ~~(b) Upon issuance of the notice of suspension and revocation of a certificate of airworthiness or restricted certificate of airworthiness the competent authority of the Member State of registry shall state the reasons for the suspension or revocation and inform the holder of the certificate of its right to appeal.~~

~~21.B.345 Record keeping~~

- ~~(a) The competent authority of the Member State of registry shall establish a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual airworthiness certificate.~~
- ~~(b) The records shall at least contain:~~
- ~~1. the documents provided by the applicant;~~
 - ~~2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.320(b) are stated; and~~
 - ~~3. a copy of the certificate or permit, including amendments.~~
- ~~(c) The records shall be archived for a minimum retention period of six years after leaving that national register.~~



SUBPART I — NOISE CERTIFICATES

~~21.B.430 Suspension and revocation of a noise certificate~~

- ~~(a) Upon evidence that some of the conditions specified in point 21.A.211(a) are not met, the competent authority of the Member State of registry shall suspend or revoke a noise certificate.~~
- ~~(b) Upon issuance of the notice of suspension and revocation of a noise certificate the competent authority of the Member State of registry shall state the reasons for the suspension and revocation and shall inform the holder of the certificate on its right to appeal.~~

~~21.B.445 Record keeping~~

- ~~(a) The competent authority of the Member State of registry shall establish a system of record-keeping with minimum retention criteria that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual noise certificate.~~
- ~~(b) The records shall at least contain:~~
- ~~1. the documents provided by the applicant;~~
 - ~~2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.420(b) are stated;~~
 - ~~3. a copy of the certificate including amendments.~~
- ~~(c) The records shall be archived for a minimum retention period of six years after leaving that national register.~~



SUBPART J — DESIGN ORGANISATION APPROVAL

21.B.430 Initial certification procedure

- (a) Upon receiving an application for the initial issue of a design organisation approval certificate, the competent authority shall verify the organisation'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 he or she fully understands the significance of the certification process, and the reason for signing the statement specified in point 21.A.243(b).
- (c) The competent authority shall record all the findings, closure actions (i.e. actions required to close a finding), and recommendations.
- (d) The competent authority shall confirm to the organisation 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 organisation complies with the applicable requirements and has corrected all the findings to its satisfaction, the competent authority shall issue a design organisation approval without undue delay.
- (f) The certificate reference number shall be included in the design organisation approval certificate in a manner specified by EASA.
- (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.

[Note: related AMC/GM:

- [AMC1 21.B.220 and 21.B.430 Initial certification procedure](#)
- [AMC1 21.B.430 and 21.B.431 Initial certification procedure](#)
- [AMC1 21.B.430\(a\) Initial certification procedure](#)
- [AMC1 21.B.430\(d\)\(1\) Initial certification procedure](#)

21.B.431 Oversight principles

- (a) The competent authority shall verify:
 - (1) compliance with the requirements that are applicable to organisations prior to issuing an organisation certificate;
 - (2) continued compliance with the applicable requirements of the organisations that it has certified;
 - (3) the implementation of appropriate safety measures mandated by the competent authority as defined in points 21.B.20(c) and (d).
- (b) This verification shall:



- (1) be supported by documentation specifically intended to provide personnel responsible for safety oversight with guidance to perform their functions;
 - (2) provide the organisations concerned with the results of safety 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.
- (c) The scope of the oversight defined in (a) and (b) shall take into account the results of past oversight activities and safety priorities.
- (d) The competent authority shall collect and process any information deemed useful for conducting oversight activities, including unannounced inspections.

[Note: related AMC/GM:

- [AMC1 21.B.431\(a\), \(b\) and \(c\) Oversight principles](#)

21.B.432 Oversight programme

- (a) The competent authority shall establish and maintain an oversight programme that covers the oversight activities required by point 21.B.431(a).
- (b) The oversight programme shall be developed taking 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 unannounced inspections, and, as applicable:
 - (i) management system assessments and process audits;
 - (ii) product audits of a relevant sample of the products, parts and appliances that are under the scope of the organisation; and
 - (iii) sampling of the work performed; and
 - (2) meetings convened between the head of the design organisation and the competent authority to ensure that both remain informed of significant issues.
- (c) For organisations certified by the competent authority, 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 they it effectively identify aviation safety hazards and manage the associated risks;
 - (2) the organisation has continuously demonstrated under point 21.A.247 that it has full control over all changes;
 - (3) no level 1 findings have been issued; and

(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.433.

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 oversight.

Note: related AMC/GM:

- [AMC1 21.B.222 and 21.B.432 Oversight programme](#)
- [AMC1 21.B.222\(b\) and 21.B.432\(b\) Oversight programme](#)
- [AMC2 21.B.222\(b\) and 21.B.432\(b\) Oversight programme](#)
- [AMC1 21.B.432\(b\)\(1\) Oversight programme](#)
- [AMC1 21.B.432\(c\) Oversight programme](#)
- [AMC2 21.B.222\(c\) and 21.B.432\(c\) Oversight programme](#)
- [AMC1 21.B.432\(d\) Oversight programme](#)

21.B.433 Findings and corrective actions

(a) The competent authority shall have a system to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when it detects a non-compliance that may lead to uncontrolled non-compliances with the applicable requirements which lowers safety or seriously endangers flight safety.

The level 1 findings shall also include:

- (1) any failure to give the competent authority access to the organisation's facilities as defined in point 21.A.9 during normal operating hours and after two written requests;
- (2) obtaining or maintaining the validity of the DOA certificate by falsification of the submitted documentary evidence;
- (3) any evidence of malpractice or of fraudulent use of the DOA certificate;
- (4) the lack of a head of the design organisation.

(c) A level 2 finding shall be issued by the competent authority when any other non-compliance with the applicable requirements of this Annex which could lower the level of safety or endanger flight safety, is detected.

- (d) A level 3 finding shall be issued by the competent authority when there is objective evidence that it could lead to a non-compliance under points (b) or (c).
- (e) 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 the delegated and implementing acts adopted on the basis thereof, communicate the finding to the organisation in writing, and request corrective action to address the non-compliance(s) identified. If a finding directly relates to an aircraft, the competent authority shall inform the State in which the aircraft is registered.
- (d) The competent authority shall:
- (1) in the case of level 1 findings 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 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 completed by the organisation;
 - (2) in the case of level 2 findings:
 - (i) grant a corrective action implementation period that is appropriate to the nature of the finding, which 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 and the past safety performance of the organisation, the competent authority may extend the 3-month period provided that a satisfactory corrective action plan has been agreed by the competent authority; and
 - (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(s), accept them;
 - (3) in the case of level 3 findings, recommend to the organisation to take action so that the item identified does not result in a non-compliance with this Annex;
 - (4) if an 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 a level 1 finding, and action shall be taken as laid down in point (d)(1)(i); and
 - (5) record all the findings that it has raised or that have been communicated to it in accordance with point (d) and, where applicable, the enforcement measures it has applied, as well as all the corrective actions and the dates of action closures for findings.

[Note: related AMC/GM:

- [GM1 21.B.125\(b\), 21.B.225\(b\) and 21.B.430\(b\) Findings and corrective actions](#)
- [AMC1 21.B.433\(d\) Findings and corrective actions](#)]



21.B.435 Changes to a design organisation approval

- (a) Upon receiving an application for a change that requires prior approval, the competent authority shall verify the organisation's compliance with the applicable requirements 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 satisfied that the organisation is in compliance with the applicable requirements, the competent authority shall approve the change.
- (d) Without prejudice to any additional enforcement measures, if the organisation implements changes that require prior approval without having received the approval of the competent authority pursuant to point (c), the competent authority shall suspend, limit or revoke the organisation's certificate.
- (e) For changes that do not require prior approval, the competent authority shall include the review of those changes in their continuing oversight activities in accordance with the principles stated in point 21.B.431. In case of any non-compliance, the competent authority shall:
 - (1) notify the organisation about the non-compliance and request further changes;
 - (2) in case of level 1 or level 2 findings, act in accordance with point 21.B.433.

[Note: related AMC/GM:

- [AMC1 21.B.435 Changes to a design organisation approval](#)



SUBPART P — PERMIT TO FLY

~~21.B.530 Revocation of permits to fly~~

- ~~(a) Upon evidence that any of the conditions specified in point 21.A.723(a) are not met for a permit to fly it has issued, the competent authority shall revoke that permit to fly.~~
- ~~(b) Upon issuance of the notice of revocation of a permit to fly the competent authority shall state the reasons for the revocation and inform the holder of the permit to fly on the right to appeal.~~

~~21.B.545 Record keeping~~

- ~~(a) The competent authority shall operate a system of record-keeping that provides adequate traceability of the process for the issue and revocation of each individual permit to fly.~~
- ~~(b) The records shall at least contain:
 - ~~1. the documents provided by the applicant;~~
 - ~~2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.520(b) are stated; and~~
 - ~~3. a copy of the permit to fly.~~~~
- ~~(c) The records shall be kept for a minimum of six years after the permit ceases to be valid.~~



APPENDICES TO ANNEX I

EASA FORMS

Regulation (EU) No 748/2012

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 1 Authorised release Certificate
- Appendix II — EASA Form 15a 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 XII — Categories of flight tests and associated flight test crew qualifications 85



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 Refs:	
7. Aircraft Registration Or Mark	8. Manufacturers Identification No	
9. Engine/Propeller Details ³		
10. Modifications and/or Service Bulletins ³		
11. Airworthiness Directives		
12. Concessions		
13. Exemptions, Waivers or Derogations ³		
14. Remarks		
15. Certificate of Airworthiness		
16. Additional Requirements		
17. Statement of Conformity It is hereby certified that this aircraft confirms conforms fully to the type-certificated design 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. Production Organisation Approval Reference		

EASA Form 52 Issue 2.

Instructions for the use of the Aircraft Statement of Conformity EASA Form 52

1. PURPOSE AND SCOPE

- 1.1. Use of the aircraft Statement of Conformity issued by a production organisation manufacturer producing under Part 21 Section A Subpart F is described under point 21.A.130 and the corresponding acceptable means of compliance.
- 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 to exercise the privilege to obtain an individual aircraft 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 format attached, 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 make the

¹ Or EASA if EASA is the competent authority.

² Delete for non-EU Member States or EASA.

³ Delete as applicable.



- Statement of Conformity unrecognisable. If in doubt, consult the competent authority.
- 2.2. 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.
 - 2.3. Completion may be either machine/computer printed or hand-written using block letters to permit 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 the blocks to make 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 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 the 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. An exception is ~~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 the address of the location of the organisation 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~~ type certificate and its associated data sheet.
- Block 6* The ~~type certificate~~ 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 production organisation manufacturer for control and traceability and product support. This is sometimes referred to as a production organisation manufacturer Serial No or Constructors No.
- Block 9** The engine type and the propeller type(s) in full as defined in the relevant type certificate type certificate and its associated data sheet. Their production organisation manufacturer identification No and the associated location should also be shown.
- 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 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 deviations to 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 aircraft. If there is no such information or data, state; 'NONE'.
- Block 15** Enter 'Certificate of Airworthiness', or 'Restricted Certificate of Airworthiness', or 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** The validity Validity of the Sstatement of Conformity is dependent on 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 POA holder. 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 system, as established by point 21.A.139, in particular 21.A.139(d)(1)(vi) 21.A.139(b)(1)(vi), to ensure that the aircraft conforms with 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 POA holder.
- Block 18** The Sstatement of Conformity may be signed by the person authorised to do so by the production approval holder in accordance with point 21.A.145(d). 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 on which the Statement of Conformity is signed should be given.

Block 21 The competent authority approval reference should be quoted.



Appendix X — Production organisation approval certificate — EASA Form 55

Regulation (EU) No 748/2012

Production Organisation Approval Certificates referred to in Subpart G of Annex I (Part 21)

[MEMBER STATE]¹

A Member of the European Union²

PRODUCTION ORGANISATION APPROVAL CERTIFICATE

Reference: [MEMBER STATE CODE]¹.21G.XXXX

Pursuant to Regulation (EU) 2018/1139 Regulation (EC) No 216/2008 of the European Parliament and of the Council and to Commission Regulation (EU) No 748/2012 ~~((EC) No 1702/2003)~~ for the time being in force and subject to the condition 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, ~~Subpart G~~ of Regulation ~~((EU) No 748/2012 ((EC) No 1702/2003)~~ [(EU) No 748/2012], approved to produce products, parts and appliances listed in the attached approval schedule and issue related certificates using the above references.

CONDITIONS:

- 1. This approval is limited to that specified in the enclosed terms of approval, and
2. This approval requires compliance with the procedures specified in the approved production organisation exposition, and
3. This approval is valid whilst the approved production organisation remains in compliance with Annex I (Part 21) of Regulation (EU) No 748/2012 ~~((EC) No 1702/2003)~~.
4. Subject to compliance with the foregoing conditions, this approval shall remain valid for an unlimited duration unless the approval has previously been surrendered, superseded, suspended or revoked.

Date of original issue:

Date of this revision:

Revision No:

Signed:

For the competent authority: [COMPETENT AUTHORITY IDENTIFICATION]¹

EASA Form 55a issue 2.

1 Or EASA if EASA is the competent authority.

2 Delete for non-EU Member States.



<p>[MEMBER STATE]¹ A Member of the European Union²</p>	<p>Terms of Approval</p>	<p>TA: [MEMBER STATE CODE¹].21G.XXXX</p>
<p>This document is part of Production Organisation Approval Number [MEMBER STATE CODE¹].21G.XXXX issued to: Company name:</p>		
<p>Section 1. SCOPE OF WORK:</p>		
<p>PRODUCTION OF</p>	<p>PRODUCTS/CATEGORIES</p>	
<p></p>	<p></p>	
<p>For details and limitations, refer to the Production Organisation Exposition, Section xxx</p>		
<p>Section 2. LOCATIONS:</p>		
<p>Section 3. PRIVILEGES:</p>		
<p></p>		
<p>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 set forth defined in 21.A.163, Subject subject to the following:</p>		
<p><i>[keep only applicable text]</i></p>		
<p>Prior to approval of the design of the product, an EASA Form 1 may be issued only for conformity purposes.</p>		
<p>A Statement of Conformity may not be issued for a non-approved aircraft</p>		
<p>Maintenance may be performed, until compliance with the maintenance regulations is required, in accordance with the Production Organisation Exposition Section xxx</p>		
<p>Permits to fly may be issued in accordance with the Production Organisation Exposition Section yyy</p>		
<p>Date of original issue:</p>	<p>Signed:</p>	
<p>Date of this revision:</p>	<p></p>	
<p>Revision No.:</p>	<p>For [COMPETENT AUTHORITY IDENTIFICATION¹]</p>	

EASA Form 55b Issue 2.

¹ Or EASA if EASA is the competent authority.

² Delete for non-EU Member States.



Appendix XI — Letter of agreement for production without production organisation approval — EASA Form 65

Regulation (EU) No 748/2012

Letter of agreement referred to in Subpart F of Annex I (Part 21)

[MEMBER STATE]¹
A Member of the European Union²

LETTER OF AGREEMENT FOR PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

[NAME OF THE APPLICANT]
[TRADE NAME (if different)]
[FULL ADDRESS OF THE APPLICANT]
Date (Day, Month, Year)
Reference: [MEMBER STATE CODE²].21F.XXXX

Dear ~~Sirs~~, 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) of Regulation ~~[(EC) No 1702/2003]~~ (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) of Regulation ~~[(EC) No 1702/2003]~~ (EU) No 748/2012].

No of Units	P/N	S/N
AIRCRAFT		
PARTS		

The following conditions are applicable to this agreement:

- (1) It is valid whilst [Company Name] remains in compliance with Section A, Subpart A and Subpart F of Annex I (Part 21) of Regulation ~~[(EC) No 1702/2003]~~ (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 ~~S~~statement of ~~C~~conformity issued by [Company Name] under the provisions of point 21.A.130 of the above-mentioned ~~R~~Regulation shall be validated by the issuing authority of this letter of agreement in accordance with the procedure of the referenced manual.
- (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 2.

¹ Or EASA if EASA is the competent authority.

² Delete for non-EU Member States.



Draft AMC & GM to Annex I (Part 21) to Regulation (EU) No 748/2012 (Draft EASA Decision)

GM1 Annex I Definitions

For the purpose of the AMC & GM to Part 21, the following definitions are used:

Audit	<p>refers to a systematic, independent, and documented process for obtaining evidence, and evaluating it objectively to determine the extent to which requirements are complied with.</p> <p><i>Note: an audit may include an inspection</i></p>
Assessment	<p>in the context of management system performance monitoring, continuous improvement and oversight, refers to a planned and documented activity performed by competent personnel to:</p> <ul style="list-style-type: none"> • review provided evidence in combination with demonstrated behaviour against the concepts and principles of a model or standard, • analyse the achieved levels of performance in relation to the organisation's strategy and objectives, and • evaluate the ability of the organisation to reach these objectives. <p><i>Note: 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 strengths and weaknesses to drive continual improvement.</i></p>
Certificate	<p>is any certificate, approval, licence, authorisation, attestation or other document issued as the result of a certification attesting compliance with the applicable requirements.</p>
Competency	<p>is a combination of individual skills, practical and theoretical knowledge, attitude, training, and experience.</p>
Correction	<p>is the action to eliminate a detected non-compliance.</p>
Corrective action	<p>is the action to eliminate or mitigate the root cause(s) and prevent the recurrence of an existing detected non-compliance, or any other undesirable condition or situation. The proper determination of the root cause(s) is crucial for defining effective corrective actions to prevent reoccurrences.</p>
Error	<p>is an action or inaction by a person that may lead to deviations from the accepted procedures or regulations.</p> <p><i>Note: errors are often associated with occasions when a planned sequence of</i></p>

	<i>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.</i>
Hazard	is a condition or an object that has the potential to cause or contribute to an aircraft incident or accident.
Human factors	is anything that affects human performance and refers to principles that apply to aeronautical design, certification, training, operations and maintenance, and which seek safe interfaces between the human and other system components by proper consideration of human performance.
Human performance	refers to human capabilities and limitations which have an impact on the safety and the efficiency of aeronautical operations.
Near miss	is an event in which an occurrence that has to be mandatorily reported according to Regulation (EU) No 376/2014 was narrowly averted or avoided. <i>Example: a staff member, on rechecking his or her work at the end of a task, realises that one work card step was not properly carried out.</i>
Inspection	in the context of compliance monitoring and oversight, refers to an independent and documented conformity evaluation by observation and judgement that is accompanied, as appropriate, by measurements, testing or gauging, in order to verify compliance with applicable requirements. <i>Note: an inspection may be part of an audit (e.g. a product audit), but may also be conducted outside the normal audit plan, for example to verify the closure of a particular finding.</i>
Just Culture	Ref. Regulation (EU) No 376/2014, Article 2.
Organisational factor	is a latent condition that affects the effectiveness of safety risk controls, related to culture, policies, processes, resources, and the workplace of an organisation.
Oversight planning cycle	refers to the time frame within which all areas of the approval and all processes should be reviewed by the competent authority by means of audits and inspections.
Oversight programme	refers to the detailed oversight schedule that defines the number of audits and inspections, the scope and duration of each audit and inspection, including details on product audits and locations, as appropriate, to be performed by the competent authority, and the tentative time frame for performing each audit and inspection.
Preventive action	is the action to eliminate the cause(s) of a potential non-compliance, or any

	other undesirable potential situation.
Risk assessment	is an evaluation 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	is an enduring set of values, norms, attitudes, and practices within an organisation 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	refers to the predicted probability and severity of the consequences or outcomes of a hazard.

– [21.1 Competent authority](#)

GM2 Annex I Acronyms

For the purpose of the AMC & GM to Part 21, the following acronyms are used:

AFM	Aircraft flight manual
AMC	Acceptable means of compliance
CoA	Certificate of airworthiness
CRI	Certification review item
CS	Certification specification
CS-CCD	Certification specification – cabin crew data
CS-FCD	Certification specification – flight crew data
CS-GEN-MMEL	Certification specification – generic master minimum equipment list
CS-MMEL	Certification specification – master minimum equipment list
CS-MCSD	Certification specification – maintenance certifying staff data
CS-SIMD	Certification specification – simulator data
DO	Design organisation
DOA	Design organisation approval

ELOS	Equivalent level of safety
ESF	Equivalent safety finding
ETSO	European technical standard order
OP	Other party
OSD	Operational suitability data
PO	Production organisation
POA	Production organisation approval
POATL	Production organisation approval team leader
POE	Production organisation exposition
GM	Guidance material
MOC	Means of compliance
RCoA	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](#)

GM1 21.1 Competent authority

RESPONSIBILITY FOR IMPLEMENTATION

Each certificate or approval in accordance with Part 21 Section A Subparts F, G, H, I and P will normally be issued and controlled by the competent authority of the Member State in whose country 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 the corresponding processes by all competent authorities.
- (b) The operation of all the competent authorities in accordance with Part 21 and its acceptable means of compliance (AMC) and guidance material (GM).
- (c) A standardisation process established and operated by EASA to assess the standard achieved, and to provide timely advice and guidance to the competent authorities of the Member States.

As a result, the responsibility for implementation consists of the 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 other Member States the necessary confidence in the certificates or approvals granted.

– [21.1 Competent authority](#)

GM1 21.1(c) Competent authority

PERMIT TO FLY

An aircraft registered in a Member State is under the responsibility of this Member State regarding continuing airworthiness aspects. Consequently, any permit to fly under Part 21 is issued by that Member State, including any cases in which the aircraft will fly 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 will take place. The applicant is also therefore required to ensure compliance with the relevant regulations of that State.

– [21.1 Competent authority](#)



SECTION A TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

AMC1 No 1 to 21.A.3A(a)(1) Occurrence reporting Collection, investigation and analysis of data related to Flammability Reduction Means (FRM) Reliability

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

Applicants for or holders Holders of a TC type-certificate, RTtype-certificate, STtype-certificate or any other relevant approval deemed to have been issued under Part 21 and which have included a an FRM in their design should assess on an on-going ongoing basis the effects of aeroplane component failures on FRM reliability. This should be part of the system for the collection, investigation and analysis of data required by point 21.A.3A(a)(1). The applicant/holder should do the following:

- (a) Demonstrate effective means to ensure collection of FRM reliability data. The means should provide data affecting FRM reliability, such as component failures.
- (b) Unless alternative reporting procedures are approved by the Agency EASA, provide a report to the Agency EASA every six 6 months for the first five years after service introduction. After that period, continued reporting every six 6 months may be replaced with other reliability tracking methods found acceptable to the Agency EASA or eliminated if it is established that the reliability of the FRM meets, and will continue to meet, the exposure specifications of paragraph M25.1 of Appendix M to CS-25.
- (c) Develop service instructions or revise the applicable aeroplane manual, according to a schedule approved by the Agency EASA, to correct any failures of the FRM that occur in service that could increase any fuel tank's Fleet Average Flammability Exposure to more than that specified by paragraph M25.1 of Appendix M to CS-25.

– [21.A.3A Occurrence reporting](#)

AMC2 No 2 to 21.A.3A(a)(1) Occurrence reporting Collection, investigation and analysis of data related to ETOPS significant occurrences

COLLECTION, INVESTIGATION AND ANALYSIS OF DATA RELATED TO ETOPS SIGNIFICANT OCCURRENCES

- (1) Applicants for or holders Holders of a TC type-certificate, RTC type-certificate, STtype-certificate or any other relevant approval deemed to have been issued under Part 21 and which includes extended range operation with two-engined aeroplane (ETOPS) capability should implement a specific tracking, reporting and resolution system for ETOPS significant occurrences, suitable to ensure the initial and continued fleet compliance with the applicable



ETOPS reliability objectives. This system should be part of the system for collection, investigation and analysis of data required by point 21.A.3A(a).

Appropriate coordination should exist between the engine TC holder, the propeller TC holder, and the APU ETSO authorisation holder with and the aircraft TC holder to ensure compliance with the ETOPS reliability objectives.

- (2) For the tracking, reporting and resolution of ETOPS significant occurrences, refer to the latest edition of AMC 20-6 (see the AMC-20 document).
- [21.A.3A Occurrence reporting](#)

GM1 21.A.3A(a) and 21.A.3A(b) Occurrence reporting ~~The system for collection, investigation and analysis of data~~

COLLECTING SYSTEM

In the context of this requirement, the word 'Collection' refers to means the setting up of systems and procedures which will enable relevant malfunctions, failures and defects to be properly reported when they occur.

- [21.A.3A Occurrence reporting](#)

GM2 21.A.3A(b)(a) and (b) Occurrence reporting

For occurrence reporting, refer to the latest edition of AMC 20-8 (see the AMC-20 document).

- [21.A.3A Occurrence reporting](#)

GM1 21.A.3A(a)(1) and (b)(1) Occurrence reporting

MANDATORY AND VOLUNTARY OCCURRENCE REPORTING

The list below provides an overview of the main elements of an occurrence reporting system that is compliant with Regulation (EU) No 376/2014, and provides references to the relevant Articles of Regulation (EU) No 376/2014.

- (a) An occurrence reporting system that caters both for mandatory and voluntary reporting (see Articles 4 and 5).

Note 1: the mandatory reporting system established under Regulation (EU) No 376/2014 is also intended for the reporting of those additional items that qualify for mandatory reporting that are defined in Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.

Note 2: the voluntary reporting system is intended to facilitate the collection of details of occurrences that may not be captured by the mandatory system, and of other safety-related information which is perceived by the reporting organisation as indicating that there is an actual or potential hazard to aviation safety.

- (b) The designation of one or more persons to independently handle the collection, evaluation, processing, analysis and storage of details of occurrences with regard to data collection and hazard identification (see Article 6(1)).

Note 1: in agreement with their competent authority, small organisations may make use of simplified mechanisms to ensure the collection, evaluation, processing, analysis and storage of details of occurrences, possibly by sharing those tasks with other similar organisations.

Note 2: an existing internal safety-reporting scheme, which collects safety-relevant data, proposals and information, including data on potential safety issues that have not resulted in any occurrence, may serve as a basis for the mandatory and voluntary occurrence reporting system. From this pool of safety-relevant information and data collected internally, the organisation will determine whether a mandatory report is required or whether a voluntary report may be adequate.

- (c) The reporting of details of occurrences collected under the mandatory scheme as soon as possible, and in any event, no later than 72 hours after becoming aware of the occurrence (see Article 4(8) & (9));

Note 1: the reference to ‘becoming aware of’ an occurrence implies that a person in the organisation identifies the occurrence as one that falls into the category of a mandatory occurrence report — usually through being involved in the occurrence or witnessing it, but also on review or investigation of information reported to the organisation’s safety reporting scheme. In the case of design or production organisations, the 72-hour period starts at the point when the unsafe condition is identified.

In the case of automated data collection systems, the 72-hour period starts when the person responsible for the analysis of the data detected the reportable occurrence.

Note 2: the 72-hour time frame does not apply to the reporting of details of occurrences which may involve an actual or potential aviation safety risk, or to safety-related information collected under the voluntary scheme. These are to be reported in a timely manner (see Article 5 (5) & (6)).

- (d) The establishment of data quality checking processes, to ensure that the information initially collected and the data stored in the database(s) are consistent (see Article 7(3)).

Note: it is understood that data quality checking processes should address four main areas:

- errors in data entry;
- the completeness of data, specially referring to mandatory data;
- the proper use of the ADREP taxonomy;
- improving the consistency of data, notably between the information collected initially and the report stored in the database (see Article 7(3)).

- (e) The storage of occurrence reports that qualify for mandatory and voluntary reporting in one or more databases (see Article 6(5)) using formats that are standardised to facilitate information exchange and are compatible with the ECCAIRS software and the ADREP taxonomy (see Article 7(4)).

Note: organisations that are able to report through an ECCAIRS software compatible reporting system provided by their competent authority are deemed automatically compliant with the reporting system requirements in Article 7(4) and do not need to have their own ECCAIRS software compatible reporting system.

- (f) The application of the safety risk management process to occurrences:
- (1) identification of the safety hazards associated with identified occurrences or groups of occurrences reported to the competent authority (see Article 13(1));
 - (2) analysis of the related risks in terms of the probability and severity of the outcomes, as well as the assessment of risks in terms of their tolerability;
 - (3) based on the result of the risk assessment: the determination of the need for mitigation action, as required to improve aviation safety (see Article 13(2)); and
 - (4) monitoring the timely implementation and effectiveness of any mitigation action that is required (see Article 13(2)).
- (g) If the organisations identify that no potential aviation unsafe condition exists as a result of their analysis of occurrences:
- (1) they can delay the reporting to EASA up to the issuance of the final report and report the occurrence as closed on issue (data exchange). In such cases, no follow-up report should be submitted. However, the report to EASA should include confirmation and justification that no unsafe condition exists. It is requested that the organisation provides information on the cause(s) of the occurrence and on the corrective or preventive actions (if any) put in place by the organisation; or
 - (2) after an initial report was sent, the closure report should include confirmation and justification that no unsafe condition exists. It is requested that the organisation provides information on the cause(s) of the occurrence and on the corrective or preventive actions (if any) put in place by the organisation.
- This way of reporting should not be understood as an accepted deviation from the requirements of Part 21 or the requirements of Regulation (EU) No 376/2014. If, at any stage during the course of the investigation, the organisation identifies that a potential unsafe condition exists, it should be reported to EASA within 72 hours.
- (h) If the organisation identifies an actual or potential aviation safety risk as a result of its analysis of occurrences or group of occurrences, it should transmit the following information to the competent authority within 30 days from the date of notification of the occurrence to the authority (see Article 13(4)):
- (1) the latest position of the organisation as to whether the (potential) unsafe condition is confirmed;
 - (2) the occurrence analysis and first investigation results — including the cause(s) of occurrence if known;
 - (3) the containment actions that have already been defined and put in place (if any);
 - (4) a risk assessment supporting that the product can be operated safely (see GM 21.A.3B(d)(4) Defect correction — Sufficiency of proposed corrective action or the relevant DOA procedure) until the corrective actions have been defined and implemented, or 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 in the event of a complex investigation or where the services of a specialist investigator are required.

The follow-up requirements are not intended to jeopardise the quality and thoroughness of an occurrence analysis. It may be detrimental to safety if rushed in order to be completed within the encouraged 3-month period without properly establishing the root cause(s) and determining the relevant remedial action.

The final (close-out) report shall include:

- (1) the final TC holder position as to whether a (potential) unsafe condition exists;
- (2) the occurrence analysis and final investigation results — including the cause(s) of occurrence;
- (3) the corrective and preventive actions; and
- (4) a risk assessment supporting that these corrective and preventive actions allow the product to be operated safely (refer to GM 21.A.3B(d)(4) Defect correction — Sufficiency of proposed corrective action or the relevant DOA procedure).

Note: the legal obligation to provide the initial results of the analysis of the occurrence, follow-up reports and final results lies with the other organisation that is the source of the initial report. If an organisation receives a copy of a report from another organisation that initially reported the occurrence to the competent authority, depending on its contribution to the actual or potential aviation safety risk that underlies the occurrence, it may, however, be required to perform its own analysis of the issue reported, and to provide a follow-up report to the competent authority.

- (i) Safety policy and just culture: consultation of staff representatives to ensure that there is mutual agreement on and adoption of rules that describe how the 'just culture' principles are guaranteed and implemented within the organisation.

Note 1: the purpose of those rules is to ensure that none of the employees and contracted personnel that report or are mentioned in occurrence reports, either mandatory or voluntary, are subjected to any prejudice by their employer or any other organisation for which the services are provided on the basis of the information supplied by the reporter (see Article 16(9)), unless an exception applies (see Article 16(10)).

Note 2: staff representatives may be nominated either by the union(s) or by the staff themselves.

- (j) Ensuring that employees and contracted personnel are regularly provided with information concerning the analysis of, and follow-up on, occurrences for which mitigation action is taken (see Article 13(3)), while ensuring that only anonymised information is distributed.
- (k) Ensuring that personal details are only made available to staff members of their organisation other than the persons designated in accordance with point (c) if this is necessary to investigate occurrences with a view to enhancing aviation safety.

- (l) Ensuring that reports addressed to the competent authority contain at least the information listed in Annex I to Regulation (EU) No 376/2014.
- [21.A.3A Occurrence reporting](#)

GM1 21.A.3A(a)(1)(ii) and (b)(1)(i) Occurrence reporting

INTERNAL SAFETY REPORTING SCHEME

The overall purpose of the internal safety reporting scheme is to use reported information to improve the level of the safety performance of the organisation, and not to attribute blame.

The objectives of the scheme are to:

- (a) enable an assessment of the safety implications of each relevant incident (errors), safety issue and hazard reported, including previous similar issues, so that any necessary action can be initiated; and
- (b) ensure that knowledge of relevant incidents, safety issues and hazards is distributed so that other persons and organisations may learn from them.

The scheme is an essential part of the overall monitoring function, and it should be complementary to the normal day-to-day procedures and 'control' systems; it is not intended to duplicate or supersede any of them. The scheme is a tool to identify those instances when routine procedures have failed or may fail.

All safety reports that are judged to be reportable by the person submitting the report should be retained, as the significance of such reports may only become obvious at a later date.

Typical occurrences to be reported are those where aviation safety was, or could have been endangered, or which could have led to an unsafe condition. If, in the view of the reporter, an occurrence did not endanger aviation safety but, if it was repeated in different but likely circumstances, would create an unsafe situation that could lead to an accident or a serious incident, then a report should be made. What is judged to be reportable on one class of product, part, or appliance may not be the same for another, and the absence or presence of a single factor, organisational, human, or technical, can transform an occurrence into an accident or serious incident.

The collection and analysis of timely, appropriate and accurate data will allow the organisation to react to the information received, and apply the necessary action.

- [21.A.3A Occurrence reporting](#)

AMC1 21.A.3A(b)(2)(d) Occurrence reporting Reporting to the Agency

REPORTING TO EASA

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

Where 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 EASA (or the competent

authority of the Member State as required) ~~expects to~~ **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 by a full written report within 72 hours. ~~An A typical~~ example would be an uncontained engine failure resulting in damage to aircraft primary structure.

~~In all other cases in which the possible unsafe condition does not result~~ **Where the occurrence is judged to have resulted in a less** ~~an~~ immediate and ~~less~~ **more** significant hazard, ~~the~~ report submission may be delayed up to the maximum of ~~three~~ **3** days in order to provide more details.

- [21.A.3A Occurrence reporting](#)

AMC1 21.A.5 Record-keeping

- (a) The record-keeping system should ensure that all the records required by point 21.A.5 are accessible within a reasonable time. These records should be organised in a manner that ensures that there is 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) Organisations approved according to Subparts G and J of Part 21 should ensure that the following records related to the management system defined in accordance with 21.A.139 and 21.A.239 are retained as long as the organisation carries out activities related to Part 21:
 - (1) the relevant records of management system key processes as defined in points 21.A.126A, 21.A.139, 21.A.239; and
 - (2) contracts, including with partners, subcontractors and suppliers,
- (e) The organisation should ensure that copies of all the documents and supporting information developed:
 - (1) under the privileges according to points 21.A.163 and 21.A.263; or
 - (2) for major repairs, major changes, STCs, and RTCs not issued under privileges according to point 21.A.263,are retained until 3 years after the date when the organisation ceases to hold the TC, RTC, STC, ETSO authorisation, major repair design approval, or production organisation approval.
- (f) The retention period starts when the record is created or when it was last amended.
- (g) If the organisation transfers a certificate or a letter of agreement to another natural or legal person, the records related to the certificate should be transferred to the new holder.

- [21.A.5 Record-keeping](#)

GM1 21.A.5 Record-keeping

For organisations that hold or have applied for a TC, RTC, STC, ETSO authorisation, major repair design approval, permit to fly, production organisation approval or letter of agreement under Part 21, the relevant design information/data includes at least, 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; and
- compliance demonstration data.

For production organisations, the relevant records include at least:

- conformity justification data with a specific focus on the production and inspection phases; and
 - conformity attestation data (e.g. EASA Form 1, EASA Form 52).
- [21.A.5 Record-keeping](#)

AMC1 21.A.5(a) and 21.A.433(a) Record-keeping

REPAIR DESIGN

- (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 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 TC, STC, or APU ETSO authorisation 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) 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; and
 - (10) any special test requirements.
- (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 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 point 21.A.433(b).
 - (e) Repairs to engines or to APU critical parts would normally only be accepted with the involvement of the TC holder.
- [21.A.5 Record-keeping](#)

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

RECORDING AND ARCHIVING SYSTEM

Records within a design or production environment satisfy two purposes. Firstly, they are required, during the:

- design process to ensure that the configuration of products, parts, or appliances is in compliance with the certification basis; or
- production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle.

Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all the prescribed stages of the design or production process have been satisfactorily completed.

Therefore, the approved design or production organisation or natural or legal person who produces products, parts and appliances under Part 21 Subpart G are required to implement a system for the compilation and retention of records during all stages of design or production, covering short-term and long-term records 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 21.A.139, 21.A.239 or in the manual required by point 21.A.125A(b), as appropriate.

All forms of recording media are acceptable (paper, film, magnetic, etc.) provided they can meet the required duration for archiving under the conditions provided.

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);
- control access to the data and provide effective protection from 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 to the following:

- production data which 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.
 - design data which supports the compliance of a product, part, or appliance is kept for not less than 3 years after the surrender or revocation of the TC, RTC, STC, major repair or ETSO authorisation. This may include minor changes and minor repairs to those TCs, RTCs, STCs, major repairs, or ETSO authorisations; and
 - data that is considered essential for continuing airworthiness is kept throughout the operational life of the product, part or appliance;
- for organisations approved according to Subparts G and J of Part 21, 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 is to retain the data record (organisation or partner, supplier or subcontractor) as well as the method for surveillance of the recording/record-keeping system of the partners, suppliers or subcontractors; and
- for natural or legal persons who produce items under Part 21 Subpart F, the data related to supplied parts may be retained by the supplier if the supplier has a system agreed under Part 21, Section A, Subpart F, by the competent authority. The production organisation manufacturer, in each case, is required to define the archiving period and satisfy itself and the competent authority that the recording media are acceptable.
- [21.A.5 Record-keeping](#)

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

RECORD OF PERSONNEL INVOLVED IN DESIGN OR PRODUCTION

- (a) The following should be the minimum information to be recorded for each person who exercises the privileges of an organisation approved according to Subparts G and J of Part 21 according to points 21.A.163 or 21.A.263, or who carries out the independent monitoring of compliance and adequacy according to point 21.A.139(f) and 21.A.239(f):
- (1) name
 - (2) date of birth
 - (3) basic training and standard attained
 - (4) specific training and standard attained
 - (5) continuation training (if appropriate)
 - (6) experience
 - (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



- (b) The record may be kept in any format and should be controlled by an internal procedure of the organisation. This procedure forms part of the management system.
 - (c) The person should be given reasonable access on request to his or her own records in respect of provisions defined by Regulation (EU) 2016/679.
 - (d) A production organisation should keep the record for at least 3 years after the:
 - (1) person has ceased employment with the organisation or has changed his or her position in the organisation, or the withdrawal of the authorisation in the case of certifying staff, whichever is the sooner.
 - (2) the organisation surrendered the TC, RTC, STC, ETSO authorisation, major repair design approval, or production organisation approval.
 - (e) A design organisation should retain the records as long as it carries out activities related to Part 21.
- [21.A.5 Record-keeping](#)

GM1 21.A.9 Investigations

ARRANGEMENTS

The arrangements made by the applicant for, or holder of a TC, RTC, STC, ETSO authorisation, major repair design approval, permit to fly, production organisation approval or 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, flight and ground tests and inspections of completed products, parts or appliances designed or produced.

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

The arrangements are required to enable the organisation to give positive assistance to the competent authority and cooperate in performing the investigation during both the initial assessment and for the subsequent surveillance.

Cooperation in performing investigations refers to the competent authority having been given full and free access to the facilities and to any information relevant to demonstrate compliance with the Part 21 requirements, and assistance (personnel support, records, reports, computer data, etc. as necessary).

Assistance to the competent authority includes all the appropriate means associated with the facilities of the organisation to allow the competent authority to perform these investigations, such as the availability of a meeting room, office and personnel support, documentation and 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 personnel are required to be nominated to facilitate this, including suitable representative(s)



to accompany competent authority staff during visits, not only at the organisation's own facilities, but also at subcontractors, partners or suppliers.

- [21.A.9 Investigations](#)



SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

AMC1 No 1 to 21.A.122 Eligibility — Link between design and production

LINK BETWEEN DESIGN AND PRODUCTION

An 'arrangement' is considered suitable if it is documented and satisfies the competent authority that ~~co-ordination~~ **coordination** is satisfactory.

To achieve satisfactory **coordination** ~~co-ordination~~, the documented arrangements must at least define the following aspects, irrespective of whether the design organisation and the person producing or intending to produce under Part 21 Subpart F are separate legal entities or not:

- (a)~~1~~ The responsibilities of a design organisation 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)~~2~~ The responsibilities and procedures of the **production organisation** ~~manufacturer~~ for receiving, managing and using the applicable design data provided by the design organisation;
- (c)~~3~~ The responsibilities and procedures of the **production organisation** ~~manufacturer~~ for developing, where applicable, its own manufacturing data in compliance with the applicable design data package;
- (d)~~4~~ The responsibilities of the **production organisation** ~~manufacturer~~ 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.);
- (e)~~5~~ The scope of the arrangements covering Subpart F requirements, in particular: **points** 21.A.126(a)(4), ~~and~~ 21.A.129(d) and ~~(f)~~ 21.A.3A and any associated GM or AMC;
- (f)~~6~~ The responsibilities of the **production organisation** ~~manufacturer~~, in the case of products prior to type certification, to assist a design organisation 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)~~7~~ The procedures to deal adequately with production deviations and non-conforming parts;
- (h)~~8~~ The means to achieve adequate configuration control of manufactured parts, to enable the **production organisation** ~~manufacturer~~ to make the final determination and identification for conformity or airworthiness release and eligibility status;
- (i)~~9~~ The identification of responsible persons/offices who ~~controls~~ **control** the above; and
- (j)~~10~~ 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~~ **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 production organisation. This is acceptable, provided that an effective link between the design approval holder and the production organisation can be maintained to satisfy the intent of point 21.A.122.

When the design organisation and the production organisation manufacturer 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).

AMC1 21.A.124 Application

An applicant should submit to the competent authority an EASA Form 60 (see below) completed in all blocks.

EASA Form 60 Application for agreement of production under Part 21 Subpart F	
<i>Competent authority of an EU Member State or EASA</i>	
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)/ design organisation(s) where different from Block 1. :	
7. Human resources:	



8. Name of the person signing the application:	
<div style="text-align: center; margin-top: 100px;">  Date </div>	<div style="text-align: center; margin-top: 100px;">  Signature </div>

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 stated in Block 1.

Block 4: this block should include further details of the manufacturing activities under the approval for the addresses indicated in Block 3. The 'Identification' block should indicate the products, parts or appliances 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 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 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 authorised to sign the application.

GM 21.A.124(a) Application – Application form

~~EASA Form 60 (see AMC 21.B.120(c)(1)) should be obtained from the competent authority and completed by the applicant.~~

~~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.~~

~~The completed form should be forwarded to the competent authority.~~



AMC1 21.A.124A Alternative means of compliance

In order to demonstrate that the requirements are met, a risk assessment should be completed and documented. The result of this risk assessment should demonstrate that the alternative means of compliance reaches a level of safety that is acceptable to the competent authority.

- [21.A.124A Alternative means of compliance](#)

~~GM No 1 to 21.A.158(a) Uncontrolled non-compliance with applicable design data~~

~~An uncontrolled non-compliance with applicable design data is a non-compliance:~~

- ~~— that cannot be discovered through systematic analysis; or~~
- ~~— that prevents identification of affected products, parts, appliances, or material.~~

~~GM No 2 to 21.A.158(a) Examples of level one findings~~

~~Examples of level one 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

CAUSAL ANALYSIS

It is important that the causal 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 a 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 (regulatory, human factors, organisational factors, technical, etc.) in addition to the direct factors.

A narrow focus on single events or failures, or the use of a simple, linear model, such as fault tree, to identify the chain of events that led to the non-compliance may not properly reflect the complexity of the issue, and, it therefore bears the risk that important factors that need to be addressed in order to prevent reoccurrences will be ignored.

Such an inappropriate or partial causal analysis often leads to defining ‘quick fixes’ that only address the symptoms of the non-conformity. A peer review of the results of the causal analysis may increase its reliability and objectivity.

A system description of the organisation that considers the organisational structures, processes and their interfaces, procedures, staff, equipment, facilities and the environment in which the organisation operates, will support both effective causal (reactive) and hazard (proactive) analysis.

- [21.A.125B Findings](#)



GM 21.A.126(b)(6) Production inspection system — Recording and record keeping

1. — Records within a production environment satisfy two purposes. Firstly, they should, during the production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.

Therefore, the person producing under Part 21 Subpart F should implement a system for the compilation and retention of records during all stages of manufacture, covering short-term and long-term records appropriate to the nature of the product and its production processes.

The management of such information should be subject to appropriate documented procedures in the Manual required by 21.A.125A(b).

All forms of recording media are acceptable (paper, film, magnetic ...) provided they can meet the required duration for archiving under the conditions provided.

2. — The related procedures should:

2.1 — Identify records to be kept.

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

2.3 — Control access and provide effective protection from deterioration or accidental damage.

2.4 — Ensure continued readability of the records.

2.5 — Demonstrate to the competent authority proper functioning of the records system.

2.6 — Clearly identify the persons involved in conformity determination.

2.7 — Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:

a) — Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate.

b) — Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.

2.8 — Data related to supplied parts may be retained by the supplier if the supplier has a system agreed under Part 21 Section A Subpart F by the competent authority. The manufacturer should, in each case, define the archiving period and satisfy himself or herself and the competent authority that the recording media are acceptable.

SUBPART G — PRODUCTION ORGANISATION APPROVAL FOR PRODUCTS, PARTS AND APPLIANCES

GM 21.A.134 Application — Application form and manner

EASA Form 50 (see ~~AMC 21.B.220(c)~~) should be obtained from the competent authority, and completed by the accountable manager of the organisation.

The completed form, an outline of the production organisation exposition, and details of the proposed terms of approval are to be forwarded to the competent authority.

AMC1 21.A.134 Application

An applicant for a POA should submit to the competent authority an EASA Form 50 (see below) completed by the applicant.

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	
<i>Competent authority of an EU Member State or EASA</i>	
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 proposed activities at the item 3 addresses	
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:	



<div style="background-color: #cccccc; width: 100px; height: 15px; margin: 0 auto;"></div> Date	<div style="background-color: #cccccc; width: 100px; height: 15px; margin: 0 auto;"></div> Signature of the accountable manager
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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 use of a logo may be indicated 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 4. 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, accompanied by the corresponding EASA Form 4. 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.

AMC1 21.A.134A Alternative means of compliance

(a) In order to demonstrate that the requirements are met, a risk assessment should be completed and documented. The result of this risk assessment should demonstrate that the alternative means of compliance reaches a level of safety that is acceptable to the competent authority.

(b) The result of the risk assessment forms an integral part of the management system records to be managed in accordance with point 21.A.139.

- [21.A.134A Alternative means of compliance](#)

GM1 21.A.139(c) Production management system

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 and contribution to aviation safety, it 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 that involves all the personnel as active contributors to the safety of the final product, part or appliance in accordance with AMC1.21.A.139(c)(1).

The requirements established 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 transposes Appendix 2 to ICAO Annex 19. The EU approach aims at facilitating the introduction of safety management systems into production organisations by inserting the components of safety management into Part 21, thus building upon the existing management systems.

Therefore, the approach aims at encouraging 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, where the organisation holds multiple organisation certificates issued under Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof (according to point 21.A.139(h)), the organisation may choose to implement a single management system to cover all of its activities. An integrated management system may not only be used to capture multiple certification requirements, but also to cover other business management systems such as quality, 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 and 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 products, parts and appliances level or at the organisational level:

- If an organisation produces parts that have a limited effect on safety, it may limit the scope of its safety management system to cover only the areas that contribute to safety (e.g. the criticality will be different for the production of parts such as safety belts, or major elements such as an autopilot system).
- 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, will require more efficient safety barriers).

As a consequence, scalability should be a function of the inherent safety risk capability of the organisation. For instance:

- the risk assessment model used may be very simple in small organisations where the identified hazards are easy to mitigate;
- expert judgement might be sufficient to measure the efficiency of safety barriers;
- the collection of data, safety information and occurrences might be very limited;
- there might be no need for software and tools to manage the SMS;
- the communication policy might be limited.

However, small organisations that are involved in activities that entail significant aviation safety risks might require greater SMS resources.

- [21.A.139 Production management system](#)

AMC1 21.A.139(c) Production management system

SAFETY MANAGEMENT ELEMENT

An organisation that has a safety management element, compliant with the SMS Industry Standard 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organizations' SM001 Issue A - September 17th, 2018¹, should be considered compliant with the EU framework for aviation safety management as described in GM1 21.A.139(c), provided that compliance with the following additional topics, as appropriate, is demonstrated.

Point	Paragraph of SMS Industry Standard SM001 Issue A - September 17 th , 2018	Additional topics
21.A.3A	§6.1.1.1 Safety Policy §6.2.1 Hazard identification §6.2.2 Safety Risk Assessment and Mitigation §6.3 Safety Assurance §6.4.2 Safety Communication §7 Interfaces between organizations	Reporting to EASA as per 21.A.3A (b)(3) (refer to AMC 20-8 and AMC1 21.A.3A(d) as acceptable means of compliance) Compliance with Regulation (EU) No 376/2014 (refer to GM1 21.A.3A(a)(1) and (b)(1) as a summary of the requirements)
21.A.5	Not available	Record-keeping (refer to the AMC and GM related to 21.A.5 as acceptable means of compliance and guidance)
21.A.139	(b) §6.1.2 Safety Accountability and Responsibilities §6.1.3 Appointment of Key Safety Personnel §6.2 Safety Risk Management (system description)	none

¹ https://www.asd-europe.org/sites/default/files/atoms/files/SMS%20Standard_final%20issue%20A_20180917.pdf

	<p>§6.3.2 Management of Change</p> <p>§6.3.3 Continuous Improvement of the SMS</p> <p>§6.4.1 Training and Education</p>	
	<p>§1 Introduction</p> <p>§6.1.1.1 Safety Policy</p> <p>§6.1.1.2 Safety Objectives</p> <p>§6.1.2 Safety Accountability and Responsibilities</p> <p>§6.1.3 Appointment of Key Safety Personnel</p> <p>§6.2 Safety Risk Management</p> <p>§6.2.1 Hazard identification</p> <p>§6.2.2 Safety Risk Assessment and Mitigation</p> <p>§6.3 Safety Assurance</p> <p>§6.3.1 Safety Performance Monitoring and Measurement</p> <p>§6.3.2 Management of Change</p> <p>§6.3.3 Continuous Improvement of the SMS</p> <p>§6.4 Safety Promotion</p> <p>§6.4.1 Training and Education</p> <p>§6.4.2 Safety Communication</p> <p>§7 Interfaces between organizations</p>	<p>Human factors in the safety policy (refer to AMC1 21.A.139(c)(1) as acceptable means of compliance)</p> <p>Functions of safety review board & safety action group (refer to AMC1 21.A.139(c)(2) and GM1 21.A.139(c)(2) for acceptable means of compliance and guidance)</p> <p>Interface risk management in case of subcontracts (refer to AMC1 21.A.139(c)(3) for acceptable means of compliance)</p> <p>Systematic management of all changes, not limited to those having substantive impact on safety management (refer to AMC1 21.A.139(c)(4)(ii) for acceptable means of compliance)</p> <p>More structured safety training (refer to AMC1 21.A.139(c)(5)(i) for acceptable means of compliance)</p>
	<p>(c)</p>	
	<p>(e)</p> <p>§6.1.5 SMS Documentation</p> <p>§6.4.2 Safety Communication</p>	<p>None</p>
	<p>(f)</p> <p>§6.3.1 Safety Performance Monitoring and Measurement (paragraph title: Need for additional measurement)</p>	<p>Independency of the monitoring of compliance and adequacy as per 21.A.139(f). Refer to AMC1 21.A.139(f) for acceptable means of compliance)</p>
	<p>(g)</p> <p>§7.3 Corporate SMS approach</p>	<p>None</p>
21.A.143	<p>§6.1.5 SMS Documentation</p>	<p>None</p>
21.A.145(c)	<p>§6.1.1.1 Safety Policy</p> <p>§6.1.2 Safety Accountability and Responsibilities</p> <p>§6.1.3 Appointment of Key Safety Personnel</p>	<p>Identification of managers responsible for the essential functions (refer to AMC1 21.A.145(c)(2) for acceptable means of compliance)</p> <p>Definition of competency of personnel (refer to AMC2 21.A.145(c)(2) for</p>



	§6.4.1 Training and Education	acceptable means of compliance)
21.A.147	§6.3.2 Management of Change	Systematic management of all changes, not limited to those having substantive impact on safety management (refer to AMC1 21.A.139(c)(4)(ii) for acceptable means of compliance)

- [21.A.139 Production management system](#)

AMC1 21.A.139(c)(1) Production management system

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, and encourage personnel to report production-related errors, incidents and hazards;
- (3) be endorsed by the accountable manager;
- (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 commitments to:

- (1) comply with all the applicable legislation, meet all the applicable requirements, and adopt practices that work towards improving safety standards;
- (2) provide the necessary resources for its implementation;
- (3) apply human factors principles;
- (4) enforce safety as a primary responsibility of all managers; and
- (5) apply 'just culture' principles, and, in particular, to not make available or use any personal information on occurrences:
 - (i) to attribute blame or liability for actions, omissions or decisions taken by personnel 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, and 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 maintain or continuously improve the overall effectiveness of the management system;



- (3) be communicated throughout the organisation; and
- (4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.

– [21.A.139 Production management system](#)

GM1 21.A.139(c)(1) Production management system

SAFETY POLICY

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, improve safety levels in all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident as far as is reasonably practicable. It 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 the issuance of 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.

For organisations that have their principal place of business in a Member State, Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).

– [21.A.139 Production Management System](#)

AMC1 21.A.139(c)(2) Production management system

SAFETY MANAGEMENT ELEMENT — ORGANISATION AND ACCOUNTABILITIES

(a) The management system should encompass safety by defining a structure that is able to administrate and maintain the processes and functions of the safety management system as described in point 21.A.139(c). The accountable manager should establish and maintain functions which act as:

- (1) the safety manager; and
- (2) a high-level committee that considers matters of strategic safety, sometimes referred to as the 'safety review board', depending on the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment that is agreed by the competent authority.

(b) The safety review board function should monitor:

- (1) the safety performance against the safety policy and objectives;
- (2) whether any safety action is taken in a timely manner; and
- (3) the effectiveness of the organisation's management system processes.

(c) The accountable manager may also establish and maintain a function, referred to as the 'safety action group', in support of the two functions above.

– [21.A.139 Production management system](#)



GM1 21.A.139(c)(2) Production management system

SAFETY MANAGEMENT ELEMENT — ORGANISATION AND ACCOUNTABILITIES

The organisation may define its structure in the manner that best fits its needs. The following is an example of a possible organisation that complies with the safety management element of the production management system.

The role of the person who assumes, or persons who assume, the function of safety manager should include, but not be limited, to:

- support of the accountable manager in ensuring that the activities described in point 21.A.139(c) are performed;
- advice to the accountable manager on safety matters; and
- provision of periodic reports on safety performance to the accountable manager and to the safety review board.

Regardless of the organisational set-up, it is important for the safety manager or a designated person to remain the unique focal point for the development, administration, and maintenance of the organisation's safety management system.

When established by the accountable manager, the function of the safety review board is to:

- ensure that appropriate resources are allocated to achieve the established safety objectives;
- review the results of compliance monitoring; and
- monitor the implementation of the related corrective and preventive actions.

It is composed of heads of functional areas, and it is chaired by the accountable manager.

The role of the safety action group is to:

- analyse specific events;
 - assess mitigation measures;
 - monitor the safety performance of the organisation;
 - define actions to control risks to an acceptable level;
 - assess the impact of organisational changes on safety;
 - ensure that safety actions are implemented within the agreed timescales; and
 - review the effectiveness of previous safety actions and safety promotion.
- [21.A.139 Production management system](#)

AMC1 21.A.139(c)(3) Production management system

SAFETY RISK MANAGEMENT — INTERFACES BETWEEN ORGANISATIONS

- (a) Safety risk management processes should specifically address the planned implementation of, or participation of the organisation in, any complex arrangements (such as when the PO subcontracts work to multiple organisations).



- (b) Hazard identification and risk assessment should start with the identification of all the parties involved in the arrangement, including independent experts and non-approved organisations. This extends to the overall control structure, assessing in particular the following elements across all subcontract levels and all parties within these arrangements:
- (1) coordination and interfaces between the different parties;
 - (2) applicable procedures;
 - (3) communication between all the parties involved, including the reporting and feedback channels;
 - (4) task allocation, responsibilities and authorities; and
 - (5) the qualifications and competency of key personnel with reference to point 21.A.145.
- (c) Safety risk management should focus on the following aspects:
- (1) clear assignment of accountability and allocation of responsibilities;
 - (2) only one party should be responsible for a specific aspect of the arrangement, with no overlapping or conflicting responsibilities, in order to eliminate coordination errors;
 - (3) the existence of clear reporting lines, both for occurrence reporting and progress reporting; and
 - (4) the possibility for staff to directly notify the organisation of any hazard that suggests that there is an obviously unacceptable safety risk as a result of the potential consequences of this hazard.
- (d) Regular communication should be ensured between all the parties to discuss work progress, risk mitigation actions, changes to the arrangements, as well as any other significant issues.
- (e) For subcontracted activities, interfaces and communication channels are also needed for the purposes of the internal safety reporting scheme (point 21.A.3A).
- [21.A.139 Production management system](#)

AMC1 21.A.139(c)(3) and (4) Production management system

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 in particular focus on the hazards that may generate a non-conformity of the product, part or appliance that is produced.
- (b) Safety risk management processes
- (1) A safety risk management process should be developed and maintained that ensures that the safety risks are:
 - (i) analysed (in terms of their probability and the severity of the consequences of hazards and occurrences);

- (ii) assessed (in terms of their tolerability); and
 - (iii) controlled (in terms of the mitigation of risks to an acceptable level).
- (2) Within the safety risk management process, the organisation should specify who has the authority to make decisions regarding the tolerability of safety risks, in accordance with (b)(1)(ii).
- (c) Regardless of the approval status of the subcontracted organisations, the production organisation is responsible for ensuring that all subcontracted activities are subject to hazard identification and safety risk management, as required by point 21.A.139(c)(3), and for monitoring of their compliance and adequacy, as required by point 21.A.139(f).
- (d) Internal investigation
 - (1) In line with its just culture policy, the organisation should define how to investigate incidents such as errors or near misses, in order to understand not only what happened, but also how it happened, to prevent or reduce the probability and/or consequences of any future recurrences (refer to AMC3 21.A.3A(a)(1) and (b)(1)).
 - (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) The organisation should establish, implement and maintain a process by which the safety performance of the organisation is continuously verified against the safety policy and safety objectives.
 - (2) This process may include, as appropriate to the size, nature and complexity of the organisation:
 - (i) safety reporting that also addresses the status of compliance with the applicable requirements;
 - (ii) safety reviews, including trend reviews, which would be conducted during introduction and deployment of new products and their components, new equipment/technologies, the implementation of new or changed procedures, or in situations 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 periodically assess the status of safety risk controls; and
 - (iv) safety surveys that examine particular elements or procedures of a specific area, such as the problem areas identified, or any bottlenecks in daily production management activities, the perceptions and opinions of the production management personnel, and any areas of dissent or confusion.
- (f) Management of change

The organisation should manage any safety risks that are related to a change. The management of change should be a documented process to identify any external or internal

change that may have an adverse effect on safety. It should make use of the organisation's existing hazard identification, risk assessment and risk mitigation processes.

(g) Continuous improvement

The organisation should continuously seek to improve its safety performance and the effectiveness of its management system. Continuous improvement may be achieved through:

- (1) compliance monitoring and audits carried out by external organisations;
- (2) assessments, including assessments of the effectiveness of the safety culture and management system, in particular to assess the effectiveness of the safety risk management processes;
- (3) staff surveys, including cultural surveys, that can provide useful feedback on how engaged personnel are with the management system;
- (4) monitoring incidents and their recurrences;
- (5) evaluating safety performance indicators and reviewing all the available safety performance information; and
- (6) identifying the lessons learned.

– [21.A.139 Production management system](#)

GM1 21.A.139(c)(4)(ii) Production management system

MANAGEMENT OF CHANGE

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. can result in the inadvertent introduction of new hazards, which can expose the organisation to new or greater risks. Effective organisations seek to improve their processes, with conscious recognition that changes can expose the organisation to potentially latent 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. Disciplined application of change management can maximise the effectiveness of the change, engage staff, and minimise the risks inherent in change.

A change may have the potential to introduce new human factor issues, or to exacerbate pre-existing ones. For example, changes in computer systems, equipment, technology, personnel changes, including changes in management personnel, procedures, the work organisation, or work processes are likely to affect performance.

Effective management of change is supported by the following:

- Implementation of a process for formal 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.
- Identification of changes that are likely to occur in business, which would have a noticeable impact on:
 - resources — material and human;

- management direction — policies, processes, procedures, training; and
 - management control.
- Safety cases/risk assessments that are aviation-safety focused.
- The involvement of key stakeholders in the change management process as appropriate.
- [21.A.139 Production management system](#)

AMC1 21.A.139(c)(4)(ii) Production management system

MANAGEMENT OF CHANGE

- (a) Regardless of the magnitude of a change, large or small, there should always be proactive consideration of the safety implications. This is primarily the responsibility of the team that proposes or implements the change. However, a change can only be successful if all the personnel affected by the change are engaged and involved, and they participate in the process. The magnitude of a change, its safety criticality, and its potential impact on human performance should be assessed in any change management process.
- (b) Special consideration, including human factor issues, should be given to the transition period during which the change will become effective. In addition, the activities utilised to manage these issues should be integrated into the change management plan. The purpose of integrating human factors into the management of change is to minimise the potential risks by specifically considering the impact of the change on the people within a system.
- (c) During the process for the management of a change, previous risk assessments and existing hazards should be reviewed for their possible effects.
- [21.A.139 Production management system](#)

AMC1 21.A.139(c)(5) Production management system

SAFETY COMMUNICATION

- (a) The organisation should establish communication with its personnel, as appropriate for their safety responsibilities, about safety matters that:
- (1) ensures that all the personnel are aware of the safety management activities;
 - (2) conveys safety-critical information, especially related to assessed risks and analysed hazards;
 - (3) explains why particular actions are taken; and
 - (4) explains why safety procedures are introduced or changed.
- (b) Regular meetings with personnel, as appropriate for their safety responsibilities, during which information, actions, and procedures are discussed, may be used to communicate safety matters.
- [21.A.139 Production management system](#)



GM1 21.A.139(c)(5) Production management system

SAFETY PROMOTION

Safety training, combined with safety communication and information sharing, is a part of safety promotion.

Safety promotion activities are intended to:

- support the organisation's policies;
- encourage a positive safety culture;
- create an environment that is favourable to the achievement of the organisation's safety objectives;
- support organisational learning;
- support the implementation of an effective safety reporting scheme; and
- support the development of a just culture.

Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation actions.

- [21.A.139 Production management system](#)

AMC1 21.A.139(c)(5)(i) Production management system

SAFETY TRAINING

- (a) The production staff, as described in points 21.A.145(c)(2) and (3), should receive initial and recurring safety training, as appropriate for their responsibilities, to ensure their continued competency, including safety management principles, the associated safety objectives and human factors. The organisation should assess the category of staff for which this training should be provided.
- (b) Adequate records of all the safety training provided should be kept in accordance with point 21.A.5.
- (c) Initial training that is compliant with the organisation's training standards should be provided to each member of the personnel within 6 months of joining the organisation, unless their competency assessment justifies that there is no need for such a training. Personnel who are recruited from another organisation and temporary staff should be assessed for whether they need to receive any additional safety management training.
- (d) Recurrent safety training should be delivered either as a dedicated course, or else integrated within other training. It should be of an appropriate duration in each 2-year period, in relation to the relevant compliance monitoring audit findings and any other internal/external sources of information that are available to the organisation on safety, and in production.

- [21.A.139 Production management system](#)

GM1 21.A.139(c)(5)(i) Production management system

SAFETY TRAINING

The main purpose of the safety training programme is to:

- support safety management policies and processes, including human factors training; and
- ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.

Each organisation should adapt the syllabus to its own needs. Typically, at least the following items should be included:

- The organisational roles and responsibilities related to safety, including the hazard identification and risk management processes, and to fostering a positive safety culture;
- Safety objectives and the associated safety performance indicators;
- Human factors principles, including human performance and limitations;
- Legislation, where applicable;
- Safety reporting systems and investigations; and
- Safety issues.

The purpose of the recurrent safety training is:

- primarily to ensure that staff remain current, notably on changes to SMS principles, processes and procedures; and
- also to share feedback on safety issues that are relevant to the organisation or lessons learned.

The training staff should have sufficient knowledge and experience to teach the topics at the required level, with the skills to influence attitudes and behaviours.

- [21.A.139 Production management system](#)

AMC1 GM No 1 to 21.A.139(d)(a) Production management system Quality system

QUALITY SYSTEM ELEMENT

The quality system is an organisational structure, included in the production management system, with responsibilities, procedures, processes, and resources which 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)(b)(1) 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 manager responsible for ensuring that the quality system is implemented and maintained should be identified.

The competent authority will verify on the basis of the exposition and by appropriate investigations that the production organisation has established and can maintain their documented quality system.

- [21.A.139 Production management system](#)

AMC1 GM 21.A.139(d)(2)(b)(1) Production management system

Quality System – Elements of the quality system

QUALITY SYSTEM — ELEMENTS OF THE QUALITY SYSTEM

- (1)- The control procedures covering the elements of [point 21.A.139\(d\)\(2\)\(b\)\(1\)](#) 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 ~~Subpart G~~:
 - Mandatory and voluntary Occurrence Reporting as required by [point 21.A.3A](#) and continued airworthiness as required by [point 21.A.165\(e\)](#)
 - Control of work occasionally performed (outside the POA facility by POA personnel)
 - ~~Co-ordination~~ 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
 - Personnel training and qualification procedures especially for certifying staff as required in [point 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 ~~Subpart G~~ of Part 21. In all cases, the competent authority will still need to be satisfied that compliance with Part 21 ~~Subpart G~~ is established.
 - [21.A.139 Production management system](#)



GM1 ~~No 2 to~~ 21.A.139(d)(1)(a) Production management system Quality System – Conformity of supplied parts or appliances

CONFORMITY OF SUPPLIED PARTS OR APPLIANCES

The 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 AMC ~~No 1 or No 2 to~~ point 21.A.139(d)(2)(ii)(b)(1)(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 supplier 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 inspection~~ 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 ~~inspection~~ inspections /tests performed by the supplier if it can establish that:

- the personnel responsible ~~in charge of~~ 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 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 released ~~under a suppliers~~ in accordance with the supplier's privileges defined in point 21.A.163 privileges.

A supplier who does not hold a POA is considered as to be a sub-contract subcontract or under the direct control of the POA quality system.

The POA holder retains direct responsibility for inspections/tests carried out either at its own facilities or at the supplier's facilities.

- [21.A.139 Production management system](#)

~~AMC No 1 to 21.A.139(d)(2)(ii)(b)(1)(ii) Production management system Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using documented arrangements with other parties for assessment and surveillance of a supplier.~~

VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT AND CONTROL — PRODUCTION ORGANISATION APPROVAL (POA) HOLDER USING DOCUMENTED ARRANGEMENTS WITH OTHER PARTIES FOR ASSESSMENT AND SURVEILLANCE OF A SUPPLIER

1. General

Note:

~~For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as 'suppliers', regardless of whether or not they hold a POA and audit and control is hereafter referred to as 'surveillance'.~~

The production organisation is required by Part 21 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 (OP OPs), such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the 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 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 OP 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. ~~Approval by the competent authority~~ Reserved

~~Implementing or changing procedures for using OP for supplier assessment and surveillance is a significant change to the quality system and requires approval in accordance with 21.A.147.~~



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 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 frequency 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' suppliers assessment and surveillance is conducted on-site by the OP.
 - (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 working works in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the other party assessment and surveillance by the other party, the items (ii) and (iv) shall be deemed to be complied with.
- (4) A definition that states to what scope extent the OP will conduct surveillance of the suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, 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-conformities 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 ~~investigation~~ investigations in accordance with ~~point 21.A.9~~ 21.A.157 to include OP activities.

– [21.A.139 Production management system](#)

AMC No 2 to 21.A.139(d)(2)(ii) ~~(b)(1)(ii)~~ Production management system Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using other party supplier certification

VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT AND CONTROL — PRODUCTION ORGANISATION APPROVAL (POA) HOLDER USING OTHER PARTY SUPPLIER CERTIFICATION

1. General

Note:

~~For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as 'suppliers', regardless of whether or not they hold a POA and audit and control is hereafter referred to as 'surveillance'.~~

Other party supplier certification is a method whereby a supplier contracts with an appropriately recognised or accredited Other Party (OP) for the purpose of obtaining a certification from that OP. Certification indicates that the supplier has satisfactorily demonstrated ~~to meet~~ 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 ~~Part 21~~ 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 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. ~~Approval by the competent authority~~ Reserved

~~Implementing or changing procedures for using suppliers that are certified by an OP is a significant change to the quality system and requires approval in accordance with 21.A.147.~~

3. Conditions and criteria for using supplier certification for the 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~~ Procedures required for use of supplier certification for the supplier assessment and surveillance should be consistent with ~~the~~ other procedures of the POA holders' quality system.

(c) ~~The procedures~~ Procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:

(1) ~~A listing~~ Listing of the ~~OPs~~ OP 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 ~~frequency~~ 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' ~~surveillance~~ is conducted on-site 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.



- (vii) Verification that the OP has access to the applicable proprietary data to the level of detail necessary to survey suppliers' suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working works in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes the requirements for the OP certification, the items (ii), (iv) and (v) shall be deemed to be complied with:

- (4) A definition that states to what scope extent the OP will conduct suppliers supplier surveillance on behalf of the POA holder. If the OP partly replaces surveillance by the POA holder in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
 - (5) Procedures that ensure that the POA is aware of the loss of an existing certification.
 - (6) Procedures that ensure that the POA holder is aware of any non-conformities and has access to detailed information of on these non-conformities.
 - (7) Procedures to evaluate the consequences of non-conformities and take appropriate actions.
- (d) The POA should make arrangements that allow the competent authority to make investigation investigations in accordance with point 21.A.9 21.A.157 to include OP activities.

- [21.A.139 Production management system](#)

GM1 21.A.139(d)(2)(ii) Production management system

VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT AND CONTROL

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', regardless of whether or not they hold POAs, and audit and control is hereafter referred to as 'surveillance'. Implementing or 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.

- [21.A.139 Production management system](#)

AMC1 21.A.139(e) Production management system

DOCUMENTATION

- (a) The manual or the exposition that is used to document the management system, should be the key instrument used by an organisation to internally communicate its approach to management systems.
- (b) The organisation may document its safety policy, safety objectives and all the safety management system key processes (as required in point 21.A.139(a)(1)) in a separate manual (e.g. a safety management manual or a management system manual) or in its exposition. Organisations that hold multiple organisation approvals, issued on the basis of Regulation (EU)

2018/1139 and the delegated and implementing acts adopted on the basis thereof, may prefer to have separate manuals in order to avoid duplication.

- (a) The organisation may also choose to place in separate documents (e.g. policy documents, procedures) some of the information that is required to be documented.
- (b) If any required information is placed in a separate document, the manual or the exposition should contain adequate references to that document. Any such referenced documents should be considered integral parts of the production management system documentation.

– [21.A.139 Production management system](#)

AMC1 21.A.139(f) Production management system

INDEPENDENT MONITORING OF COMPLIANCE AND ADEQUACY

- (a) The function that carries out independent monitoring of the compliance and adequacy of the documented procedures of the production management system should ensure that:
 - (1) the activities of the organisation are monitored for their adequacy and compliance with the applicable requirements and with any additional requirements as established by the organisation, and that these activities are carried out properly under the supervision of the nominated persons referred to in point 21.A.145(c)(2);
 - (2) an objective review of the complete set of production-management-related activities is provided through independent audits;
 - (3) the independence of an audit is established by always ensuring that audits and inspections are carried out by personnel who are not responsible for the function, procedure or products that they audit or inspect;
 - (4) an audit plan is established to show when and how often the activities required by Part 21 will be audited;
 - (5) the audit cycle is determined through a risk assessment agreed by the competent authority and that does not exceed the applicable audit planning cycle according to point 21.B.222. That determination should consider at least:
 - (i) the criticality of the items checked during the audit; and
 - (ii) the safety performance of the organisation, including any previous findings and root causes;
 - (6) when a non-compliance is found, the root cause(s) and contributing factor(s) are identified and corrective actions are defined. The feedback part of 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;
 - (7) the compliance monitoring function that ensures the aspects above performs 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 in order to demonstrate compliance with Part 21.

- [21.A.139 Production management system](#)

GM No 1 to 21.A.139(b)(2) Quality System – Independent quality assurance function

The quality assurance function which is part of the organisation is required to be independent from the functions being monitored. This required independence relates to the lines of reporting, authority and access within the organisation and assumes an ability to work without technical reliance on the monitored functions.

GM1 No 2 to 21.A.139(f)(b)(2) Production management system Quality System – Adequacy of procedures and monitoring function

ADEQUACY OF PROCEDURES AND MONITORING FUNCTION

Adequacy of procedures means that the production management system, through the use of the procedures as set forth defined, is capable of meeting the conformity objectives identified in point 21.A.139(d)(1)(a).

The quality assurance function to ensure the above should perform planned continuing and systematic evaluations or audits of factors that affect the conformity (and, where required, safe operation) of the products, parts or appliances to the applicable design. This evaluation should include all elements of the quality system in order to demonstrate compliance with Part 21 Subpart G.

- [21.A.139 Production management system](#)

GM1 21.A.143 Exposition – Production Organisation Exposition (POE)

- (a) The purpose of the production organisation exposition (POE) is to set forth state in a concise document 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 instruction instructions, the POE should provide a summary of the information and an appropriate cross-reference.

- (b) The document does not require approval in itself, but it will be considered as such approved by virtue of the approval of the organisation.
- (c) When changes to the organisation occur, according to point 21.A.143(b), the POE is required to be kept up to date. This should be done as per a procedure, laid down in the POE. If the changes are significant, significant changes to the organisation shall not amend the exposition before the competent authority has approved the change in accordance with point 21.A.147. (as defined in GM 21.A.147(a)) should be approved by the competent authority prior to update of the POE.

When an organisation is approved against any other implementing rule containing a requirement for an exposition, a supplement covering the differences may suffice to meet the requirements of Part

21 Subpart G except that the supplement should have an index identifying where those parts missing from the supplement are covered. Those items then formally become part of the POE. In any combined documents the POE should be easily identifiable.

– [21.A.143 Exposition](#)

AMC1 21.A.143(a)(1) Exposition

- (a) All personnel should be familiar with those parts of the POE that are relevant to their tasks.
- (b) A paragraph in the POE should provide the description of the organisation, the safety policy and the 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 chief executive officer, if different), confirming that the POE and any associated manuals will be complied with at all times.

This statement should read as follows, or embrace the intent of the following paragraph.

'This exposition defines the organisation and procedures upon which the competent authority's production organisation approval is based.*

These procedures are approved by the undersigned, and must be complied with, as applicable, in order to ensure that all production activities are carried out on time and to an approved standard.

It is understood that the approval of the production organisation is based on the continuous compliance of the organisation with the applicable requirements of Part 21, and with the organisation's procedures described in this exposition. The competent authority is entitled to limit, suspend, or revoke the approval if the organisation fails to fulfil the obligations imposed by Part 21, or any conditions according to which the approval was issued.*

Signed

Dated

Accountable manager and ... (quote position)

Chief executive officer ...

For and on behalf of ... (quote organisation's name)'

**Where 'competent authority' is stated, please insert the actual name of the approving competent authority organisation or administration granting the POA approval.*

The statement should be re-issued at the earliest opportunity, whenever the accountable manager is changed.

- (d) The POE should include the description of the internal safety reporting scheme that is required by point 21.A.3A(a)(1)(ii);
- (e) If the organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, so that the organisation is required to establish another exposition, the organisation may combine the documents by establishing a separate manual or supplement that covers the



differences between the production organisation exposition and that other exposition. In such a case, the supplement should identify where in the other exposition the remaining information on the production organisation is covered. That remaining information then formally becomes part of the exposition.

- [21.A.143 Exposition](#)

AMC1 21.A.145(a) Resources

- (a) 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 which affect the critical dimensions and values of products should demonstrate compliance with, and be traceable to, national or international standards.
- (b) Sufficient personnel means that according to the nature of the work and the production rate of each function, the organisation has a sufficient quantity of qualified personnel to accomplish all the specified manufacturing tasks and to attest their conformity. The number of personnel should be such that the relevant airworthiness considerations may be applied in all areas without any undue pressure.
- (c) An evaluation of the competence of the personnel 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. Training should be organised to establish and maintain the competence of the personnel at the levels determined to be necessary by the organisation.

- [21.A.145 Resources](#)

GM1 21.A.145(a) Resources Approval Requirements

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.

~~Equipment and tools should be such as to enable all specified tasks to be accomplished in a repeatable manner without detrimental effect. Calibration control of equipment and tools which affect critical dimensions and values should demonstrate compliance with, and be traceable to, national or international standards.~~

~~Sufficient personnel means that the organisation has for each function according to the nature of the work and the production rate, a sufficient quantity of qualified personnel to accomplish all specified manufacturing tasks and to attest the conformity. Their number should be such that airworthiness consideration may be applied in all areas without undue pressure.~~

~~An evaluation of the competence of personnel is performed as part of the quality system. This should include, where appropriate, verification that specific qualification standards have been implemented, for example NDT, welding, etc. Training should be organised to establish and maintain the personal competence levels determined by the organisation to be necessary.~~

- [21.A.145 Resources](#)



GM1 21.A.145(b)(2) Resources Approval Requirements— Airworthiness, noise, fuel venting and exhaust emissions /production data procedures

AIRWORTHINESS, NOISE, FUEL VENTING AND EXHAUST EMISSIONS/PRODUCTION DATA PROCEDURES

- 1—When a POA holder or an applicant for a POA is developing its own manufacturing data, such as computer based data, from the design data package delivered by a design organisation, procedures are required to demonstrate the right correct transcription of the original design data.
 - 2—Procedures are required to define the manner in which airworthiness, noise, fuel venting and exhaust emissions data is used to issue and update the production/quality data, which determines the conformity of products, parts and appliances. The procedure must 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 issuing a Statement of Conformity or EASA Form 1.
- [21.A.145 Resources](#)

AMC1 21.A.145(c)(1) Resources

ACCOUNTABLE MANAGER

The accountable manager should:

- (a) have sufficient knowledge and authority to be able to respond to the competent authority regarding major issues of the production approval, and to implement any necessary improvements;
- (b) promote the quality and safety policies of the organisation; and
- (c) demonstrate a basic understanding of this Regulation.

— [21.A.145 Resources](#)

GM1 21.A.145(c)(1) Resources Approval Requirements— Accountable manager

ACCOUNTABLE MANAGER

Accountable manager refers to means the manager who is responsible, and has corporate authority for ensuring that all production work is carried out to the required standard. This function may be carried out by the Chief Executive chief executive officer or by another person in the organisation, nominated by him or her the chief executive officer to fulfil the function, provided that the his or her position and authority of the person in the organisation permits permit him or her to discharge the attached responsibilities.

The manager is responsible for ensuring that all necessary resources are available and properly used in order to produce under the production approval in accordance with Part 21 Section A Subpart G.



~~The manager needs to have sufficient knowledge and authority to enable him or her to respond to the competent authority regarding major issues of the production approval and implement necessary improvements.~~

~~The manager needs to be able to demonstrate that he or she is fully aware of and supports the quality policy and maintains adequate links with the quality manager.~~

- [21.A.145 Resources](#)



AMC1 GM 21.A.145(c)(2) Resources Approval Requirements – Responsible managers

RESPONSIBLE MANAGERS

- (a) The person or group of persons nominated in accordance with 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, Section A Subpart G. It therefore follows that, depending on the size of the Part 21 Section A Subpart G approved production organisation, 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 who are responsible for:
- (1) monitoring the adequacy of the organisation and its compliance with Part 21;
 - (2) ensuring the effectiveness of the safety management system,
- and they should be able to request other managers or the accountable manager to carry out any necessary and appropriate remedial action. They should have direct access to the accountable manager.
- (c) The competent authority requires the Each nominated managers manager to should be identified and their credentials submitted on an EASA Form 4 (see EASA Form 4 for Production Organisations on the EASA website under: <http://easa.europa.eu/certification/application-forms.php>) to the competent authority in order 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 Part 21 Section A Subpart G approved production organisation.
- (d) The responsibilities and the tasks of each individual manager are required to should be clearly defined, in order to prevent any uncertainties about the relations, within the organisation. In the case of organisation organisational structures where staff members staff members are responsible to more than one person, as, for instance, in matrix and project organisations, the responsibilities of the managers should be defined in such a way that all the responsibilities are covered.
- (e) Where a Part 21 Section A Subpart G an approved production organisation chooses to appoint managers for all or for any combination of the functions identified in Part 21 functions because of the size of the undertaking, it is necessary that these managers should ultimately report ultimately to the accountable manager. In cases where a manager does not directly report to the accountable manager, he or she should have a formally established direct access to the accountable manager formally established.
- (f) 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 terms of approval.
- (g) The organisation should establish and control the competency of the personnel involved in production, compliance monitoring, safety management, and, if applicable, in issuing permits to fly, in accordance with a procedure and to a standard agreed by the competent authority. In addition to the necessary expertise related to the job function, the competency of each



person should include an understanding of the safety management and human factors principles that are appropriate to the person's function and responsibilities in the organisation.

- (h) The person or group of persons responsible for the monitoring of compliance and adequacy should:
- (1) not be one of the persons referred to in point 21.A.145(c)(2);
 - (2) be able to demonstrate their relevant knowledge, background and appropriate experience related to the activities of the organisation, including knowledge and experience in compliance monitoring; and
 - (3) have access to all parts of the organisation, and as necessary, to any supplier.
- (i) If any of the functions related to compliance monitoring or safety management are combined with other duties, the organisation should ensure this does not result in any conflicts of interest.
- (j) Subject to a risk assessment and agreement by the competent authority, with due regard to the size of the organisation and the nature and complexity of its activities, the functions of the compliance monitoring manager and the safety manager may be exercised by the accountable manager provided that he or she has demonstrated the related level of competence.

~~One such manager, normally known as the quality manager is responsible for monitoring the organisation's compliance with Part 21 Section A Subpart G and requesting remedial action as necessary by the other managers or the accountable manager as appropriate. He or she should have a direct access to the accountable manager.~~

- [21.A.145 Resources](#)

AMC2 21.A.145(c)(2) Resources

COMPETENCY OF PERSONNEL

- (a) To assist in the assessment of competency and to perform the training needs analysis, the organisation should establish job descriptions for all the job functions in the organisation. These job descriptions should contain sufficient criteria to enable the competency of each person to be assessed.
- (b) The organisation should provide initial and recurrent training, to the persons or group of persons nominated in accordance with point 21.A.145(c)(2), which is adequate to their job function, and which ensures that their continued competency is maintained throughout the duration of their employment/contract.
- (c) The organisation should record the training provided in accordance with point (a).
- (d) All prospective members of the production management staff should be assessed for their competency, qualifications, and capabilities related to their intended duties.
- (e) All the staff nominated according to point 21.A.145(c)(2) should be able to demonstrate their knowledge of, and compliance with, the production management organisation procedures that are applicable to their job function.



- (f) All the staff nominated according to point 21.A.145(c)(2) should be able to demonstrate an understanding of the safety management principles, human factors and human performance issues related to their tasks.
- (g) The competency of the person who assumes, or persons who assume, the function of safety manager should include, but not be limited to, the following:
- (1) knowledge of the ICAO standards and European 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 human factors;
 - (6) an understanding of a positive safety culture and its promotion; and
 - (7) operational experience related to the activities of the organisation.
- (h) The organisation should develop a procedure that describes the process for assessing the competency of the person. The procedure should specify:
- (1) the persons responsible for this process;
 - (2) the means and methods for the initial assessment;
 - (3) the means and methods for the continuous control of their competency, including feedback on their performance;
 - (4) the actions to be taken if the assessment is not satisfactory; and
 - (5) how to record assessment results.

– [21.A.145 Resources](#)

AMC1 21.A.145(d)(1) Resources Approval Requirements – Certifying staff

CERTIFYING STAFF

- (a) Certifying staff should be nominated by the production organisation to ensure that each of their products, parts and/or appliances qualify for a Statements of Conformity or a Release Certificates. The position and number of Certifying Staff positions and numbers are to be appropriate to the complexity of the product and the production rate.
- (b) The qualifications of certifying staff is should be based on their knowledge, background and experience and on a specific training (or testing) established by the organisation to ensure that it is appropriate to the product, part, or appliance to be released.
- (c) Training must be given to develop a satisfactory level of knowledge of organisation the organisation's procedures, safety management systems (including compliance monitoring), aviation legislation, and the associated regulations implementing rules, CS and GM that are relevant to their particular role.



- (d) For that purpose, in addition to the general training policy, the organisation should ~~must~~ 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 management system, and its appropriateness forms a part of the ~~investigation~~ investigations by the competent authority within the organisation approval process, and of the subsequent surveillance of the persons proposed by the managers.
 - (f) The training ~~must~~ 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 ~~must~~ should be put in place to ensure the continuing compliance of personnel ~~to~~ with authorisation requirements.
 - (h) For the release of products, parts or appliances, the responsibilities to issue statements of conformity ~~or~~/release certificates (EASA Form 1) or ~~permit~~ permits to fly, including the approval of flight conditions, are allocated to the certifying staff identified in point 21.A.145(d)(2).
 - (i) The competent authority holds the right to reject those personnel, appointed by the organisation, if they are found to have inappropriate experience or not to otherwise comply with its requirements.
- [21.A.145 Resources](#)

AMC 21.A.145(d)(2) Approval requirements – Record of certifying staff

1. The following is the minimum information to be recorded in respect of each certifying person:
 - (a) Name
 - (b) Date of Birth
 - (c) Basic Training and standard attained
 - (d) Specific Training and standard attained
 - (e) If appropriate – Continuation Training
 - (f) Experience
 - (g) Scope of the authorisation
 - (h) Date of first issue of the authorisation
 - (i) If appropriate – expiry date of the authorisation
 - (j) Identification Number of the authorisation
2. The record may be kept in any format and must be controlled by an internal procedure of the organisation. This procedure forms part of the quality system.



3. ~~Persons authorised to access the system must be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner and that confidential records cannot become accessible to unauthorised persons.~~
4. ~~The certifying person must be given reasonable access on request to his or her own records.~~
5. ~~Under the provision of 21.A.157 the competent authority has a right of access to the data held in such a system.~~
6. ~~The organisation must keep the record for at least two years after the certifying person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.~~

AMC1 21.A.145(d)(2)(3) Resources Approval requirements – Evidence of authorisation

EVIDENCE OF AUTHORISATION

- (1) The authorisation document ~~must~~ **should** be in a style that makes its scope clear to the certifying staff and any authorised person who may require to examine the authorisation. 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 **after** ~~of~~ a request from an authorised person. Authorised persons include the competent authority.

– [21.A.145 Resources](#)

AMC1 21.A.147 Changes to the production management system

APPLICATION FOR VARIATION OF SCOPE AND TERMS OF THE POA

- (a) An application for approval should be submitted in writing to the competent authority, and the production organisation should demonstrate to the competent authority, on the basis of the submission of any proposed changes to the exposition, and before the implementation of the change, that it will continue to comply with Part 21 after the implementation.
- (b) The approved production organisation should provide to the competent authority an application for any significant changes, or for a variation in the scope or terms of their POA, on an EASA Form 51 (see below) completed by the applicant.

– [21.A.147 Changes to the production management system](#)



EASA Form 51	
Application for significant changes or a variation of the scope or terms of a Part 21 POA	
<i>Competent authority of an EU Member State or EASA</i>	
1. Name and address of the POA holder:	
2. Approval reference number:	
3. Location(s) for which changes in the terms of approval are requested:	
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:	
<div style="border: 1px solid black; width: 150px; height: 15px; margin: 0 auto;"></div> Date	<div style="border: 1px solid black; width: 150px; height: 15px; margin: 0 auto;"></div> 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' here 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' here if no change is anticipated.

Block 5: this block should state the changes to the organisation as it is defined in the current production organisation exposition, 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). A change in the nomination of the responsible managers should be accompanied by the corresponding EASA Forms 4. State 'not applicable' here if no change is anticipated.

Block 6: state the position and name of the accountable manager here. Where there is a change in the nomination of the accountable manager, the information should refer to the nominee for this position. State 'not applicable' here 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 this position. In all other cases, EASA Form 51 should be signed by the accountable manager.

- [21.A.147 Changes to the production management system](#)

GM 21.A.147(a) Changes to the approved production management system organisation — Significant changes

SIGNIFICANT CHANGES

1 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 quality and safety;
- A change of the accountable manager or of any other person nominated under point 21.A.145(c)(2);
- Changes in the production or quality in the production management systems that may have an important impact on the conformity or airworthiness of each product, part or appliance including reporting lines between the personnel nominated in accordance with point 21.A.145(c)(2)), and the accountable manager; and
- Changes in the placement or control of significant sub-contracted subcontracted work or supplied parts.

2 To ensure that changes do not result in non-compliance with Part 21, Section A Subpart G 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)).



3 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.

4 Changes of location are addressed in point 21.A.148, and changes of ownership in point 21.A.149, and the change of scope of approval in point 21.A.153.

– [21.A.147 Changes to the production management system](#)

GM1 21.A.149 Transferability

Transfer of approval would normally only be agreed in cases where the ownership changes but the organisation itself remains effectively unchanged. For example:

An acceptable transfer situation could be a change of company name (supported by the appropriate certificate from the National Companies Registration Office or equivalent) but with no changes to the site address, facilities, type of work, staff, accountable manager or person nominated under point 21.A.145.

Alternatively, in the event of receivership (bankruptcy, insolvency or other equivalent legal process), there may be good technical justification for continuation of the approval, provided that the company continues to function in a satisfactory manner in accordance with their POE. It is likely that at a later stage, the approval might be voluntarily surrendered or the organisation transferred to new owners, in which case the former paragraphs apply. If it does not continue to operate satisfactorily, then the competent authority could suspend or revoke the approval under point 21.B.65 21.B.245.

In order for the competent authority to agree to a transfer of approval, it will normally prescribe, it as a condition in accordance with point 21.B.240(b) 21.A.147(b), that the obligations and responsibilities of the former organisation should be transferred to the new organisation, otherwise a transfer is not possible and an application for a new approval will be required.

AMC1 21.A.153 Changes to the terms of approval — ~~Application for a change to the terms of approval~~

APPLICATION FOR A CHANGE TO THE TERMS OF APPROVAL

EASA Form 51 (see AMC1 21.A.147 ~~AMC No 1 to 21.B.240~~) must should be obtained from the competent authority and completed in accordance with the procedures of the POE.

The information entered on the form is the minimum required by the competent authority to assess the need for a change of to the production organisation approval.

The completed form and an outline of the changed POE, and details of the proposed change to the POA terms of approval, must be forwarded to the competent authority.

GM 21.A.157 Investigations — Arrangements

~~The arrangements made by the applicant for, or holder of an approval under Part 21 Section A Subpart G should allow the competent authority to make investigations that include the complete~~

production organisation including partners, sub-contractors and suppliers, whether they are in the State of the applicant or not.

The investigation may include; audits, enquiries, questions, discussions and explanations, monitoring, witnessing, inspections, checks, flight and ground tests and inspection of completed products, parts or appliances produced under the POA.

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

The arrangements should enable the organisation to give positive assistance to the competent authority and co-operate in performing the investigation during both initial assessment and for the subsequent surveillance to maintain the POA.

Co-operation in performing investigation means that the competent authority has been given full and free access to the facilities and to any information relevant to demonstrate compliance to Part 21 Section A Subpart G requirements, and assistance (personnel support, records, reports, computer data, etc., as necessary).

Assistance to the competent authority includes all appropriate means associated with the facilities of the production organisation to allow the competent authority to perform these investigations, such as the availability of a meeting room, office and personnel support, documentation and data, and communication facilities, all properly and promptly available as necessary.

The competent authority seeks to have an open relationship with the organisation and suitable liaison personnel should be nominated to facilitate this, including suitable representative(s) to accompany competent authority staff during visits not only at the organisations own facilities but also at sub-contractors, partners or suppliers.

GM No 1 to 21.A.158(a) Uncontrolled non-compliance with applicable design data

An uncontrolled non-compliance with applicable design data is a non-compliance:

- that cannot be discovered through systematic analysis; or
- that prevents identification of affected products, parts, appliances, or material.

GM No 2 to 21.A.158(a) Examples of level one findings

Examples of level one findings are non-compliances with any of the following points, that could affect the safety of the aircraft:

21.A.139, 21.A.145, 21.A.147, 21.A.148, 21.A.151, 21.A.163, 21.A.165(b), (c), (d), (e), (f) and (g).

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.

In addition, the failure to arrange for investigations under 21.A.157, in particular to obtain access to facilities, after denial of one written request should be classified as a level one finding.

GM 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings

CAUSAL ANALYSIS

It is important that the causal 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 a 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 (regulatory, human factors, organisational factors, technical, etc.) in addition to the direct factors.

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, it therefore bears the risk that important factors that need to be addressed in order to prevent reoccurrence will be ignored.

Such an inappropriate or partial causal analysis often leads to defining 'quick fixes' that only address the symptoms of the non-conformity. A peer review of the results of the causal analysis may increase its reliability and objectivity.

A system description of the organisation that considers organisational structures, processes and their interfaces, procedures, staff, equipment, facilities and the environment in which the organisation operates, will support both effective causal (reactive) and hazard (proactive) analysis.

– [21.A.158 Findings](#)

GM 21.A.165(d) and (h) Obligations of the holder – Recording and archiving system

Records within a production environment satisfy two purposes. Firstly, they are required, during the production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.

Therefore, the approved production organisation should implement a system for the compilation and retention of records during all stages of manufacture, covering short-term and long-term records appropriate to the nature of the product and its production processes.

The management of such information should be subject to appropriate procedures in the Quality System required by [21.A.139](#).

All forms of recording media are acceptable (paper, film, magnetic, ...) provided they can meet the required duration for archiving under the conditions provided.

The related organisation procedures should:

- Identify records to be kept.
- Describe the organisation of and responsibility for the archiving system (location, compilation, format) and conditions for access to the information (e.g., by product, subject).
- Control access and provide effective protection from deterioration or accidental damage.

- ~~— Ensure continued readability of the records.~~
- ~~— Demonstrate to the competent authority proper functioning of the records system.~~
- ~~— Clearly identify the persons involved in conformity determination.~~
- ~~— Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:
 - ~~a) Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate.~~
 - ~~b) Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.~~~~
- ~~— Ensure that the recording and record keeping system used by the partners, supplier and sub-contractors meet the objective of conformity of the product, part or appliance with the same level of confidence as for their own manufacture. They should define in each case who is to retain the record data (organisation or partner, supplier or sub-contractor). They should also define method for surveillance of the recording/record keeping system of the partners, suppliers or sub-contractors.~~



SUBPART J — DESIGN ORGANISATION APPROVAL

GM1 21.A.239(c) Design management system

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 and contribution to aviation safety, it 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 that involves all the personnel as active contributors to the safety of the final product, part or appliance in accordance with AMC1.21.A.239(c)(1).

The requirements established 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 transposes Appendix 2 to ICAO Annex 19. The EU approach aims at facilitating the introduction of the safety management system into design organisations by inserting the components of safety management into Part 21, thus building upon the existing management systems.

Therefore, the approach aims at encouraging 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 issued under Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof (according to point 21.A.239(h)), the organisation may choose to implement a single management system to cover all of its activities. An integrated management system may not only be used to capture multiple certification requirements, but also to cover other business management systems such as quality, 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 and 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 level or at the organisational level:

- For instance, the criticality of variants may have no impact on safety, in which case, the safety management system may not need to address this aspect; however, if a large number of variants need to be managed, this may generate additional hazards that need to be mitigated.
- The risks that are inherent in a complex structure require a robust safety risk management process (e.g. complex interfaces with different partners who participate in the design of a



product may induce hazards that are complex to mitigate, due to the management of organisational or technical changes).

As a consequence, scalability should be a function of the inherent safety risk capability of the organisation. For instance:

- the risk assessment model used may be very simple in small organisations where the identified hazards are easy to mitigate;
- expert judgement might be sufficient to measure the efficiency of safety barriers;
- the collection of data, safety information and occurrences might be very limited;
- there might be no need for software or tools to manage the SMS;
- the communication policy might be limited.

However, small organisations that are involved in activities that entail significant aviation safety risks might require greater SMS resources.

- [21.A.239 Design management system](#)

AMC1 21.A.239(c) Design management system

SAFETY MANAGEMENT ELEMENT

An organisation that has a safety management element that is compliant with the SMS Industry Standard ‘Implementing a Safety Management System in Design, Manufacturing and Maintenance Organizations’ SM001 Issue A - September 17th, 2018¹, should be considered compliant with the EU framework for aviation safety management as described in GM1 21.A.239(c), provided that compliance with the following additional topics, as appropriate, is demonstrated.

Point	Paragraph of SMS Industry Standard SM001 Issue A - September 17 th , 2018	Additional topics
21.A.3A	<p>§6.1.1.1 Safety Policy</p> <p>§6.2.1 Hazard identification</p> <p>§6.2.2 Safety Risk Assessment and Mitigation</p> <p>§6.3 Safety Assurance</p> <p>§6.4.2 Safety Communication</p> <p>§7 Interfaces between organizations</p>	<p>Reporting to EASA as per 21.A.3A (a)(3) (refer to AMC 20-8 and AMC1 21.A.3A(d) as acceptable means of compliance)</p> <p>Compliance with Regulation (EU) No 376/2014 (refer to GM1 21.A.3A(a)(1) and (b)(1) as a summary of the requirements)</p> <p>Collection, investigation and analysis of data related to flammability reduction means (FRM) reliability</p> <p>Collection, investigation and analysis of data related to ETOPS significant occurrences</p>
21.A.5	Not available	Record-keeping (refer to the AMC and GM related to 21.A.5 as acceptable means of compliance and guidance)

¹ https://www.asd-europe.org/sites/default/files/atoms/files/SMS%20Standard_final%20issue%20A_20180917.pdf

21.A.239	(b)	<p>§6.1.2 Safety Accountability and Responsibilities</p> <p>§6.1.3 Appointment of Key Safety Personnel</p> <p>§6.2 Safety Risk Management (system description)</p> <p>§6.3.2 Management of Change</p> <p>§6.3.3 Continuous Improvement of the SMS</p> <p>§6.4.1 Training and Education</p>	none
	(c)	<p>§1 Introduction</p> <p>§6.1.1.1 Safety Policy</p> <p>§6.1.1.2 Safety Objectives</p> <p>§6.1.2 Safety Accountability and Responsibilities</p> <p>§6.1.3 Appointment of Key Safety Personnel</p> <p>§6.2 Safety Risk Management</p> <p>§6.2.1 Hazard identification</p> <p>§6.2.2 Safety Risk Assessment and Mitigation</p> <p>§6.3 Safety Assurance</p> <p>§6.3.1 Safety Performance Monitoring and Measurement</p> <p>§6.3.2 Management of Change</p> <p>§6.3.3 Continuous Improvement of the SMS</p> <p>§6.4 Safety Promotion</p> <p>§6.4.1 Training and Education</p> <p>§6.4.2 Safety Communication</p> <p>§7 Interfaces between organizations</p>	<p>Human factors in the safety policy (refer to AMC1 21.A.239(c)(1) as acceptable means of compliance)</p> <p>Functions of safety review board & safety action group (refer to AMC1 21.A.239(c)(2) and GM1 21.A.239(c)(2) for acceptable means of compliance and guidance)</p> <p>Interface risk management in case of subcontracts (refer to AMC1 21.A.239(c)(3) for acceptable means of compliance)</p> <p>Systematic management of all changes, not limited to those having substantive impact on safety management (refer to AMC1 21.A.239(c)(4)(ii) for acceptable means of compliance)</p> <p>More structured safety training (refer to AMC1 21.A.239(c)(5)(i) for acceptable means of compliance)</p>
	(e)	<p>§6.1.5 SMS Documentation</p> <p>§6.4.2 Safety Communication</p>	None
	(f)	<p>§6.3.1 Safety Performance Monitoring and Measurement (paragraph title: Need for additional measurement)</p>	Independency of the monitoring of compliance and adequacy as per 21.A.239(f). Refer to AMC1 21.A.239(f) for acceptable means of compliance)
	(g)	<p>§7.3 Corporate SMS approach</p>	None

21.A.243	§6.1.5 SMS Documentation	None
21.A.245(c)	§6.1.1.1 Safety Policy §6.1.2 Safety Accountability and Responsibilities §6.1.3 Appointment of Key Safety Personnel §6.4.1 Training and Education	Identification of managers responsible for the essential functions (refer to AMC1 21.A.245(c)(2) for acceptable means of compliance) Definition of competency of personnel (refer to AMC2 21.A.245(c)(2) for acceptable means of compliance)
21.A.247	§6.3.2 Management of Change	Systematic management of all changes, not limited to those having substantive impact on safety management (refer to AMC1 21.A.239(c)(4)(ii) for acceptable means of compliance)

– [21.A.239 Design management system](#)

AMC1 21.A.239(c)(1) Design management system

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, and encourage personnel to report design-related errors, incidents and hazards;
- (3) be endorsed by the head of the design organisation;
- (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.

(c) The safety policy should include commitments to:

- (1) comply with all the applicable legislation, meet all the applicable requirements, and adopt practices that work towards improving safety standards;
- (2) provide the necessary resources for its implementation;
- (3) apply human factors principles;
- (4) enforce safety as a primary responsibility of all managers; and
- (5) apply 'just culture' principles and, in particular, to not make available or use any personal information on occurrences:
 - (i) attribute blame or liability for actions, omissions or decisions taken by personnel that are commensurate with their experience and training; or
 - (ii) for any purpose other than the improvement of aviation safety.



- (d) Senior management should continuously promote the safety policy to all personnel, and demonstrate their commitment to it and provide the necessary human and financial resources for its implementation.
 - (e) 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 maintain or continuously improve the overall effectiveness of the management system;
 - (3) be communicated throughout the organisation; and
 - (4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.
- [21.A.239 Design management system](#)

GM1 21.A.239(c)(1) Design management system

SAFETY POLICY

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, improve safety levels in all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident as far as is reasonably practicable. It 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 the issuance of 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.

For organisations that have their principal place of business in a Member State, Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).

- [21.A.239 Design management system](#)

AMC1 21.A.239(c)(2) Design management system

SAFETY MANAGEMENT ELEMENT — ORGANISATION AND ACCOUNTABILITIES

- (a) The management system should encompass safety by defining a structure that is able to administrate and maintain the processes and functions of the safety management system as described in point 21.A.239(c). The head of the design organisation should establish and maintain functions which act as:
 - (1) the safety manager; and
 - (2) a high-level committee that considers matters of strategic safety, sometimes referred to as the 'safety review board', depending on the size of the organisation and the nature

and complexity of its activities, and subject to a risk assessment that is agreed by the competent authority.

(b) The safety review board function should monitor:

- (1) the safety performance against the safety policy and objectives;
- (2) whether any safety action is taken in a timely manner; and
- (3) the effectiveness of the organisation's management system processes.

(c) The head of the design organisation may also establish and maintain a function, referred to as the 'safety action group', in support of the two functions above.

– [21.A.239 Design management system](#)

GM1 21.A.239(c)(2) Design management system

SAFETY MANAGEMENT ELEMENT — ORGANISATION AND ACCOUNTABILITIES

The organisation may define its structure in the manner that best fits its needs. The following is an example of a possible organisation that complies with the safety management elements of the design management system.

The role of the person who assumes, or persons who assume, the function of safety manager should include, but not be limited, to:

- support of the head of the design organisation in ensuring the activities described in AMC1 21.A.239(c) are performed
- advice to the head of the design organisation on safety matters; and
- provision of periodic reports on safety performance to the head of the design organisation and to the safety review board.

Regardless of the organisational set-up, it is important for the safety manager or a designated person to remain the unique focal point for the development, administration, and maintenance of the organisation's management system.

When established by the head of the design organisation, the function of the high-level committee (safety review board) is to:

- ensure that appropriate resources are allocated to achieve the established safety objectives;
- review the results of compliance monitoring; and
- monitor the implementation of related corrective and preventive actions.

It is composed of heads of functional areas and it is chaired by the head of the design organisation.

The role of the safety action group is to:

- analyse specific events;
- assess mitigation measures;
- monitor the safety performance of the organisation;
- define actions to control risks to an acceptable level;



- assess the impact of organisational changes on safety;
 - ensure that safety actions are implemented within the agreed timescales; and
 - review the effectiveness of previous safety actions and safety promotion.
- [21.A.239 Design management system](#)

AMC1 21.A.239(c)(3) and (4) Design management system

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 in particular focus on hazards that may result from non-compliances or errors in the design of the product, part or appliance.

(b) Risk management processes

- (1) A safety risk management process should be developed and maintained that ensures that the safety risks are:
 - (i) analysed (in terms of their probability and the severity of the consequences of hazards and occurrences);
 - (ii) assessed (in terms of their tolerability); and
 - (iii) controlled (in terms of the mitigation of risks to an acceptable level).
- (2) Within the risk management process, the organisation should specify, who has the authority to make decisions regarding the tolerability of safety risks, in accordance with (b)(1)(ii).

(c) Regardless of the approval status of the subcontracted organisations, the design organisation is responsible for ensuring that hazard identification and risk management activities are conducted on all subcontracted activities, as required by point 21.A.239(c)(3), as well as for monitoring of their compliance and adequacy, as required by point 21.A.239(f).

(d) Internal investigation

- (1) In line with its just culture policy, the organisation should define how to investigate incidents such as errors or near misses, in order to understand not only what happened, but also how it happened, and to prevent or reduce the probability and/or consequences of any future recurrences (refer to AMC3 21.A.3A(a)(1) and (b)(1)).
- (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) The organisation should establish, implement and maintain a process by which the safety performance of the organisation is continuously verified against the safety policy and safety objectives.



- (2) This process may include, as appropriate to the size, nature and complexity of the organisation:
- (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 and their components, new equipment/technologies, the implementation of new or changed procedures, or in situations 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 periodically assess the status of safety risk controls; and
 - (iv) safety surveys that examine particular elements or procedures of a specific area, such as the problem areas identified, or any bottlenecks in the daily design management activities, the perceptions and opinions of the design management personnel, and any areas of dissent or confusion.

(f) Management of change

The organisation should manage any safety risks that are related to a change. The management of change should be a documented process to identify any external or internal change that may have an adverse effect on safety. It should make use of the organisation's existing hazard identification, risk assessment and mitigation processes.

(g) Continuous improvement

The organisation should continuously seek to improve its safety performance and the effectiveness of its management system. Continuous improvement may be achieved through:

- (1) compliance monitoring and audits carried out by external organisations;
- (2) assessments, including assessments of the effectiveness of the safety culture and the management system, in particular to assess the effectiveness of safety risk management processes;
- (3) staff surveys, including cultural surveys, that can provide useful feedback on how engaged personnel are with the management system;
- (4) monitoring incidents and their recurrences;
- (5) evaluating the safety performance indicators and reviewing all the available safety performance information; and
- (6) identifying the lessons learned.

– [21.A.239 Design management system](#)

AMC1 21.A.239(c)(3) Design management system - SAFETY MANAGEMENT ELEMENT — INTERFACES BETWEEN ORGANISATIONS



- (a) The safety risk management processes should specifically address the planned implementation of, or participation of the organisation in, any complex arrangements (such as when the DO subcontracts work to multiple organisations).
- (b) Hazard identification and risk assessment start with the identification of all the parties involved in the arrangement, including any independent experts and non-approved organisations. It extends to the overall control structure, assessing in particular the following elements across all subcontract levels and all parties within these arrangements:
- (1) coordination and interfaces between the different parties;
 - (2) applicable procedures;
 - (3) communication between all the parties involved, including the reporting and feedback channels;
 - (4) task allocation, responsibilities and authorities; and
 - (5) the qualifications and competency of key personnel with reference to point 21.A.245.
- (c) Safety risk management should focus on the following aspects:
- (1) clear assignment of accountability and allocation of responsibilities;
 - (2) only one party should be responsible for a specific aspect of the arrangement, with no overlapping or conflicting responsibilities, in order to eliminate coordination errors;
 - (3) the existence of clear reporting lines, both for occurrence reporting and progress reporting; and
 - (4) the possibility for staff to directly notify the organisation of any hazard that suggests an obviously unacceptable safety risk as a result of the potential consequences of this hazard.
- (d) Regular communication should be ensured between all the parties to discuss work progress, risk mitigation actions, changes to the arrangements, as well as any other significant issues.
- (e) For any subcontracted activities, interfaces and communication channels are also needed for the purposes of the internal safety reporting scheme (point 21.A.3A).

– [21.A.239 Design management system](#)

AMC1 21.A.239(c)(4)(ii) Design management system

MANAGEMENT OF CHANGE

- (a) Regardless of the magnitude of change, large or small, there should always be proactive consideration of the safety implications. This is primarily the responsibility of the team that proposes or implements the change. However, a change can only be successful if all the personnel affected by the change are engaged and involved, and they participate in the process. The magnitude of a change, its safety criticality, and its potential impact on human performance should be assessed in any change management process.
- (b) Special consideration, including human factor issues, should be given to the transition period during which the change will become effective. In addition, the activities utilised to manage



these issues should be integrated into the change management plan. The purpose of integrating human factors into the management of change is to minimise the potential risks by specifically considering the impact of the change on the people within a system.

- (c) During the process for the management of a change, previous risk assessments and existing hazards should be reviewed for their possible effects.

– [21.A.239 Design management system](#)

GM1 21.A.239(c)(4)(ii) Design management system

MANAGEMENT OF CHANGE

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. can result in the inadvertent introduction of new hazards, which can expose the organisation to new, or greater risks. Effective organisations seek to improve their processes, with conscious recognition that changes can expose the organisation to potentially latent 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. Disciplined application of change management can maximise the effectiveness of the change, engage staff, and minimise the risks inherent in change.

A change may have the potential to introduce new human factor issues, or to exacerbate pre-existing ones. For example, changes in computer systems, equipment, technology, personnel changes, including changes in management personnel, procedures, the work organisation, or work processes are likely to affect performance.

Effective management of change is supported by the following:

- Implementation of a process for formal 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.
- Identification of changes that are likely to occur in business, which would have a noticeable impact on:
 - resources — material and human;
 - management direction — policies, processes, procedures, training; and
 - management control.
- Safety cases/risk assessments that are aviation-safety focused.
- The involvement of key stakeholders in the change management process, as appropriate.
- [21.A.239 Design management system](#)

AMC1 21.A.239(c)(5) Design management system

SAFETY COMMUNICATION

- (a) The organisation should establish communication with its personnel, as appropriate for their safety responsibilities, about safety matters that:

- (1) ensures that all the personnel are aware of the safety management activities;
 - (2) conveys safety-critical information, especially related to assessed risks and analysed hazards;
 - (3) explains why particular actions are taken; and
 - (4) explains why safety procedures are introduced or changed.
- (b) Regular meetings with personnel, as appropriate for their safety responsibilities, during which information, actions, and procedures are discussed, may be used to communicate safety matters.
- [21.A.239 Design management system](#)

GM1 21.A.239(c)(5) Design management system

SAFETY PROMOTION

Safety training, combined with safety communication and information sharing, is a part of safety promotion.

Safety promotion activities are intended to:

- support the organisation's policies;
- encourage a positive safety culture;
- create an environment that is favourable to the achievement of the organisation's safety objectives;
- support organisational learning;
- support the implementation of an effective safety reporting scheme; and
- support the development of a just culture.

Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation actions.

- [21.A.239 Design management system](#)

AMC1 21.A.239(c)(5)(i) Design management system

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 for their responsibilities, to ensure their continued competency, including safety management principles and the associated safety objectives. The organisation should assess the category of staff for which this training should be provided.
- (b) Adequate records of all the safety training provided should be kept in accordance with point 21.A.5.
- (c) Initial training that is compliant with the organisation's training standards should be provided to each member of the personnel within 6 months of joining the organisation, unless their



competency assessment justifies that there is no need for such a training. Personnel who are recruited from another organisation and temporary staff should be assessed for whether they need to receive any additional safety management training.

- (d) Recurrent safety training should be delivered either as a dedicated course, or else integrated within other training. It should be of an appropriate duration in each 2-year period, in relation to the relevant compliance monitoring audit findings and any other internal/external sources of information available to the organisation on safety, and in design.

- [21.A.239 Design management system](#).

GM 21.A.239(c)(5)(i) Design management system

SAFETY TRAINING

The main purpose of the safety training programme is to:

- support safety management policies and processes, including human factors training; and
- ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.

Each organisation should adapt the syllabus to its own needs. Typically, at least the following items should be included:

- The organisational roles and responsibilities related to safety, including the hazard identification and risk management processes, and to fostering a positive safety culture;
- Safety objectives and the associated safety performance indicators;
- Human factors principles, including human performance and limitations;
- Legislation, where applicable;
- Safety reporting systems and investigations; and
- Safety issues.

The purpose of the recurrent safety training is:

- primarily to ensure that staff remain current, notably on changes to SMS principles, processes and procedures; and
- also to share feedback on safety issues that are relevant to the organisation or lessons learned.

The training staff should have sufficient knowledge and experience to teach the topics at the required level, with the skills to influence attitudes and behaviours.

- [21.A.239 Design management system](#)

GM ~~No 1 to~~ 21.A.239(d)(a) Design assurance management system

DESIGN ASSURANCE ELEMENT

- (a)~~1~~ Purpose

This GM outlines some basic principles and objectives of [21.A.239\(a\)](#) the design assurance element.

(b)2. Definitions

2.(1) The design assurance system includes the organisational structure, responsibilities, procedures and resources to ensure the proper functioning of the design organisation.

2.(2) ~~The design~~ Design assurance refers to means all those planned and systematic actions necessary to provide adequate confidence that the organisation has the capability to:

- ~~to~~ design products or parts in accordance with the applicable type certification basis, the OSD certification basis CS and the environmental protection requirements;
- ~~to~~ demonstrate and verify the compliance with these type certification basis, the OSD certification basis CS and the environmental protection requirements; and
- ~~to~~ demonstrate to the Agency EASA this compliance.

2.(3) ~~The 'Type Investigation'~~ means refers to the tasks of the organisation in support of the TCtype-certificate, STCtype-certificate or other design approval processes necessary to demonstrate and verify and to maintain compliance with the applicable type certification basis, OSD certification basis CS and environmental protection requirements.

3. ~~Design Assurance~~

~~The complete process, starting with the CS and environmental protection requirements and product specifications and culminating with the issuing of a type certificate, is shown in the diagram on Figure 1. This identifies the relationship between the design, the Type Investigation and design assurance processes.~~

~~Effective design assurance demands a continuing evaluation of factors that affect the adequacy of the design for intended applications, in particular that the product, or part, complies with applicable CS and environmental protection requirements and will continue to comply after any change.~~

~~Two main aspects should therefore be considered:~~

- ~~How the planned and systematic actions are defined and implemented, from the very beginning of design activities up to continued airworthiness activities;~~
- ~~How these actions are regularly evaluated and corrective actions implemented as necessary.~~

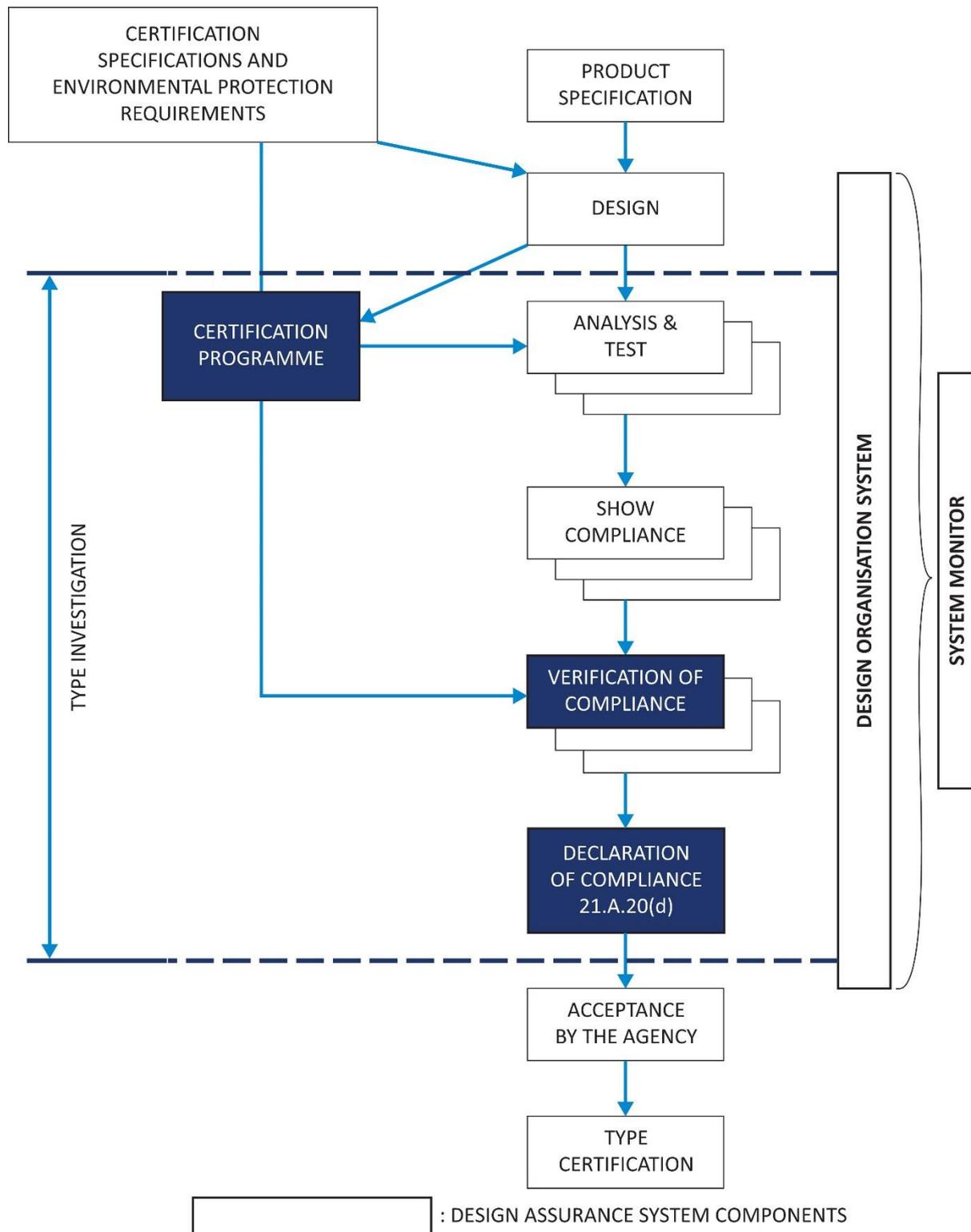


Figure 1 – RELATIONSHIPS BETWEEN DESIGN, DESIGN ASSURANCE AND TYPE INVESTIGATION

3.1 Planned and Systematic Actions

For design organisations carrying out Type Investigation of products, the planned and systematic actions should cover the following tasks and procedures should be defined accordingly:

3.1.1 General

- a. To issue or, where applicable, supplement or amend the handbook in accordance with 21.A.243, in particular to indicate the initiation of design activities on a product.
- b. To assure that all instructions of the Handbook are adhered to.
- c. To conduct Type Investigation.
- d. To nominate staff as 'compliance verification engineers' responsible to approve compliance documents as defined in paragraph 3.1.3.
- e. To nominate personnel belonging to the Office of Airworthiness responsible as defined in paragraph 3.1.4.
- f. In the case of an applicant for a supplemental type certificate, to obtain the agreement of the type certificate holder for the proposed supplemental type certificate to the extent defined in 21.A.115.
- g. To ensure full and complete liaison between the type design organisation and related organisations having responsibility for products manufactured to the type certificate.
- h. To provide the assurance to the Agency that prototype models and test specimens adequately conform to the type design (see 21.A.33(b)(1)).

3.1.2 Chief Executive and Head of design organisation (or his or her Deputy)

- a. The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.
- b. The Head of the design organisation, or an authorised representative, should sign a declaration of compliance (see 21.A.20(d) and 21.A.97(a)(3)) with the applicable CS and environmental protection requirements after verification of satisfactory completion of the Type Investigation. In accordance with 21.A.20(e) and 21.A.97(a)(4), his or her signature on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).
- c. The functions of Chief Executive and Head of the design organisation may be performed by the same person.

3.1.3 Compliance Verification

- a. Approval by signing of all compliance documents, including test programmes and data, necessary for the verification of compliance with the applicable CS and environmental protection requirements as defined in the certification programme.



- ~~b. — Approval of the technical content (completeness, technical accuracy...), including any subsequent revisions, of the manuals approved by the Agency (Aircraft Flight Manual, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable).~~

~~3.1.4 Office of Airworthiness~~

- ~~a. — Liaison between the design organisation and the Agency with respect to all aspects of the certification programme.~~
- ~~b. — Ensuring that a handbook is prepared and updated as required in 21.A.243.~~
- ~~c. — Co-operation with the Agency in developing procedures to be used for the type certification process.~~
- ~~d. — Issuing of guidelines for documenting compliance.~~
- ~~e. — Co-operation in issuing guidelines for the preparation of the manuals required by the applicable implementing rules, Service Bulletins, drawings, specifications, and standards.~~
- ~~f. — Ensuring procurement and distribution of applicable CS and environmental protection requirements and other specifications.~~
- ~~g. — Co-operating with the Agency in proposing the type certification basis~~
- ~~h. — Interpretation of CS and environmental protection requirements and requesting decisions of the Agency in case of doubt.~~
- ~~i. — Advising of all departments of the design organisation in all questions regarding airworthiness, operational suitability, environmental protection approvals and certification.~~
- ~~j. — Preparation of the certification programme and co-ordination of all tasks related to Type Investigation in concurrence with the Agency.~~
- ~~k. — Regular reporting to the Agency about Type Investigation progress and announcement of scheduled tests in due time.~~
- ~~l. — Ensuring co-operation in preparing inspection and test programmes needed for demonstration of compliance.~~
- ~~m. — Establishing the compliance checklist and updating for changes.~~
- ~~n. — Checking that all compliance documents are prepared as necessary to demonstrate compliance with all CS and environmental protection requirements, as well as for completeness, and signing for release of the documents.~~
- ~~o. — Checking the required type design definition documents described in 21.A.31 and ensuring that they are provided to the Agency for approval when required.~~



- ~~p. Preparation, if necessary, of a draft for a type certificate data sheet and/or type certificate data sheet modification.~~
- ~~q. Providing verification to the head of the design organisation that all activities required for Type Investigation have been properly completed.~~
- ~~r. Approving the classification of changes in accordance with 21.A.91 and granting the approval for minor changes in accordance with 21.A.95(b).~~
- ~~s. Monitoring of significant events on other aeronautical products as far as relevant to determine their effect on airworthiness or operational suitability of products being designed by the design organisation.~~
- ~~t. Ensuring co operation in preparing Service Bulletins and the Structural Repair Manual, and subsequent revisions, with special attention being given to the manner in which the contents affect airworthiness and environmental protection and granting the approval on behalf of the Agency.~~
- ~~u. Ensuring the initiation of activities as a response to a failure (accident/incident/in-service occurrence) evaluation and complaints from the operation and providing of information to the Agency in case of airworthiness or operational suitability impairment (continuing airworthiness and continued operational suitability).~~
- ~~v. Advising the Agency with regard to the issue of airworthiness directives in general based on Service Bulletins.~~
- ~~w. Ensuring that the manuals approved by the Agency, including any subsequent revisions (the Aircraft Flight Manual, MMEL, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable) are checked to determine that they meet the respective requirements, and that they are provided to the Agency for approval.~~

~~3.1.5 Maintenance and Operating Instructions~~

- ~~a. Ensuring the preparation and updating of all maintenance and operating instructions (including Services Bulletins) needed to maintain airworthiness (continuing airworthiness) in accordance with relevant CS. For that purpose, the applicant should:
 - ~~— establish the list of all documents it is producing to comply with the Appendix referred to in CS 23.1529, CS 25.1529, CS 27.1529, CS 29.1529, CS-E 25 or CS-P 40 (NPA-P-3);~~
 - ~~— define procedures and organisation to produce and issue these documents, using where applicable and so elected 21.A.263(c)(3) privilege.~~~~



- b. In accordance with ~~21.A.57, 21.A.61, 21.A.107, 21.A.119, 21.A.120A and 21.A.449~~, ensuring that these documents are provided to all affected operators and all involved authorities.

~~3.1.6 Operational Suitability Data~~

- a. Ensuring the preparation and updating of all operational suitability data in accordance with relevant CS. For that purpose, the applicant should:
- ~~— establish the list of all documents it is producing to comply with CS-MMEL or CS-GEN-MMEL, CS-FCD, CS-CCD, CS-SIMD and CS-MCSD as applicable;~~
 - ~~— define procedures and organisation to produce and issue these documents, using where applicable and so elected 21.A.263(c)(3) privilege.~~
- b. In accordance with ~~21.A.57, 21.A.62, 21.A.108, 21.A.119 and 21.A.120B~~, ensuring that these documents are provided to all affected operators and training organisations and all involved authorities.

~~3.2 Continued effectiveness of the design assurance system. The organisation should establish the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective.~~

~~21.A.239 Design management system~~

AMC1 21.A.239(d) Design management system

DESIGN ASSURANCE ELEMENT

- (a) Reserved
- (b) Reserved
- (c) Design assurance system

The complete design process, starting with the type certification basis, OSD certification basis and environmental protection requirements and product specifications and culminating with the issuing of a TC, is shown in the diagram on Figure 1. This identifies the relationship between the design, the type investigation and the design assurance processes.

Effective design assurance demands a continuing evaluation of any factors that affect the adequacy of the design for the intended applications. In particular, it must be ensured that the product or part complies with the applicable type certification basis, the OSD certification basis and the environmental protection requirements, and will continue to comply after any change.

Two main aspects should therefore be considered:

- How the planned and systematic actions are defined and implemented from the very beginning of the design activities up to the continued airworthiness activities;
- How these actions are regularly evaluated and corrective actions are implemented as necessary.



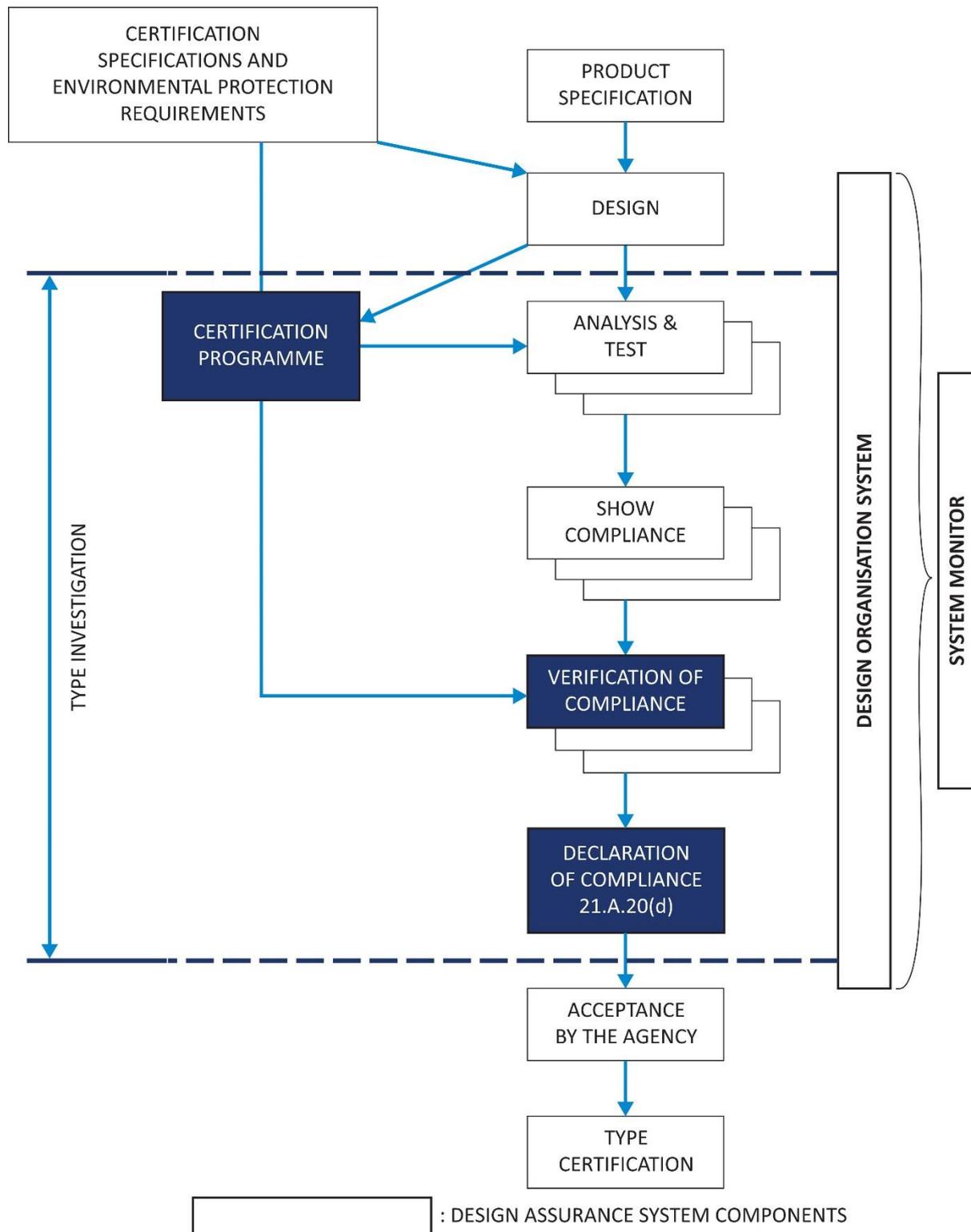


Figure 1 — RELATIONSHIPS BETWEEN DESIGN, DESIGN ASSURANCE AND TYPE INVESTIGATION

(1) Planned and systematic actions

For design organisations that carry out type investigations of products, their planned and systematic actions should cover the following tasks, and the related procedures should be defined accordingly:

(i) General

- (A) To 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) To assure that all the instructions of the handbook are adhered to.
- (C) To conduct type investigations.
- (D) To nominate staff as 'compliance verification engineers' who are responsible for approving compliance documents as defined in point (c)(1)(iii).
- (E) To nominate personnel who belong to the Office of Airworthiness and are responsible as defined in point (c)(1)(iv).
- (F) In the case of an applicant for a STC, to obtain the agreement of the TCholder for the proposed STC to the extent defined in point 21.A.115.
- (G) To ensure that there is full and complete liaison between the type design organisation and the related organisations who have responsibility for the products manufactured to the TC.
- (H) To provide assurance to EASA that any prototype models and test specimens adequately conform to the type design (see point 21.A.33(b)(1)).

(ii) Chief executive officer and head of the design organisation (or his or her deputy)

- (A) The chief executive officer should provide the necessary resources for the proper functioning of the design organisation.
- (B) The head of the design organisation, or an authorised representative, should sign a declaration of compliance (see points 21.A.20(d) and 21.A.97(a)(3)) with the applicable type certification basis, the OSD certification basis and the environmental protection requirements after verifying the satisfactory completion of the type investigation. In accordance with points 21.A.20(e) and 21.A.97(a)(4), his or her signature on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).
- (C) The functions of the chief executive officer and the head of the design organisation may be performed by the same person.

(iii) Compliance verification

- (A) Approval by 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, the OSD certification basis and the 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 approved by EASA (the aircraft flight manual, the airworthiness limitations section of the instructions for continued airworthiness and the certification maintenance requirements (CMR) document, where applicable).

(iv) Office of Airworthiness

- (A) Liaison between the design organisation and EASA with respect to all aspects of the certification programme.
- (B) Ensuring that a handbook is prepared and updated as required in 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 required by the applicable requirements, service bulletins, drawings, specifications, and standards.
- (F) Ensuring procurement and distribution of the applicable type certification basis, OSD certification basis and environmental protection requirements and other specifications.
- (G) Cooperating with EASA in proposing the type certification basis
- (H) The interpretation of the type certification basis, the OSD certification basis and the environmental protection requirements and requesting decisions from EASA in cases of doubt.
- (I) Advising all the departments of the design organisation on all questions regarding airworthiness, operational suitability, environmental protection approvals and certification.
- (J) Preparation of the certification programme and coordination of all the tasks related to type investigations in concurrence with EASA.
- (K) Regular reporting to EASA about the progress of type investigations, and announcing scheduled tests in due time.
- (L) Ensuring cooperation in preparing the inspection and test programmes needed for demonstrations of compliance.
- (M) Establishing the compliance checklist and updating it with any changes.
- (N) Checking that all the compliance documents are prepared that are necessary to demonstrate compliance with the type certification basis, the



- OSD certification basis and the environmental protection requirements, as well as for completeness, and signing the documents for release.
- (O) Checking the required type design definition documents 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 TCDS and/or a modification to a TCDS.
 - (Q) Providing verification to the head of the design organisation that all the activities required for a type investigation have been properly completed.
 - (R) Approving the classification of changes in accordance with point 21.A.91 and granting approvals for minor changes in accordance with point 21.A.95(b).
 - (S) Monitoring significant events on other aeronautical products, as far as they are relevant, to determine their effect on the airworthiness or the operational suitability of the products designed by the design organisation.
 - (T) Ensuring that there is cooperation in preparing service bulletins and the structural repair manual, and any subsequent revisions, with special attention being given 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 as a response to a failure (accident/incident/in-service occurrence) evaluation and complaints from the operation, and providing information to EASA if the airworthiness or the operational suitability are impaired (continuing airworthiness and continued operational suitability).
 - (V) Advising EASA on the issuing of airworthiness directives in general based on Service Bulletins.
 - (W) Ensuring that the manuals approved by EASA, including any subsequent revisions (to the aircraft flight manual, the MMEL, the airworthiness limitations section of the instructions for continued airworthiness and the certification maintenance requirements (CMR) document, where applicable) are checked to determine whether they meet their respective requirements, and that they are provided to EASA for approval.
- (v) Maintenance and operating instructions
- (A) Ensuring the preparation and updating of all the maintenance and operating instructions (including instructions for continued airworthiness and service bulletins) that are needed to maintain airworthiness (i.e. continuing airworthiness) in accordance with the relevant CSs. For that purpose, the applicant should:

- establish the list of all the documents it is producing to comply with the Appendix referred to in CS 23.1529, CS 25.1529, CS 27.1529, CS 29.1529, CS-E 20/25 or CS-P 40 (NPA P-3);
 - establish a system to collect in-service experience to be used for the improvement of the instructions;
 - define the procedures and the organisation that will produce and issue these documents, under the obligation of point 21.A.265(h); the procedures should cover the:
 - preparation, including the format and language (available industrial standards can be referred to and used);
 - proofreading (checking for clarity, readability, typos, etc.);
 - checking of technical consistency with the corresponding approved change(s), repair(s) or approved data, including the effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;
 - checking of feasibility in practical applications; and
 - responsibilities and authorised signatories.
- (B) In accordance with points 21.A.57, 21.A.61, 21.A.107, 21.A.119, 21.A.120A and 21.A.449, ensuring that these documents are provided to all known operators and all the involved authorities.

(vi) Operational suitability data (OSD)

- (A) Ensuring the preparation and updating of all OSD in accordance with the relevant CSs. For that purpose, the applicant should:
- establish the list of all the documents it is producing to comply with CS-MMEL or CS-GEN-MMEL, CS-FCDD, CS-CCD, CS-SIMD and CS-MCSD, as applicable;
 - define the procedures and the organisation that will produce and issue these documents, under the obligation of point 21.A.265(h); the procedure should cover the aspects described in (c)(1)(v)(A) above.
- (B) In accordance with points 21.A.57, 21.A.62, 21.A.108, 21.A.119 and 21.A.120B, ensuring that these documents are provided to all the affected operators and training organisations, and all the involved authorities.

(d) Continued effectiveness of the design assurance system

The organisation should establish the means by which the independent monitoring of the compliance and adequacy of the design assurance system will be performed in order to ensure that it remains effective.



– [21.A.239 Design management system](#)

~~AMC2 GM No 2 to 21.A.239(d)(a) Design management system~~
~~Design assurance system for minor changes to type design or minor repairs to products~~

DESIGN ASSURANCE ELEMENT FOR MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

~~(a)1.~~ Purpose

This ~~GM~~ AMC outlines some basic principles and objectives in order to comply with ~~21.A.239(a)~~ the design assurance element for organisations designing only minor changes to type design or minor repairs to products.

~~(b)2.~~ Design assurance system

The design assurance system should include the following:

- an organisational structure to:
 - control the design;
 - demonstrate compliance with the applicable type certification basis, the OSD certification basis CS and the environmental protection requirements;
 - independently check demonstrations of compliance;
 - liaise with the Agency EASA;
 - continuously evaluate the design organisation; and
 - control ~~sub-contractors~~ 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.

– [21.A.239 Design management system](#)

~~AMC 21.A.239(a)(3) Design assurance system – Independent system monitoring~~

~~The system monitoring function required by 21.A.239(a)(3) may be undertaken by the existing quality assurance organisation when the design organisation is part of a larger organisation.~~

~~AMC1 21.A.239(d)(2)(b) Design management assurance system - Independent checking function of the demonstration of compliance~~

INDEPENDENT VERIFICATION FUNCTION OF THE DEMONSTRATION OF COMPLIANCE

- ~~(a)1.~~ The independent verification ~~checking~~ function of the demonstration of compliance should consist of the verification by a person ~~who did not creating~~ create the compliance data. Such a person may work in conjunction with the individuals who prepare compliance data.

- (b)2. The verification should be shown by signing compliance documents, including test programmes and data.
- (c)3. For a product, there is normally only one compliance verification engineer nominated for each relevant subject. A procedure should cover the non-availability of nominated persons and their replacement when necessary.
- (d)4. For STC cases, when compliance statement and associated documentation are produced by the TC holder, and when this these data is are 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 checking function required in point 21.A.239(d)(2)(b) for these this data.
- [21.A.239 Design management system.](#)

GM1 21.A.239(d)(3)(c) Design management system ~~Design assurance system~~

DESIGN ASSURANCE ELEMENT

In meeting the requirements of point 21.A.239(d)(3)(c), the applicant for a design organisation approval under Subpart J may adopt the following policy:

- (a)1. The satisfactory integration of the Partner/Sub-contractor partner/subcontractor and applicant's design assurance systems should be is demonstrated for the activities covered under the applicant's terms of approval.
- (b)2. In the event that a Partner/Sub-contractor partner/subcontractor holds a design organisation approval (DOA), then in accordance with point 21.A.239(d)(3)(c), the applicant may take this into account in demonstrating the effectiveness of this integrated system.
- (c)3. When any Partner/Sub-contractor partner/subcontractor does not hold a DOA, then the applicant will need to establish to its own satisfaction and the satisfaction of the Agency EASA, the adequacy of that partner's/sub-contractor' subcontractor's design assurance system in accordance with point 21.A.243(b).
- [21.A.239 Design management system](#)

AMC1 21.A.239(e) Design management system

DOCUMENTATION

- (a) The manual or the handbook that is used to document the management system should be the key instrument used by an organisation to internally communicate its approach to management systems.
- (b) The organisation may document its safety policy, safety objectives and all the safety management system key processes (as required in point 21.A.239(a)(1)) in a separate manual (e.g. a safety management manual or management system manual) or in its handbook. Organisations that hold multiple organisation approvals, issued on the basis of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, may prefer to have a separate manual in order to avoid duplication.



- (c) The organisation may also choose to place in separate documents (e.g. policy documents, procedures) some of the information that is required to be documented.
- (d) If any required information is placed in a separate document, the manual or the handbook should contain adequate references to that document. Any such referenced documents should be considered integral parts of the organisation's management system documentation.

– [21.A.239 Design management system](#)

AMC1 21.A.239(f) Design management system

INDEPENDENT MONITORING OF COMPLIANCE AND ADEQUACY

- (a) The function that carries out independent monitoring of the compliance and adequacy of the documented procedures of the design management system should ensure that:
 - (1) the activities of the organisation are monitored for their adequacy and compliance with the applicable requirements and with any additional requirements as established by the organisation, and that these activities are carried out properly under the supervision of the nominated persons referred to in point 21.A.245(b);
 - (2) all subcontracted design activities are monitored;
 - (3) an objective review of the complete set of design management related activities is provided through independent audits;
 - (4) the independence of the audit is established by always ensuring that audits and inspections are carried out by personnel who are not responsible for the function, procedure or products that they audit or inspect;
 - (5) an audit plan is established to show when and how often the activities required by Part 21 will be audited; and
 - (6) the audit cycle should be determined through a risk assessment agreed by the competent authority and that it does not exceed the applicable audit planning cycle according to 21.B.432. That determination should consider at least the following aspects:
 - (i) the criticality of the items checked during the audit; and
 - (ii) the safety performance of the organisation, including any previous findings and root causes;
 - (7) when a non-compliance is found, the root cause(s) and contributing factor(s) are identified and corrective actions are defined. The feedback part of 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.
- (c) The independent monitoring of compliance and adequacy required by point 21.A.239(f) may be undertaken by the existing quality assurance organisation if the design organisation is part of a larger organisation.

– [21.A.239 Design management system](#)



AMC1 No 1 to 21.A.243(a) Data requirements Handbook

- (a) 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 covered by the design organisation approval.
- (1)- A description of the tasks which can be performed under the approval, according to the following classification:
- (i)a- General areas, like subsonic turbojet aeroplanes, ~~turbopropeller~~ turboprop aeroplanes, small aeroplanes, rotorcraft.
- (ii)b- Technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.)
- (iii)c- 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.
- (iv)d- 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 assurance management system, together with a chart indicating the functional and hierarchical relationship of the design assurance management system to the Management and to other parts of the organisation; also the chains of responsibilities within the design assurance management system, and the control of the work of all partners and ~~sub-contractors~~ 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)a- The procedures followed and forms used in the type investigation ~~Type Investigation~~ 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, the OSD certification basis ~~CS~~ and the environmental protection requirements, including specific requirements for import by importing authorities
- (ii)b- The procedures for classifying design changes as 'major' or 'minor' and for the approval of minor changes.
- (iii)c- The procedures for classifying and approving unintentional deviations from the approved design data occurring in production (concessions or non-conformities ~~non-conformance's~~).

- (iv)d. 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 ~~co-operation~~ cooperation with the production organisation when dealing with any continuing airworthiness actions that are 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 staff Staff of the organisation of current changes in engineering drawings, specifications and design assurance management procedures.
- (8) A description of the recording system for:
- (i)a. The the type design, including relevant design information, drawings and test reports, including inspection records of test specimens;
- (ii)b. The the means of compliance; and
- (iii)c. The the compliance documentation (compliance checklist check-list, reports, etc....).
- (9) A description of the record-keeping system to comply with point 21.A.5 21.A.55 and 21.A.105.
- (10) A description of the means by which the organisation monitors and responds to problems affecting the airworthiness or operational suitability of its product during design, production and in service in particular to comply with point 21.A.3A (see also AMC1 21.A.239(d), GM No 1 to 21.A.239(a), paragraphs points (c)(1)(iv)(S) and (U).
- (11) The names of the design organisation authorised signatories. Nominated persons with specific responsibilities such as mentioned in points 21.A.33 and 21.A.35 should be listed.
- (12) (Reserved) The description of the organisation's safety policy and the objectives of the organisation as required by point 21.A.239(c)(1).
- (13) A clear definition of the tasks, competence and areas of responsibility of the Office of Airworthiness.
- (14) A description of the procedures for the establishment and the control of the maintenance and operating instructions (see points 21.A.57, 21.A.61, 21.A.107, 21.A.119, 21.A.120A and 21.A.449).
- (15) A description of the means by which the continuing evaluation (system monitoring) of the design assurance management system will be performed in order to ensure that it remains effective.
- (16) A description of the procedures for the establishment and the control of the operational suitability data (see points 21.A.57, 21.A.62, 21.A.108, 21.A.119 and 21.A.120B).

- (17) A description of the internal safety reporting scheme as required by point 21.A.3A(a)(1)(ii);
- (18) A statement, signed by the head of the design organisation (and countersigned by the chief executive officer, if different), confirming that the design management handbook and any associated manuals will be complied with at all times.

This statement should read as follows, or embrace the intent of the following paragraph:

'This handbook defines the organisation and procedures upon which EASA's design organisation approval is based.

These procedures are approved by the undersigned, and must be complied with, as applicable, in order to ensure that all design activities are carried out on time and to an approved standard.

It is understood that the approval of the design organisation is based on the continuous compliance or the organisation with the applicable requirements of Part 21, and with the organisation's procedures described in this handbook. EASA is entitled to limit, suspend, or revoke the approval, if the organisation fails to fulfil the obligations imposed by Part 21, or any conditions according to which the approval was issued.

Signed

Dated

Head of the design organisation and ... (quote position)

Chief executive officer...

For and on behalf of ... (quote organisation's name)

The statement should be re-issued, at the earliest opportunity, whenever the head of the design organisation is changed.

– [21.A.243 Handbook](#)

AMC2 No 2 to 21.A.243(a) Data requirements – Model content of handbook for organisations designing minor changes to type design or minor repairs to products Handbook

MODEL CONTENT OF HANDBOOK FOR ORGANISATIONS DESIGNING MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

Part 1. Organisation

- 1.1 Objective of the handbook and binding statement
- 1.2 Responsible person for 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 (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 GM No 2 to 21.A.243(d), paragraph 2)
- 1.12 Independent system monitoring

Part 2. Procedures

- 2.1 Management of changes to type design and design of repairs
 - configuration control
 - classification
 - approval of minor changes to type design and minor repairs
- 2.2 Control of design sub-contractors subcontractors
- 2.3 Collecting/Investigating of failures, malfunctions and defects
- 2.4 Co-ordination Coordination with production
- 2.5 Documentation control
 - in relations relation with the changes and repairs
 - in relation with failures/malfunctions and defects (i.e. Services Bulletins)
- 2.6 Record-keeping
 - [21.A.243 Handbook](#)

AMC1 21.A.243(d) Handbook

STATEMENT OF QUALIFICATIONS AND EXPERIENCE

(a) The following statements should be provided:

(1) Other management staff

The person nominated represents, or persons nominated represent, the management structure of the organisation and is, or are, responsible through the head of the design organisation to the chief executive officer for the execution of all the functions specified in Subpart J of Part 21. Depending on the size of the organisation, the functions may be subdivided under individual managers.

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 this data to EASA on EASA Form 4-DOA (see EASA website: <http://easa.europa.eu/certification/application-forms.php>) to show that they are

suitable in terms of their relevant knowledge and satisfactory experience related to the nature of the design activities performed by the organisation.

The responsibilities and the tasks of each individual manager should be clearly defined, in order to prevent any uncertainties about the relations within the organisation. The responsibilities of the managers should be defined in a way that all responsibilities are covered.

- (2) The personnel who make decisions that affect airworthiness, operational suitability and environmental protection

For these personnel, no individual statements are required. The organisation should demonstrate that there is a system to select, train, maintain and identify them for all the tasks for which they are needed.

- (b) The personnel defined in (a) should be identified in the handbook or in a document linked to the handbook. This, and the corresponding procedures, should enable them to carry out the assigned tasks and to properly discharge the associated responsibilities.
- (c) The number of these personnel who are needed to sustain the design activities should be identified by the organisation.
- (d) The personnel defined in (a) 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.
- (f) Training policy forms a part of the design management system, and its appropriateness forms a part of investigation by EASA within the organisation approval process and the subsequent surveillance of the persons proposed by the organisation.
- (g) This training should be adapted in response to experience gained within the organisation
- (h) The organisation should maintain a record of the personnel defined in (a) as defined in AMC 21.A.5(d).

– [21.A.243 Handbook](#)

GM1 No 1 to 21.A.243(d) Handbook Statement of qualifications and experience

STATEMENT OF QUALIFICATIONS AND EXPERIENCE

1. Purpose

This GM provides guidelines on the following points:

— Who are the persons covered by 21.A.243(d)?

— What is requested from the applicant for these persons?



2. Who are the persons?

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, using qualified and experienced personnel:

- the Chief Executive chief executive officer [see GM No 1 to 21.A.239(a) AMC1 21.A.239(d), point (c)(1)(ii) para.3.1.2, GM 21.A.249, GM 21.A.265(b)]
- the other management staff:
 - the Head head of the design organisation [see GM No 1 to 21.A.239(a) AMC1 21.A.239(d), point (c)(1)(ii) para.3.1.2, GM No 1 21.A.245 AMC1 21.A.245, point (d)(1)4.1, GM 21.A.265(b)]
 - the Chief of the Office of Airworthiness, or [see GM No 1 21.A.245 AMC1 21.A.245, point (d)(2) 4.2]
 - the Chief of the independent monitoring function of the design assurance system [see point 21.A.239(a)(3) and AMC1 No 1 to 21.A.243(a), point (b)(2) para.2]
 - the safety manager function [see AMC1 21.A.239(c)(2)]
 - the safety review board function, depending on the size of the organisation, the nature and complexity of its activities [see AMC1 21.A.239(c)(2)]
- the personnel making decisions affecting airworthiness, operational suitability and environmental protection:
 - compliance verification engineers [see AMC1 to 21.A.239(d), para.3.1.3; AMC 21.A.239(b) AMC1 21.A.239(d)(2)]
 - personnel of the Office of Airworthiness making decisions affecting airworthiness, operational suitability and environmental protection, especially those linked with the point 21.A.263 privileges (signing documents for release, approving classification of changes and repairs, and granting the approval of minor changes and minor repairs, granting the approval of SBs, and minor revisions to the aircraft flight manual) [see AMC1 to 21.A.239(d), para. 3.1.4].
- A statement of the qualifications and experience of the chief executive officer is not required.

3. Kind of statement

3.1 Chief Executive

The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.

A statement of the qualification and experience of the Chief Executive is normally not required.

3.2 Other management staff



The person or persons nominated should represent the management structure of the organisation and be responsible through the Head of design organisation to the Chief Executive for the execution of all functions as specified in Part 21, Subpart J. Depending on the size of the organisation, the functions may be subdivided under individual managers.

The nominated managers should be identified and their credentials furnished to the Agency on EASA Form 4-DOA (see EASA website:

<http://easa.europa.eu/certification/application-forms.php>) in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.

The responsibilities and the tasks of each individual manager should be clearly defined, in order to prevent uncertainties about the relations, within the organisation. Responsibilities of the managers should be defined in a way that all responsibilities are covered.

3.3 Personnel making decisions affecting airworthiness, operational suitability and environmental protection

For these personnel, no individual statement is required. The applicant should show to the Agency that there is a system to select, train, maintain and identify them for all tasks where they are necessary.

The following guidelines for such a system are proposed:

————— These personnel should be identified in the handbook, or in a document linked to the handbook. This, and the corresponding procedures, should enable them to carry out the assigned tasks and to properly discharge associated responsibilities.

————— The needs, in terms of quantity of these personnel to sustain the design activities, should be identified by the organisation.

————— These personnel should be chosen on the basis of their knowledge, background and experience.

————— When necessary, complementary training should be established, to ensure sufficient background and knowledge in the scope of their authorization. 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 relevant for the particular role.

————— Training policy forms part of the design assurance system and its appropriateness forms part of investigation by the Agency within the organisation approval process and subsequent surveillance of persons proposed by the organisation.

————— This training should be adapted in response to experience gained within the organisation



~~———— The organisation should maintain a record of these personnel which includes details of the scope of their authorisation. The personnel concerned should be provided with evidence of the scope of their authorisation.~~

~~———— The following minimum information should be kept on record:~~

- ~~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) — If appropriate, date of expiry of the authorisation~~
- ~~h) — Identification number of the authorisation.~~

~~The record may be kept in any format and should be controlled.~~

~~———— Persons authorised to access the system should be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner or that such confidential records do not become accessible to unauthorised persons.~~

~~———— Personnel should be given access to their own record.~~

~~———— Under the provision of 21.A.257 the Agency has a right of access to the data held in such a system.~~

~~———— The organisation should keep the record for at least two years after a person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.~~

— [21.A.243 Handbook](#)

GM No AMC2 to 21.A.243(d) Handbook Data requirements – – Statement of the qualification and experience – Organisations designing minor changes to type design or minor repairs to products

STATEMENT OF THE QUALIFICATION AND EXPERIENCE — ORGANISATIONS DESIGNING MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

For organisations designing minor changes to type design designs or minor repairs to products, the statement of the qualifications and experience required by point 21.A.243(d) should be addressed as follows:

- (a) ~~1-~~ 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 credentials submitted to the Agency EASA on EASA Form 4 - DOA (see EASA

website: <http://easa.europa.eu/certification/application-forms.php>) in order that they may be seen 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)2. The persons responsible to for:

- classify classifying changes to type design designs or repairs;
- verify verifying compliance [point 21.A.239(b)];
- approve approving minor changes to type design designs and minor repairs [point 21.A.263(c)(2)]; and
- issue issuing information or instructions [point 21.A.263(c)(3)],

should be selected by the organisation in accordance with a procedure and criteria agreed with the Agency EASA.

– [21.A.243 Handbook](#)

AMC GM No 1 to 21.A.245 Requirements for approval Resources

See 21.A.245

(a)1. *General.* The data handbook submitted in accordance with point 21.A.243 should show that sufficient skilled personnel are available, and suitable technical and organisational provisions have been made for carrying out the type investigation Type Investigation defined by GM No-1 to 21.A.239(a)(d), point (b)(3) paragraph 2.3.

(b)2. *Personnel.* The applicant organisation should show that the personnel available to comply with point 21.A.245(a)(c)(1) are, due to their special qualifications and number numbers, able to provide assurance of the design or modification of a product, as well as the compilation and verification of all data needed to meet the applicable type certification basis, OSD certification basis CS and environmental protection requirements while taking into account the present state of the art and new experience.

(c)3. *Technical.* The applicant should have access to:

- (1)a. Workshops and production facilities which are suitable for manufacturing prototype models and test specimens; and-
- (2)b. Accommodation and test facilities which are suitable for carrying out the tests and measurements needed to demonstrate compliance with the type certification basis, OSD certification basis CS and environmental protection requirements. The test facilities may be subjected to additional technical conditions related to the nature of tests performed.

(d)4. *Organisation.* The data handbook submitted in accordance with point 21.A.243 should show that:

- 4.(1) the The Head head of the design organisation for which an application for approval has been made, has the direct or functional responsibility for all departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the Head head of the design organisation

still carries the ultimate responsibility for the compliance of the organisation with Part 21 Subpart J.

- 4.(2) ~~an~~ An Office of Airworthiness, or equivalent function, has been established and staffed on a permanent basis to act as the focal point for ~~co-ordinating~~ coordinating airworthiness, operational suitability and environmental protection matters (see ~~GM No 1 to 21.A.239(a)~~ AMC1 21.A.239(d) point (c)(1)(iv) ~~paragraph 3.1.4~~); it reports directly to the ~~head~~ Head of the design organisation or is integrated into an independent quality assurance organisation reporting to the ~~Head~~ head of the design organisation.
- 4.(3) [Reserved]
- 4.(4) The responsibilities ~~Responsibilities~~ for all the tasks related to Type Investigations are assigned in such a way that gaps in authority are excluded.
- 4.(5) The responsibility for a number of tasks as in point (c)(4) ~~paragraph 4.4~~ may be assigned to one person, especially in the ~~case~~ cases of simple projects.
- 4.(6) ~~Co-ordination~~ Coordination between technical departments and the persons in charge of the system monitoring required by point 21.A.239(f)(a)(3) has been established to:
- (i) ~~to~~ ensure the quick and efficient reporting and resolution of difficulties encountered using the handbook and associated procedures;
 - (ii) ~~to~~ maintain the design assurance management system; and
 - (iii) ~~to~~ optimise auditing activities.

– [21.A.245 Resources](#)

AMC ~~GM No 2 to 21.A.245 Resources~~ Requirements for approval – Organisations designing minor changes to type design or minor repairs to products

ORGANISATIONS DESIGNING MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

The ~~data~~ handbook submitted in accordance with point 21.A.243 should show that:

- (a)1. ~~The~~ the manager responsible for design has the direct or functional responsibility for all the departments of the organisation which are involved in the design of minor changes to type ~~design~~ designs or minor repairs to products;
- (b)2. a person has, or persons have, ~~Person(s) have~~ been nominated to liaise with the Agency EASA and to ~~coordinate~~ ~~co-ordinate~~ airworthiness, operational suitability and environmental protection matters. Their position in the organisation should allow them to ~~directly~~ direct report to the manager responsible for design;
- (c)3. the responsibilities ~~Responsibilities~~ for all tasks related to the design and approval of minor changes to type ~~design~~ designs or minor repairs to products are assigned to ensure that all areas are covered; and
- (d)4. the ~~The~~ responsibility for a number of tasks as in point (c) ~~paragraph 3~~ may be assigned to one person, especially in the ~~case~~ cases of simple projects.



– [21.A.245 Resources](#)



AMC1 21.A.245(a) Resources

HEAD OF THE DESIGN ORGANISATION

The head of the design organisation should:

- (a) have sufficient knowledge and authority to enable him or her to respond to the competent authority regarding major issues of the design approval, and to implement necessary improvements;
- (b) promote the safety policy specified in AMC1 21.A.239(c)(1); and
- (c) demonstrate a basic understanding of this Regulation.

– [21.A.245 Resources](#)

AMC1 21.A.245(b) Resources

RESPONSIBLE 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. Depending on the size of the design organisation, the functions may be subdivided under individual managers (and further subdivided), or combined.
- (b) The nominated managers should be identified in accordance to GM1 21.A.243(d).
- (c) The responsibilities and the tasks of each individual manager should be clearly defined, in order to prevent uncertainties about the relations within the organisation. For organisations with structures in which staff-members are responsible to more than one person, as, for instance, in matrix and project organisations, the responsibilities of the managers should be defined in such a way that all the responsibilities are covered.
- (d) If an approved design organisation chooses to appoint managers for all or any combination of the functions identified in Part 21 because of the size of the undertaking, these managers should ultimately report to the head of the design organisation. If a manager does not directly report to the head of design organisation, he or she should have direct access to the head of the design organisation formally established.
- (e) 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 terms of approval.
- (f) The organisation should establish and control the competency of personnel involved in design, compliance monitoring and safety management and, if applicable, issuing permits to fly, in accordance with a procedure and to a standard agreed by the competent authority. In addition to the necessary expertise related to the job function, the competency of the personnel should include an understanding of safety management and human factors principles that is appropriate to the person's function and responsibilities in the organisation.
- (g) The chief of the function for the independent monitoring of compliance and adequacy should:
 - (1) not be one of the persons referred to in point 21.A.245(b);



- (2) be able to demonstrate relevant knowledge, background and appropriate experience related to the activities of the organisation, including knowledge and experience in compliance monitoring; and
 - (3) have access to all parts of the organisation, and as necessary, any subcontracted organisations.
- (h) If functions related to compliance monitoring or safety management are combined with other duties, the organisation should ensure that this does not result in any conflicts of interest.
- (i) Subject to a risk assessment and agreement by the competent authority, with due regard to the size of the organisation and the nature and complexity of its activities, the compliance monitoring manager function and the safety manager function may be exercised by the head of the design organisation provided that he or she has demonstrated the related competence.
- [21.A.245 Resources](#)

AMC2 21.A.245(b) Resources

COMPETENCY OF PERSONNEL

- (a) To assist in the assessment of competency and to perform the training needs analysis, the organisation should establish job descriptions for all the job functions in the organisation. These job descriptions should contain sufficient criteria to enable the competency of each person to be assessed.
- (b) The organisation should provide initial and recurrent training, to the persons or group of persons nominated in accordance with point 21.A.245(b), which is adequate to their job function, and which ensures that their continued competency is maintained throughout the duration of their employment/contract.
- (c) The organisation should record the training provided in accordance with point (a).
- (d) All prospective members of the design management staff should be assessed for their competency, qualifications, and capabilities related to their intended duties.
- (e) All the staff nominated according to point 21.A.245(b) should be able to demonstrate their knowledge of, and compliance with, the design management organisation procedures that are applicable to their tasks.
- (f) All the staff nominated according to point 21.A.245(b) should be able to demonstrate an understanding of the safety management principles, human factors and human performance issues related to their tasks.
- (g) The competency of the person who assumes, or persons who assume, the function of safety manager should include, but not be limited to, the following:
 - knowledge of the ICAO standards and European requirements for safety management;
 - an understanding of management systems, including compliance monitoring systems;
 - an understanding of risk management;
 - an understanding of safety investigation techniques;
 - an understanding of human factors;



- an understanding of a positive safety culture and its promotion; and
 - operational experience related to the activities of the organisation.
- (h) The organisation should develop a procedure that describes the process for assessing the competency of the person. The procedure should specify:
- (1) the persons responsible for this process;
 - (2) the means and methods for the initial assessment;
 - (3) the means and methods for the continuous control of their competency, including feedback on their performance;
 - (4) the actions to be taken if the assessment is not satisfactory; and
 - (5) how to record assessment results.
- [21.A.245 Resources](#)

AMC1 21.A.247 Changes to the design management system

APPLICATION FOR A SIGNIFICANT CHANGE OR A VARIATION OF SCOPE AND TERMS OF THE DOA

An application for a significant change or a variation of scope should be submitted in writing to the competent authority, and the design organisation should demonstrate to the competent authority, on the basis of the submission of the proposed changes to the handbook, and before the implementation of the change, that it will continue to comply with Part 21 after the implementation.

- [21.A.247 Changes to the design management system](#)

GM1 21.A.247 Changes to the design management assurance system

In addition to a change in ownership (see point 21.A.249), the following changes to the design assurance management system should be considered as '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 suppliers, design work sharing), unless it can be shown that the independent verification checking 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 checking function, Office of Airworthiness office of airworthiness [or equivalent]);
- A change to the independent monitoring principles of compliance and adequacy (see point 21.A.239(f)(3))



(b)2. Responsibilities

- Change of the management staff
 - the head Head of the design organisation [GM No 1 to 21.A.239(a) AMC1 21.A.239(d), point (c)(1)(ii) para.3.1.2, GM No 1 to 21.A.245 AMC1 21.A.245, point (d)(1) para.4.1, GM 21.A.265(b)]
 - the Chief of the Office of Airworthiness [GM No AMC1 to 21.A.245, point (d)(2) para.4.2]
 - the Chief of the independent monitoring function of compliance and adequacy of the design management assurance system [point 21.A.239(f)(a)(3) and AMC No 1 to 21.A.243(a), para.2 point (b)(2)]
- Reporting lines between the personnel nominated in accordance with point 21.A.245(b), and the head of the design organisation;
- New distribution Allocation of responsibilities affecting safety, airworthiness, operational suitability or environmental protection; and
- For organisations designing minor changes to type design designs or minor repairs to products, change of the persons identified in GM No 2 to 21.A.243(d).

(c)3. Procedures

Change to the principles of procedures related to:

- the type certification;
- the classification of changes and repairs as ‘major’ or ‘minor’ [point 21.A.263(c)(1)];
- the treatment handling of major changes and major repairs;
- the approval of the design of minor changes and minor repairs [point 21.A.263(c)(2)];
- the issue issuing of information and instructions under the privilege of point 21.A.263(c)(3);
- the approval of minor revisions to the Aircraft Flight Manual [point 21.A.263(c)(4)];
- the approval approvals of the design designs of major repairs [point 21.A.437 or 21.A.263(c)(5)];
- continued airworthiness or continued operational suitability (see point 21.A.3B);
- the configuration control, when airworthiness, operational suitability or environmental protection is affected; and
- the acceptability of design tasks undertaken by partners or sub-contractors subcontractors [point 21.A.239(d)(3)(e)].

(d)4. Resources

- A substantial Substantial reduction in the number and/or experience of staff (see point 21.A.245(d)(1)(a)).



– [21.A.247 Changes to the design management system](#)

GM 21.A.257(a) Investigations

Arrangements that allow the Agency to make investigations include the complete design organisation including partners, sub-contractors and suppliers, whether they are in the State of the applicant or not, assisting and co-operating with the Agency in performing inspections and audits conducted during initial assessment and subsequent surveillance.

Assistance to the Agency includes all appropriate means associated with the facilities of the design organisation to allow the Agency to perform these inspections and audits, such as a meeting room and office support.

GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings

CAUSAL ANALYSIS

It is important that the causal 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 a 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 (regulatory, human factors, organisational factors, technical, etc.) in addition to the direct factors.

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, it therefore bears the risk that important factors that need to be addressed in order to prevent reoccurrences will be ignored.

Such an inappropriate or partial causal analysis often leads to defining 'quick fixes' that only address the symptoms of the nonconformity. A peer review of the results of the causal analysis may increase its reliability and objectivity.

A system description of the organisation that considers organisational structures, processes and their interfaces, procedures, staff, equipment, facilities and the environment in which the organisation operates, will support both effective causal (reactive) and hazard (proactive) analysis.

– [21.A.258 Findings](#)



SUBPART M — REPAIRS

~~AMC 21.A.433(a) and 21.A.447 Repair design and record keeping~~

- ~~1. Relevant substantiation data associated with a new major repair design and record keeping should include:
 - a. damage identification and reporting source,
 - b. major repair design approval sheet identifying applicable specifications and references of justifications,
 - c. repair drawing and/or instructions and scheme identifier,
 - d. correspondence with the TC, STC, or APU ETSO authorisation holder, if its advice on the design has been sought,
 - e. structural justification (static strength, fatigue, damage tolerance, flutter etc.) or references to this data,
 - f. effect on the aircraft, engines and/or systems, (performance, flight handling, etc., as appropriate)
 - g. effect on maintenance programme,
 - h. effect on Airworthiness limitations, the Flight Manual and the Operating Manual,
 - i. weight and moment change,
 - j. special test requirements.~~
- ~~2. Relevant minor repair documentation includes paragraphs 1(a) and (c). Other points of paragraph 1 may be included where necessary. If the repair is outside the approved data, justification for classification is required.~~
- ~~3. 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, number of repaired turbine blades per set, oversizing of fastener holes, etc.).~~
- ~~4. Special consideration should also be given to Life Limited parts and Critical Parts, notably with the involvement of the type-certificate or STC holder, when deemed necessary under 21.A.433(b).~~
- ~~5. Repairs to engine or APU critical parts would normally only be accepted with the involvement of the TC holder.~~



SUBPART P — PERMIT TO FLY

GM 21.A.705 Competent authority

~~An aircraft registered in a Member State is under the responsibility of this Member State for continuing airworthiness aspects. Consequently, any permit to fly under Part 21 should be issued by that Member State including cases where the aircraft will fly in another State. The permit to fly contains all the conditions and restrictions to ensure safe flight but other airspace and operational rules remain the competence of the authority of the State where the flight will take place. The applicant should therefore also ensure compliance with the relevant regulations of that State.~~



SECTION B PROCEDURES FOR COMPETENT AUTHORITIES

SUBPART A — GENERAL PROVISIONS

GM 21.B.20 Responsibility for implementation

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

- ~~a) The establishment and maintenance of an effective organisation and corresponding processes by all competent authorities.~~
- ~~b) The operation of all competent authorities in accordance with Part 21 and its Acceptable Means of Compliance (AMC) and guidance material (GM).~~
- ~~c) A standardisation process established and operated by the Agency to assess the standard achieved, and to provide timely advice and guidance to the competent authorities of the Member States.~~

~~As a result the responsibility for implementation comprises of the 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 sufficient visibility of the processes to give the Agency and the other Member States the necessary confidence in the certificates or approvals granted.~~

AMC1 21.B.25 Management system

GENERAL

- (a) In deciding upon the required airworthiness organisational structure, the competent authority should review:
 - (1) the number of certificates, approvals, authorisations and letters of agreement to be issued,
 - (2) the number, complexity and sizes 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, parts and appliances; and
 - (5) the potential growth of activities in the field of civil aviation.
- (b) The competent authority should retain effective control of the important inspection 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.

– [21.B.25 Management system](#)

AMC2 GM-21.B.25(a) Organisation Management system

GENERAL

- (a) The competent authority designated by each Member State should have an organisation in such a way that:
- a)(1) there is specific and effective management authority in the conduct of all the relevant activities;
 - b)(2) the functions and processes described in Part 21 and its AMC and GM may be properly implemented;
 - c)(3) the competent authority of the Member State's policy policies, organisation and operating procedures for the implementation of Part 21 are properly documented and applied;
 - d)(4) all the personnel of the competent authority of the Member State personnel involved in the related activities are provided with training where necessary;
 - e)(5) specific and effective provision is made for the communication and interface as necessary with the Agency EASA and the competent authorities of the Member States; and
 - f)(6) all the functions related to the implementation of Part 21 are adequately described and shown (Standardisation).
- (b) A general policy in respect of Part 21 the activities related to the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof should be developed, sponsored promoted and implemented by the manager at the highest appropriate level, for example, the top of the functional area of the competent authority of the Member State that is responsible for the related matters.
- (c) Appropriate steps should be taken to ensure that the policy is known and understood by all the personnel staff involved, and all the necessary steps should be taken to implement and maintain the policy.
- (d) The general policy, whilst whilst also satisfying also the additional national regulatory responsibilities, the general policy should, in particular, take into account:
- (1) the provisions of the Regulation (EU) 2018/1139 (EC) No 216/2008;
 - (2) the provisions of the applicable requirements and their Part 21 and its AMC and GM;
 - (3) the needs of industry; and
 - (4) the needs of the Agency and of the other competent authorities of the Member States.



- (d) The policy should define specific objectives for the key elements of the organisation and processes for the implementation of the related Part 21 activities, including the corresponding control procedures and the measurement of the achieved standard.

– [21.B.25 Management system](#)

GM 21.B.25(b) Resources

- (a) ~~The organisation for related Part 21 activities should be clearly defined within the general organisation of the competent authority of the Member State, with the hierarchical and functional links, and the names of the senior staff. Although final responsibility should be placed at the top of the functional area that is responsible for the related Part 21 activities as a whole, all subordinate levels of management should be suitably resourced and empowered to fulfil their delegated tasks.~~
- (b) ~~The definition of an organisation for the implementation of related Part 21 activities should include the specification of~~
- ~~(1) a manager responsible for the specific Part 21 activity acting as internal and external focal point. The responsibility is best placed with the manager who is in control of the day-to-day functions concerning the specific Part 21 activity, although he may delegate specific tasks to other individuals;~~
 - ~~(2) individual or group responsibilities, duties and associated reporting lines;~~
 - ~~(3) the resources, human and material;~~
 - ~~(4) the documented procedures to be operated in respect of the relevant Part 21 activities.~~
- (c) ~~The various tasks and responsibilities of the personnel involved in the related Part 21 activities should be clearly identified. The authority attached to the responsibilities should be enough to ensure that the activities will be performed correctly.~~
- (d) ~~These responsibilities include among others:~~
- ~~(1) the management of the organisation~~
 - ~~(2) the management of investigation teams~~
 - ~~(3) the team leadership/membership~~
 - ~~(4) the investigation and surveillance activities~~
 - ~~(5) the administrative management of certificates and approvals, , including record keeping;~~
 - ~~(6) the external and internal interface activities including feedback to the Agency;~~
 - ~~(7) the control and distribution of documentation~~

~~The definition of the organisation should include means to ensure continued effectivity of the organisation. The means should provide for a regular assessment of the organisation and its related activities as well as a feedback system for the follow up of necessary corrective actions (e.g., through the implementation of a quality system, internal audit system, etc.).~~



GM 21.B.25(c) Qualification and training

The competent authority of the Member State should ensure appropriate and adequate training of its personnel to meet the standard that is considered by the Agency necessary to perform the work. Arrangements should be made for initial and continuation training as required.

It is understood that the basic competence of the competent authority of the Member State staff is a matter of recruitment and normal management functions in selection of staff for particular duties. Moreover, it is understood that the competent authority of the Member State provides training in the basic skills as required for those duties.

However, to avoid differences in understanding and interpretation, it is considered important that all personnel involved in Part 21 activities should be provided with further training specifically related to the relevant Part 21 activity up to the common Agency standard.

The competent authority of the Member State should provide training through its own training organisation with qualified trainers or through another qualified training source (e.g., training provided by other competent authorities, the Agency or qualified entities).

AMC1 21.B.25(a)(1) Management system

DOCUMENTED POLICIES AND PROCEDURES

- (a) The various elements of the organisation for the activities related Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof 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 it will facilitate their use. They should be clearly identified, kept up-to-date and made readily available to all the personnel involved in the relevant activities.
- (c) The documented procedures should cover, as a minimum, the following aspects:
 - (1) policies and objectives;
 - (2) the structure of the organisation;
 - (3) responsibilities and the associated authority;
 - (4) procedures and processes;
 - (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) The information may be held in more than one document or in a series of documents, in which case suitable cross-reference information 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.

– [21.B.25 Management system](#)

GM1 21.B.25(a)(2) Management system

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 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 21.B.25; and
 - (2) the following qualitative elements:
 - (i) the size, nature, and complexity of the activities of certified organisations, taking into account:
 - (A) the privileges of the organisation;
 - (B) the type of the approval, the scope of the approval;
 - (C) the possible use of industry certification standards;
 - (D) the number of personnel; and
 - (E) the structure of the organisational;
 - (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 the:
 - (A) number and the levels of findings;
 - (B) time frame for the implementation of corrective actions; and
 - (C) maturity of the management systems implemented by the organisation, and its ability to effectively manage safety risks; and
 - (iv) the size and complexity of the aviation industry under its oversight, 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, authorisations and letters of agreement 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 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 a good practice to use a spreadsheet application 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.

– [21.B.25 Management system](#)

AMC1 21.B.25(a)(3) Management system

QUALIFICATIONS AND TRAINING — GENERAL

- (a) It is essential that the competent authority has 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 required qualifications;
 - (3) establish initial and recurrent training programmes in order to maintain and to enhance competency at the level necessary to perform the allocated tasks; and
 - (4) ensure that the training provided meets the established standards and is regularly reviewed and updated whenever necessary.
- (c) The competent authority may provide training through its own training organisation with qualified trainers, or through another qualified training source.
- (d) When training is not provided through an internal training organisation, adequately experienced and qualified persons may act as trainers, provided that their training skills have been assessed. If required, an individual training plan should be established that covers specific training skills. Records should be kept of such a training, and of the assessment, as appropriate.

– [21.B.25 Management system](#)

AMC2 21.B.25(a)(3) Management system

QUALIFICATIONS AND TRAINING — TECHNICAL PERSONNEL INCLUDING INSPECTORS

- (a) Competent authority technical personnel 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 the implementing rules, AMC, CSs and GM;



- (ii) the competent authority's procedures;
 - (iii) their rights and obligations;
 - (iv) systems based on the EU management system requirements (including compliance monitoring) and on ICAO Annex 19; and
 - (v) design- or production-, as applicable, related human factors and human performance principles;
- (3) a relevant engineering degree or an aircraft maintenance technician qualification with additional education. 'Relevant engineering degree' means an engineering degree from aeronautical, mechanical, electrical, electronic, avionic or other studies relevant to the design and production of aircraft/aircraft components; and
- (4) knowledge of design or production standards, as applicable.
- (b) In addition, competent authority inspectors should have:
- (1) training on auditing techniques and on assessing and evaluating management systems and safety risk management processes; and
 - (2) 5 years of relevant work experience to be allowed to work independently as an inspector. This may include experience gained during training to obtain the qualifications described in point (a)(2).
- (c) In addition to their technical competency, the technical personnel should have a high degree of integrity, be impartial in carrying out their tasks, be tactful, and have a good understanding of human nature.
- (d) A programme for recurrent training should be developed to ensure that technical personnel remain competent to perform their allocated tasks. As a general policy, it is not desirable for the technical personnel to obtain technical qualifications from those entities that are under their direct regulatory oversight.
- [21.B.25 Management system](#)

AMC3 21.B.25(a)(3) Management system

INITIAL AND RECURRENT TRAINING — INSPECTORS

(a) Initial training programme:

The initial training programme for inspectors should include, as relevant to their role, current knowledge, experience and skills in at least all of 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 the basis thereof, and the related AMC, CSs, and GM;



- (5) specific knowledge of Regulation (EU) No 748/2012, its related AMC, GM and CSs, 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) competent authority procedures 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; 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 competence 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) competent authority procedures that are relevant to the inspector's tasks;
- (3) technical training 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.

– [21.B.25 Management system](#)

AMC1 21.B.25(a)(5) Management system

SAFETY RISK MANAGEMENT PROCESS

- (a) The safety risk management process required by point 21.B.25 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 their tolerability); and
 - (iii) control (in terms of the mitigation of risks to an acceptable level);
 - (3) who holds the responsibilities for hazard identification and risk management;
 - (4) who holds the responsibilities 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) 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 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; and
 - (8) the results of risk assessments are periodically reviewed to check whether they remain relevant (e.g. are the assumptions still valid? Is there any new information?).

– [21.B.25 Management system](#)

GM1 21.B.25(a)(5) Management system

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 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 as a substitute for the State safety risk management SARPs defined in ICAO Annex 19, Chapter 3, component 3.3. This does not mean, however, that the competent authority may not use information and data obtained through its 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.

– [21.B.25 Management system](#)

AMC1 21.B.25(d) Management system

PROCEDURES AVAILABLE TO EASA

- (a) Copies of the procedures related to the management system of the competent authority of the Member States, 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 personnel;
 - (2) for personnel who are involved in oversight activities, the minimum professional qualification requirements and experience, and the principles that guide their appointment (e.g. assessment);
 - (3) how the following are carried out: the assessment of applications and evaluations of compliance, the issuance of certificates, approvals, authorisations and letters of agreement, the performance of continuing oversight, 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 adequate 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 amendments). These additional details are the procedures and related guidance material that describe the working methods for the competent authority personnel who conduct oversight activities.
- (c) Information related to the competent authority's management system may be submitted in an electronic format.
- [21.B.25 Management system](#)

AMC 21.B.30(a) Documented procedures

The various elements of the organisation for the related Part 21 activities must be documented in order to establish a reference source for the establishment and maintenance of this organisation. The documented procedures must be established in a way that it will facilitate its use. They must be clearly identified, kept up to date and made readily available to all the personnel involved in the relevant activities.

The documented procedures must cover, as a minimum, the following aspects:

- a) — policy and objectives,
- b) — organisation structure,
- c) — responsibilities and attached authority,
- d) — procedures and processes,
- e) — internal and external interfaces,
- f) — internal control procedures,
- g) — training of personnel,
- h) — cross references to associated documents,
- i) — assistance from other competent authorities or the Agency (where required).

Except for smaller competent authorities, it is likely that the information is held in more than one document or series of documents, and suitable cross-reference information must be provided. For example, organisational structure and job descriptions are not usually in the same documentation as the detailed working procedures. In such cases it is recommended that the documented procedures include an index of cross references to all such other related information, and the related documentation must be readily available when required.

GM1 21.B.30 Allocation of tasks to qualified entities

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 the Regulation (EU) No 748/2012.

- [21.B.30 Allocation of tasks to qualified entities](#)



AMC 21.B.35(a) Changes

~~Standardisation is based on the assessment of the organisation and procedures of the competent authorities of the Member States and their implementation and suitability by the Agency. Consequently, a significant change in the competent authority of the Member State organisation and documented procedures validated by the Agency needs a reassessment to maintain the confidence in the standardisation process.~~

~~Examples of significant changes include changes in the organisation hierarchy, decision making levels, number and qualification of personnel, etc.~~

~~The competent authority of the Member State must notify any of these changes to the Agency and must be prepared to provide any further explanation/information requested by the Agency. The Agency may decide to review the documented organisation and procedures of the competent authority of the Member State and request any clarification or changes. This might also apply when a change in the regulations takes place and the Agency decides that a specific assessment/monitoring of the competent authorities related to that change is necessary.~~

GM No 1 to 21.B.45 Co-ordination with other related activities

~~The purpose of co-ordination with other related activities is to~~

- ~~a) — harmonise the effects of various approval and certification teams especially when dealing with one organisation / applicant to prevent conflicts of conclusions,~~
- ~~b) — ensure efficient flow of information between the various approval and certification teams to facilitate the execution of their duties~~
- ~~c) — optimise the use of the Agency and the competent authorities resources to minimise disruption and cost.~~

~~Therefore, for a given organisation / applicant the responsible person(s) of the Agency or competent authorities of the Member State should arrange for exchange of information with, and provide necessary assistance, as appropriate, to the relevant competent authority of the Member State or Agency teams or staff — e.g.:~~

- ~~a) — the appropriate certification teams;~~
- ~~b) — the design organisation approval team;~~
- ~~c) — the production organisation approval team;~~
- ~~d) — the maintenance organisation approval team; or~~
- ~~e) — other approval or certification teams as appropriate.~~

GM No 2 to 21.B.45 Co-ordination

~~An exchange of information should especially take place in accordance with Article 15 of the Regulation (EC) No 216/2008:~~

- ~~(a) — an immediate reaction of a competent authority of the Member State to a safety problem~~

- (b) ~~granting of exemptions by the competent authority of the Member State from the substantive requirements of the Regulation (EC) No 216/2008 and its implementing rules (for a period of more than two months or when the exemptions become repetitive)~~
- (c) ~~granting of approvals on an equivalent level of protection by the competent authority of the Member State by derogation from the Part 21 requirements~~

GM No 3 to 21.B.45 Reporting – Information relevant to registers established by the Agency

~~When so requested by the Agency, the competent authority of the Member State should notify any certificate or approval issued, changed or revoked including details of the scope of that certificate or approval to the Agency for inclusion in a central register managed by the Agency.~~

AMC1 21.B.55(a) Record-keeping

GENERAL

- (a) The record-keeping system should ensure that all records are accessible whenever needed within a reasonable time. These records should be organised in a manner that ensures that there is traceability and retrievability throughout the required retention period.
- (b) All records that contain sensitive data regarding applicants or organisations should be stored in a secure manner with controlled access to ensure their confidentiality.
- (c) Records should be kept in paper form, or in an electronic format, or a combination of the two. 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 or was last amended.
- (d) Paper systems should use robust material which can withstand normal handling and filing. Computer systems should have at least one backup system, which should be updated within 24 hours of any new entry. Computer systems should include safeguards against any unauthorised personnel from altering the data.
- (e) All the computer hardware used to ensure data backup should be stored in a different location from the one that contains the working data, and in an environment that ensures 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 at least throughout the full period specified in point 21.B.25(d).

– [21.B.55 Record-keeping](#)

AMC1 21.B.55(a)(1) Record-keeping

COMPETENT AUTHORITY MANAGEMENT SYSTEM

Records 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, and corrective, preventive and risk mitigation actions; and
 - (d) the contract(s) established with qualified entities that perform certification or oversight tasks on behalf of the competent authority.
- [21.B.55 Record-keeping](#)

GM1 21.B.55 Record-keeping

FOR DESIGN APPROVALS TRANSFERRED TO EASA

Record-keeping related to design approvals, for which the responsibility is transferred to the Agency EASA, will remain initially with the competent authority of the Member State that has granted the approvals, at the disposal the Agency EASA. This GM specifies the administrative documents to be kept for the various kinds of design approvals. It does not repeat the requirements put on holders of design approvals to keep records (ref. ~~21.A.5, 21.A.55, 21.A.105, 21.A.118A(a)(1), 21.A.447, 21.A.605~~).

(a)1. Type certificate Type certificate

- ~~a)~~ (1) Copy of the type certificate TC
- ~~b)~~ (2) Copy of the type certificate TCDS
- ~~c)~~ (3) Environmental protection approval data
- ~~d)~~ (4) Documents defining the type-certification basis including information to justify special conditions, equivalent safety findings and exemptions (Certification Review Items or equivalent)
- ~~e)~~ (5) List of approved modifications,
- ~~f)~~ (6) List of the competent authority's approved publications (Flight Manual, Repair Manual, Airworthiness Limitations, Certification Maintenance Requirements)
- ~~g)~~ (7) Airworthiness directives
- ~~h)~~ (8) Master Minimum Equipment List
- ~~i)~~ (9) Maintenance Review Board Report

(b)2. Supplemental type certificate

- (1) Copy of 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)3. ~~JTSO~~ETSO Authorisation

- (1) Copy of ~~JTSO~~the-ETSO authorisation letter
- (2) Copy of Declaration of Design and Performance
- (3) Statement of compliance with applicable standards
- (4) Airworthiness directives

(d)4. Other part or appliance approvals

- a(1) Copy of ~~the~~ approval letter,
- b(2) Copy of Declaration of Design and Performance or equivalent
- c(3) Statement of compliance with applicable standards
- d(4) Airworthiness ~~D~~irectives

(e)5. Changes from non TC or STC holders

- a(1) Modification approval sheet, or equivalent document
- b(2) Documents required by ~~point 21.A.5~~ 21.A.105, or equivalent national requirement

Note: Not applicable to minor design changes approved under a DOA privilege, for which record-keeping is under the DOA holder responsibility.

(f)6. Repair design approvals

- a(1) Repair approval sheet
- b(2) Documents listed in ~~point 21.A.5~~ 21.A.447, or equivalent national requirement

Note: Not applicable to repair design approved under a DOA privilege, for which record-keeping is under the DOA holder responsibility.

– [21.B.55 Record-keeping](#)

GM1 21.B.55(e) Record-keeping

TRACEABILITY OF RELEASE CERTIFICATES

The record-keeping for those EASA Forms 52 and 1 that have been 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.55 Record-keeping](#)

AMC1 21.B.65 Suspension, limitation and revocation

CORRECTIVE ACTION PLAN

It is expected that any established organisation approved according to Subparts G or J will move quickly to re-establish compliance with Part 21 and will not risk the possibility of their approval being suspended. Therefore, the corrective action period granted by the competent authority should be appropriate to the nature of the finding, and in any case, it should not initially be more than 3 months. In certain circumstances and subject to the nature of the finding, the competent authority

may vary the 3-month period provided that a satisfactory corrective action plan has been agreed by the competent authority.

If the organisation fails to comply within the time period agreed by the competent authority, a provisional suspension of the approval, in whole or in part, should proceed.

- [21.B.65 Suspension, limitation and revocation](#)

AMC1 21.B.65(c) Suspension, limitation and revocation

INFORMATION ON SECURITY SITUATION

- (a) The European Commission Security Directorate generally advises against any non-essential travel to a country where hostile conditions, or a combination of the following conditions, reduce the level of security, and pose a high level of threat to personnel, as follows:
- (1) international or internal armed conflict with frequent armed confrontation taking place, numerous casualties, and/or serious damage to infrastructures;
 - (2) a situation that could lead to war, or characterised by high internal or external tension that could escalate into instability in the short term; very poorly functioning institutions;
 - (3) relatively frequent terrorist attacks due to the presence of active terrorist groups, either domestic or transnational, and state authorities that are unable to ensure a satisfactory level of security; and
 - (4) frequent criminal violence that also targets non-nationals. State authorities have a limited ability to counter criminal activities and ensure security.
- (b) Countries where the above conditions apply should not be considered compatible with the performance of on-site audits by the competent authority.

- [21.B.65 Suspension, limitation and revocation](#)

GM1 21.B.65 Suspension, limitation and revocation

(a) GENERAL

Decisions on the suspension or revocation of a certificate, approval, authorisation or letter of agreement 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.

(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) SUSPENSION

A suspension is a temporary withdrawal of all the privileges of an organisation's approval. The approval remains valid, but no activities that invoke the approval can be made while the suspension is in force. Approval privileges may be re-instated when the circumstances that caused the suspension are corrected and the organisation can once again demonstrate full compliance with the requirements.

(d) 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.

- [21.B.65 Suspension, limitation and revocation](#)



SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

GM1 21.B.115 and 21.B.215 Alternative means of compliance

Alternative means of compliance that are used by a competent authority, or by a person or organisation under its oversight, may be used by other competent authorities, persons, or organisations only if they are processed again in accordance with points 21.B.115(d) and (e) or 21.B.215(d).

- [21.B.115 Alternative means of compliance](#)

AMC1 21.B.115(d) and 21.B.215(d) Alternative means of compliance

DEMONSTRATION OF COMPLIANCE

In order to demonstrate that the implementing rules are met, a risk assessment should be completed and documented.

- [21.B.115 Alternative means of compliance](#)

AMC1 21.B.120(a) Initial certification procedure

INVESTIGATION TEAM

- (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 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(a).
- (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 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 applications 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 or revocation of a letter of agreement.

– [21.B.120 Initial certification procedure](#)

AMC2 21.B.120(a) Initial certification procedure ~~Investigation team~~ – ~~Qualification criteria for the investigation team members~~

QUALIFICATION CRITERIA FOR THE INVESTIGATION TEAM MEMBERS

The competent authority ~~must~~ **should** ensure that the team leader and team members have received appropriate training in the relevant ~~Subpart~~ **Subparts** of Part 21 and in the related competent authority documentation before performing investigations in accordance with AMC2 21.B.25(a)(3). They ~~must~~ **should** also have knowledge and experience at the appropriate level in aviation production and inspection activities ~~relative~~ **related** to the particular application for a letter of agreement.

– [21.B.120 Initial certification procedure](#)

AMC3 21.B.120(a)(~~e~~)(1) Initial certification procedure

EVALUATION OF APPLICATIONS

(a)~~1~~. General

When applying Part 21 Section A, Subpart F and Section B, Subpart F, the competent authority ~~should~~ **must** consider that these Subparts are only ~~an alternative way~~ **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 ~~must~~ **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 ~~the Agency~~ **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 ~~is~~ **are** provided for such a case on the basis of the following principles:

- (1)~~a~~) Subpart F ~~should~~ **must** be considered as an alternative option for particular cases.
- (2)~~b~~) Its adoption ~~should~~ **must** be done on an individual basis, as a consequence of an assessment by the competent authority (see ~~point~~ **point** 21.A.121, ~~21.A.133(a)~~ and ~~its~~ **their** associated ~~CS~~ **AMC** and GM).

(b)~~2~~. Application

The competent authority ~~should~~ **must** receive an application for a letter of agreement on an EASA Form 60 (see below) completed by the applicant. The eligibility of the application should be verified in relation to the competent authority procedures, based on ~~point~~ **point** 21.A.121 and its associated ~~AMC~~ **CS** 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)3. 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.

- [21.B.120 Initial certification procedure](#)



EASA Form 60 Application for agreement of production under Part 21 Subpart F	
<i>Competent authority of an EU Member State or EASA</i>	
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 <u>21.A.124(b)</u> :	
6. Links/arrangements with design approval holder(s)/ design organisation(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 must be entered. For legal entities the name must 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 must be provided to the competent authority.

Block 2: State the trade name by which the applicant is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.



Block 3: State all locations of manufacturing activities that are covered by the application. Only those locations must be stated that are directly under the control of the applicant stated in Block 1.

Block 4: This Block must include further details of the manufacturing activities under the approval for the addresses indicated in Block 3. The Block 'Identification' must indicate the products, parts or appliances intended to be produced, while the Block 'Termination' must 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 must state evidence supporting the determination of applicability as stated in 21.A.121. In addition an outline of the manual required by 21.A.125A(b) must be provided with the application.

Block 6: The information entered here is essential for the evaluation of eligibility of the application. Therefore special attention must be given concerning the completion of this Block either directly or by reference to supporting documentation in relation to the requirements of 21.A.122 and AMC No 1 to 21.A.122.

Block 7: The information to be entered here must reflect the number of staff, or in case of an initial approval the intended number of staff, for the manufacturing activities under this application and therefore must include also any associated administrative staff.

Block 8: State the name of the person authorised to sign the application.

AMC4 GM 21.B.120(a)(e)(3) Initial certification procedure Investigation preparation and planning

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 another Member State where the investigation of the organisation should include a there is seen to be a need to visit a production facility in that Member State for one of the following reasons:
 - (1)a) where a manufacturer production organisation has contracted part of the production to another organisation holding a production organisation approval 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)b) to inspect a product (or part or appliance) under production where the sub-contractor subcontractor is does not hold holding a POA.
- (c) co-ordinate coordinate with the competent authority of a third country and/or the Agency EASA where the investigation of the organisation should include there is seen to be a need to visit a production a facility in that country for one of the following reasons:
 - (1)a) where a manufacturer production organisation has contracted part of the production to another organisation holding a production organisation approval issued by the Agency EASA or accepted through an recognition agreement in accordance with Article 68 of the Basic-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 the Agency EASA and/or the competent authority agrees;

to inspect a product (or part or appliance) under production where the sub-contractor subcontractor is does not holding hold a POA.

- [21.B.120 Initial certification procedure](#)

GM1 21.B.120(c)(5) and (6) Initial certification procedure Auditing and investigation findings

AUDITING AND INVESTIGATION FINDINGS

During its investigation process, the competent authority may make findings which should then be recorded. These may be non-conformities to the requirements, the manual as supplied by the production organisation manufacturer 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.

- [21.B.120 Initial certification procedure](#)

AMC1 21.B.120(d) Initial certification procedure

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 pre-defined 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.120 Initial certification procedure](#)

GM1 21.B.125(a) 21.B.125(b), 21.B.225(b) and 21.B.430(b) Findings and corrective actions Objective evidence

OBJECTIVE EVIDENCE

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; and
 - (c) information from interview questions and observations of production or design activities, as applicable.
- [21.B.120 Initial certification procedure](#)

GM1 21.B.125(b) Findings and corrective actions

EXAMPLES OF LEVEL 1 FINDINGS

Examples of level 1 findings are non-compliances with any of the following points that could affect the safety of the aircraft are found under points:

- 21.A.126;
- 21.A.127;
- 21.A.128; and
- 21.A.129.

It should be anticipated that a non-compliance with these points is only considered a level 1 finding if there is objective evidence that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.

- [21.B.125 Findings and corrective actions](#)

GM1 21.B.125(b)(1) and 21.B.225(b)(1) Findings and corrective actions

UNCONTROLLED NON-COMPLIANCE WITH APPLICABLE DESIGN DATA

An uncontrolled non-compliance with applicable design data is a non-compliance that:

- (a) cannot be discovered through systematic analysis; or
- (b) prevents the identification of the affected products, parts, appliances, or material.

- [21.B.125 Findings and corrective actions](#)

AMC1 21.B.125(d) Findings and corrective actions

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. This oversight may include intermediate communication, such as letters as necessary, to remind the approval holder to verify that the corrective action plan is followed.

- [21.B.125 Findings and corrective actions](#)

AMC 21.B.130 Issue of the letter of agreement

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.

GM 21.B.130(b) Issue of the letter of agreement

The agreement should include or reference a pre-defined 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 21.A.129 and 21.B.120(c)(5) and its associated CS and GM. The plan should clearly identify inspection point, places, inspection subjects (materials, process, tooling documentation, human resources, etc.), as well as the focal points and the method of communication between the manufacturer and the competent authority.

The competent authority should detail a method how it will assure itself that the manufacturer is working in accordance with the manual and the agreed inspection procedures during the validity period of the agreement. For renewal of this validity period the procedure as defined in 21.B.140 should be used.

Any conditions under which the agreement will expire (such as termination date and/or number of units to produce), should be clearly stated in the letter of agreement.

AMC1 21.B.140 Amendment of a letter of agreement

The competent authority ~~must~~ **should** be satisfied that any change affecting a letter of agreement ~~comply~~ **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)~~21.B.130~~. 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.

GM 21.B.150(d) Record keeping – Traceability of release certificates

The recordkeeping for those EASA Forms 52 and 1 that have been validated by the competent authority should allow verification of such validation by concerned parties including the recipients of the release certificates.

SUBPART G — PRODUCTION ORGANISATION APPROVAL

GM1 21.B.115 and 21.B.215 Alternative means of compliance

Alternative means of compliance that are used by a competent authority, or by a person or organisations under its oversight, may be used by other competent authorities, persons, or organisations only if they are processed again in accordance with points 21.B.115(d) and (e) or 21.B.215(d).

- [21.B.215 Alternative means of compliance](#)

AMC1 21.B.115(d) and 21.B.215(d) Alternative means of compliance

DEMONSTRATION OF COMPLIANCE

In order to demonstrate that the implementing rules are met, a risk assessment should be completed and documented.

- [21.B.215 Alternative means of compliance](#)

AMC1 21.B.220 and 21.B.221 Initial certification procedure

INVESTIGATION TEAM

- (a) The competent authority should appoint a production organisation investigation team for each applicant for, or 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 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(c).
- (b) The competent authority should perform sufficient investigation activities for an applicant for a production organisation approval, or a holder of one, to justify the recommendations for the issuance, maintenance, amendment, suspension or revocation of the approval.
- (c) The competent authority should prepare procedures for the investigation of a production organisation approval as part of the documented procedures that cover at least the following elements:
 - (1) evaluation of the applications received;
 - (2) appointment of the organisation approval 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, amendment, suspension or revocation of a production organisation approval; and
- (8) continued surveillance.

– [21.B.220 Initial certification procedure](#)

AMC1 21.B.220 and 21.B.430 Initial certification procedure

VERIFICATION OF COMPLIANCE

- (a) In order to verify the organisation's compliance with the applicable requirements, the competent authority should conduct an audit of the organisation, including interviews of the personnel, and inspections 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 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 law.

– [21.B.220 Initial certification procedure](#)

AMC1 ~~GM No 1 to 21.B.220(c)~~ Procedures for investigation – Investigation preparation and planning Initial certification procedure

INVESTIGATION PREPARATION AND PLANNING

Following the acceptance of the application for a production organisational approval and before commencing an investigation, the competent authority should, for the preparation and planning of the investigation:

- (a) identify the site locations needing investigation taking into account the scope of any other POA issued by a Member State according to Part 21, which are valid in the circumstances;
- (b) when EASA is not the competent authority, liaise with the Agency EASA for the appointment of any necessary observer(s) for standardisation purposes and seek any necessary advice and guidance from EASA;
- (c) establish any necessary liaison arrangement with other competent authorities;

- (d) agree the size and composition of the POAT investigation team and any specialist tasks likely to be covered and to select suitable team members from all involved competent authorities; and
- seek any necessary advice and guidance from the Agency
- (e) liaise with the competent authority of the other a Member State where the investigation of the organisation should include a there is seen to be a need to visit a production approval holder facility in that Member State for one of the following reasons:
 - (1) where a production organisation manufacturer has subcontracted production to another organisation and therefore a need arises to ensure that contract has the same meaning for all the parties to the contract, and the competent authority of the Member State agrees
 - (2) to inspect a product, part, appliance, or material under production for its own, Member States or non-EU register.
- [21.B.220 Initial certification procedure](#)

AMC 2 GM 21.B.220(a) Initial certification procedure Investigation team

INVESTIGATION TEAM

(a) 1. Type of Team team

Where the applicant is located in a Member State, the competent authority should appoint a production organisation approval team (POAT) leader and members appropriate to the nature and scope of the applicant's organisation.

If EASA is not the competent authority and 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 production organisation approval team POAT leader and members appropriate to the nature and scope of the applicant's organisation.

(b) 2. 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) a) the capability to lead and manage a team;
- (2) b) the capability to prepare reports and be diplomatic;
- (3) c) experience in approval team investigations (not necessarily only Part 21 Section A, Subpart G); and
- (4) d) a knowledge of production and quality systems for aircraft and related products and parts.

(c) 3. Team member selection



The team leader should agree with the The competent authority should determine on the size of the POA 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:

- (a) training, which is mandatory, for Part 21 Section A, Subpart Subparts A and G and Section B, Subpart Subparts A and G;
- (b) education and experience, to cover appropriate aviation knowledge, audit practices and approval procedures; and
- (c) the ability to verify that an applicant’s organisation conforms to its own POA procedures, and that its key personnel are competent.

– [21.B.220 Initial certification procedure](#)

AMC 21.B.220(c) Procedures for investigation – Evaluation of applications

The competent authority must receive an application for POA on an EASA Form 50 (see below) completed by the applicant. The eligibility and appropriateness of the application must be evaluated in accordance with 21.A.133 at that time and the applicant must be advised about acceptance or rejection of its application in writing accordingly.

EASA Form 50	
Application for Part 21 production organisation approval	
<i>Competent authority of an EU Member State or EASA</i>	
1. Registered name and address of the organisation:	
2. Trade name (if different):	
3. Locations for which the approval is applied for:	
4. Brief summary of proposed activities at the item 3 addresses	
— 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:	
<div style="text-align: center;"> <hr style="width: 80%; margin: 0 auto;"/> Date </div>	<div style="text-align: center;"> <hr style="width: 80%; margin: 0 auto;"/> Signature of the accountable manager </div>

EASA Form 50

~~Block 1: The name of the organisation must 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 must be provided to the competent authority.~~

~~Block 2: State the trade name by which the organisation is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.~~

~~Block 3: State all locations for which the approval is applied for. Only those locations must be stated that are directly under the control of the legal entity stated in Block 1.~~

~~Block 4: This Block must include further details of the activities under the approval for the addresses indicated in Block 4. The Block 'General' must include overall information, while the Block 'Scope of approval' must address the scope of work and products/categories following the principles laid down in the GM 21.A.151. The Block 'nature of privileges' must indicate the requested privileges as defined in 21.A.163(b) (c). For an application for renewal state 'not applicable'.~~

~~Block 5: This Block must state 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 21.A.145(c)(2) must be included as far as possible, accompanied by the corresponding EASA Forms 4.~~

~~For an application for renewal state 'not applicable'.~~

~~Block 6: The information entered here is essential for the evaluation of eligibility of the application. Therefore special attention must be given concerning the completion of this Block either directly or by reference to supporting documentation in relation to the requirements of 21.A.133(b) and (c) and the AMC to 21.A.133(b) and (c).~~

~~Block 7: The information to be entered here must reflect the number of staff, or in case of an initial approval the intended number of staff, for the complete activities to be covered by the approval and therefore must include also any associated administrative staff.~~

~~Block 8: State the position and name of the accountable manager.~~

GM1 No 2 to 21.B.220(c) Initial certification procedure Procedures for investigation — General PROCEDURES FOR INVESTIGATION

ORGANISATION APPROVAL — GENERAL

(a)1. Purpose of the Procedures



The purpose of the procedures is to investigate the applicant's production organisation for compliance with Part 21 Subpart G in relation to the requested terms of approval. When appropriate, these procedures should also be used to investigate significant changes or applications for variations of in the scope of approval.

The following procedure assumes that the application has been accepted and that an investigation team has been selected.

(b)2. Initiation

The POA Team Leader initiates the procedure by:

- 2.(1) arranging a meeting with the POAT 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. knowledge that the POAT members have regarding the production standards of the applicant;
- 2.(2) obtaining collecting information from other teams of a competent authorities authority of the Member State or the Agency EASA on the functioning of the applicant's organisation (see GM No 1 GM1 21.B.25(c) to 21.B.45);
- 2.(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 the reason for signing the statement specified in point 21.A.143(a)(1);
 - (iii) enable the investigation team POAT to describe the proposed investigation process; and
 - (iv) enable the investigation team POAT to confirm to the applicant the identity of those managers nominated in accordance with Part 21 Subpart G who need to complete an EASA Form 4 (See EASA Form 4 for Production Organisations on EASA website: <http://easa.europa.eu/certification/application-forms.php>). The applicant should provide a completed copy of EASA Form 4 for each of the key management staff identified by Part 21 Subpart G. The EASA Form 4 is a confidential document and will be treated as such.

(c)3. Preparation

The investigation team POAT:

- 3.(1) studies the information gathered in the initiation phase;
- 3.(2) establishes an investigation plan which:
 - (i) takes account of the location of the POA applicant's facility as identified per GM3 No 3 to 21.B.65220(c);
 - (ii) defines areas of coverage and work-sharing between team POAT 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 POAT 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.(3) ~~co-ordinates~~ coordinates with the appropriate Part 21 Section A, Subpart J design organisation approval Teams sufficiently for both parties to have confidence in the applicants ~~co-ordination~~ coordination links with the holder of the approval of the design (as required by point 21.A.133) ; and
- 3.(4) establishes liaison with the applicant to plan mutually suitable dates and times for visits at each location that ~~need investigation~~ needs to be investigated, and also to agree the investigation plan and approximate time scales with the applicant.

(d)4. Investigation

The investigation team POAT:

- 4.(1) makes a check of the ~~exposition~~ POE for compliance with Part 21; ~~Subpart G~~
- 4.(2) audits the organisation, its organisational structure, and its procedures for compliance with Part 21 ~~Subpart G~~, using EASA Form 56 as a guide during the investigation, and as a checklist at the end of it;
- 4.(3) generates compliance checklists for investigations of working processes and procedures on site as required;
- 4.(4) accepts or rejects each EASA Form 4 completed by the key nominated personnel in accordance with point 21.A.145(c)(2) ;
- 4.(5) checks that the ~~exposition production organisation exposition (POE)~~ standard reflects the organisation, its procedures, practices and the requirements defined in point 21.A.143. Having checked and agreed a ~~an~~ ~~exposition~~ POE issue or subsequent amendment, the competent authority should have a clear procedure to indicate its acceptance or rejection;
- 4.(6) makes sample audits at working level to verify that:
 - (i) work is performed in accordance with the system described in the ~~exposition~~ POE;
 - (ii) products, parts, appliances or material produced by the organisation are in conformity with the applicable design data (see GM 21.B.235(b)(4));



- (iii) facilities, working conditions, equipment and tools are in accordance with the ~~exposition~~ POE and appropriate for the work being performed;
 - (iv) ~~competence~~ competency and numbers of personnel is ~~is~~ are appropriate for the work being performed; and
 - (v) ~~co-ordination~~ coordination between production and design is satisfactory; and
- 4.(7) 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 POATL should ~~co-ordinate~~ coordinate the work of the team POAT members for an efficient investigation process, which will provide a consistent and effective investigation and reporting standards.

(e) 5. Conclusions

- 5.(1) The team leader POATL holds a team meeting to review the findings and observations so as to produce a final agreed report of findings.
- 5.(2) The team leader POATL, on completion of the investigation, holds a meeting to verbally ~~presents~~ present the report to the applicant.
- The team leader POATL should be the chairman of this meeting, but individual team members may present their own findings and observations.
- 5.(3) The meeting should agree the findings, corrective action time scales, and preliminary arrangements for any follow-up that may be necessary.
- 5.(4) Some items may as a result of this meeting be withdrawn by the team leader POATL but if the investigation has been correctly performed, at this stage there should be no disagreement over the facts presented.
- 5.(5) Inevitably there will be occasions when the team POAT member carrying out the audit may find situations in the applicant or POA 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 Part 4 of EASA Form 56.
- 5.(6) The team leader POATL will transmit the final signed report on EASA Form 56 together with notes of the final meeting with the applicant to the competent authority of the country in which where the applicant is located, or to EASA according to the competence defined in point 21.1. The report will include recommendations and significant findings, together with appropriate conclusions and corrective actions. In

particular, it should indicate if whether the exposition POE is acceptable, or changes are required.

- 5.(7) Completion of EASA Form 56 includes the need to record in Part 4 comments, criticisms, etc., and this must should reflect any problems found during the visit and must should be the same as the comments, criticisms made to the organisation during the debrief. Under no circumstances should additional comments, criticisms, etc., be included in Part 4 of the report unless the applicant or POA approval holder has previously been made aware of such comments.

Many applicants Applicants 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 summarised in Part 4 of the EASA Form 56 and a copy always given to the applicant, so that there is a common understanding of the actions necessary before approval can be granted.

The intention of the EASA Form 56 Part 4 is to provide a summary report of findings and outstanding items during initial investigation and major changes. The competent authority will need to operate a supporting audit system to manage corrective action monitoring, closure, etc. While the EASA Form 56 Part 4 format may be used for monitoring purposes, it is not adequate on its own to manage such a system.

- 5.(8) If the findings Findings made during the investigation mean that approval recommendation will not or cannot be issued, then it is essential that such findings are confirmed in writing to the organisations within two weeks of the visit. 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.

(f)6- Management Involvement

The investigation team shall see the accountable manager will be seen 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 grant granting and subsequent maintenance of the production organisation approval. Two Twice is the preferred number of visits to the accountable manager, with one being conducted at the beginning of the audit to explain the investigation process, and the second, at the end, to debrief on the results of the investigation.

— [21.B.220 Initial certification procedure](#)



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 ONE OF FIVE PARTS: **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 is on the files of the competent authority.



Competent authority
of an EU Member State or
EASA

**RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE /
CONTINUATION / VARIATION/SIGNIFICANT CHANGE**

PART TWO OF FIVE PARTS: **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 Failures, malfunctions and defects

(a) N/A

(b) Without prejudice to Regulation (EU) No 376/2014, all natural or legal persons who hold or have applied for a production approval under Subpart G, or who produce a product, part or appliance under Subpart F, shall:

(1) establish and maintain a system for collecting and assessing internal mandatory and voluntary occurrence reports, including reports on internal errors, near misses, and hazards, in order to identify any adverse trends or to address any deficiencies, and extract reportable occurrences. This system shall include the evaluation of relevant information related to occurrences, and the promulgation of the related information;

(2) report to the holder of the type certificate, restricted type certificate or design approval, all cases in which products, parts or appliances have been released by the production organisation and subsequently identified to have deviations from the applicable design data, and investigate with the holder of the type certificate, restricted type certificate or design approval to identify those deviations which could lead to an unsafe condition;

(3) report to EASA and the competent authority of the Member State the deviations that were identified according to point (2) which could lead to an unsafe condition; and

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

(c) The reports defined in points (a) and (b) shall appropriately safeguard the confidentiality of the reporter and of the persons mentioned in the report and be made in a form and manner



established by the competent authority, as soon as practicable and in any case dispatched not later than 72 hours after the identification of the possible unsafe condition, unless exceptional circumstances prevent this.

- (d) Without prejudice to Regulation (EU) No 376/2014, if an occurrence reported under points (a)(3) or (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 Annex, or the production organisation as appropriate, shall investigate the reason for the deficiency and report to EASA the results of its investigation and any action it is taking or proposes to take to correct that deficiency.
- (e) If the competent authority finds that an 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 Annex, or the production organisation as appropriate, shall submit the relevant data to the competent authority.

21.A.5 Record-keeping

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

- (a) N/A
- (b) when producing a product, part or appliance:
- (1) maintain the relevant records produced under the production system that was used to justify the conformity of the products, parts or appliances, and retain them in order to provide the information necessary to ensure the continued airworthiness of the product, part or appliance; and
 - (2) for production organisations approved in accordance with Subpart G, record all details of work carried out and establish a record-keeping system that incorporates the requirements imposed on its partners, suppliers and subcontractors, and ensures the conservation of the data used to justify the conformity of the products, parts or appliances. This data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances;
- (c) regarding permits to fly:
- (1) maintain documents produced to establish and justify the flight conditions, and retain them at the disposal of EASA and the competent authority in order to provide the information necessary to ensure the continued airworthiness of the aircraft; and
 - (2) when issuing a permit to fly under the privilege of approved organisations, maintain the documents associated with it, including inspection records, documents that support the approval of flight conditions and the permit to fly itself, retain them at the disposal of EASA or the competent authority, in order to provide the information necessary to ensure the continued airworthiness of the aircraft;
- (d) retain records of competence and the qualifications of personnel who are involved in design or production, in independent monitoring of compliance and adequacy, and in safety management if required by points 21.A.139, 21.A.145, 21.A.239 or 21.A.245; and

- (e) when employing personnel who exercise the privileges of the approved organisation according to points 21.A.163 or 21.A.263, or who carry out the independent monitoring of compliance and adequacy according to points 21.A.139(f) and 21.A.239(f), retain the records of their authorisation.

21.A.9 Investigation

- (a) All organisations who hold or who have applied for a type certificate, restricted type certificate, supplemental type certificate, ETSO authorisation, major repair design approval, permit to fly, design organisation approval, production organisation approval or letter of agreement under this Annex, shall make arrangements that allow the competent authority to make any investigations, including investigations of partners, suppliers and subcontractors, that are necessary to determine the compliance and the continued compliance of the organisation with the applicable requirements of this Annex.
- (b) Design and production organisations and applicants for, or holders of, permits to fly or of ETSO authorisations shall allow the competent authority to review any report and make any inspection and perform or witness any test that is necessary to check the compliance of the organisation with this Annex, and to inspect the technical data files.

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 ~~co-ordination~~ 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.

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PART TWO OF FIVE (CONTINUED):

SURVEY REFERENCE:

21.A.139 ~~Quality System~~ Production management system

- (a) The production organisation shall establish, implement, and maintain a production management system that includes a safety management system and a quality system with clear lines of responsibility and accountability throughout the organisation ~~demonstrate that it has established and is able to maintain a quality system.~~
- (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; and
 - (2) be established under the direct accountability of a single accountable manager according 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 to execute the safety policy in accordance with point 21.A.145(c)(2);
 - (3) establish, implement and maintain a safety risk management process that includes:
 - (i) hazard identification in all domains of the organisation and its production activities, resulting from analysis of occurrences collected according to point 21.A.3A; and
 - (ii) safety risk assessment and mitigation;
 - (4) establish, implement and maintain a safety assurance process including:
 - (i) the measurement and monitoring of safety performance;
 - (ii) the management of changes in accordance with points 21.A.143(b) and 21.A.147; and
 - (iii) principles for continuous improvement of the safety management system; and
 - (5) promote safety in the organisation through:
 - (i) training and education; and
 - (ii) communication.
- (d) As part of the quality management element of the production management system, the production organisation shall:
- (1) ~~The quality system shall be documented. This quality system shall be such as to enable the organisation to 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, and thus exercise the privileges set forth as defined in point 21.A.163-;~~
 - (2) ~~The quality system shall contain~~ establish, implement, and maintain, as applicable, within the scope of approval, 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) airworthiness co-ordination coordination with the applicant for, or holder of, a design approval;
- (x) records the completion and retention of records;
- (xi) personnel the competence and qualification 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 carried out after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation; and
- (xvii) issue issuance of permits to fly and approval of associated flight conditions-;
- (3) The control procedures need to include specific provisions for any critical parts in the control procedures for any critical parts.
- (e) The production organisation shall document in accordance with point 21.A.143 all production management system key processes, and maintain a process for:
- (1) amending that documentation; and

- (2) making personnel aware of their responsibilities under the production management system.
- (f) The production organisation shall include in the production management system ~~An independent quality assurance function to monitor~~ monitoring of compliance with, and the adequacy of, the production management system and its documented procedures ~~of the quality system~~. This monitoring shall include a feedback system to the person or group of persons referred to in point 21.A.145(c)(2) and ultimately to the manager referred to in point 21.A.145(c)(1) to ensure, as necessary, corrective action.
- (g) If the organisation holds other organisation certificates 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).

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PART TWO OF FIVE (CONTINUED):

SURVEY REFERENCE:

21.A.143 Exposition

- (a) As part of the production management system, the ~~The~~ organisation shall ~~establish~~ ~~submit to the competent authority~~ a production organisation exposition ~~that provides~~ ~~providing~~ directly or by ~~cross reference~~ the following information: (see Part 3 of this Form)
- (b) The production organisation exposition shall be amended as necessary to remain an up-to-date description of the organisation, and copies of any amendments shall be supplied to the competent authority.

21.A.145 ~~Approval requirements~~ Resources

The production organisation shall demonstrate, ~~on the basis of the information submitted in accordance with point 21.A.143~~ that:

- (a) ~~with regard to general approval requirements~~, facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and general organisation are adequate to discharge the obligations under point 21.A.165;
- (b) with regard to all necessary airworthiness, noise, fuel venting and exhaust emissions data:
- (1) the production organisation is in receipt of such data from ~~the Agency EASA~~, and from the holder of, or applicant for, the ~~type certificate~~ ~~type certificate~~, restricted ~~type certificate~~ ~~type certificate~~ or design approval to determine conformity with the applicable design data;
 - (2) the production organisation has established a procedure to ensure that airworthiness, noise, fuel venting and exhaust emissions data are correctly incorporated in its production data; ~~and~~
 - (3) such data ~~is~~ ~~are~~ 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) ~~a~~ ~~an~~ accountable manager has been nominated by the production organisation, ~~and is accountable to the competent~~ ~~with~~ authority to ensure that, ~~His or her responsibility~~ within the organization, ~~shall consist of ensuring that~~ all production is performed to the required standards and that the production organisation is continuously in compliance with the ~~requirements of the management system referred to in point 21.A.139~~, and the data and the procedures identified in the exposition referred to in point 21.A.143.
 - (2) the accountable manager shall nominate a person or a group of persons ~~have been nominated by the production organisation~~ to ensure that the organisation is in compliance with the requirements of this Annex I ~~(Part 21)~~, and are identified, together with the extent of their authority. Such a person (or persons) shall act under the direct authority of the accountable manager ~~referred to in point (1)~~. The knowledge, background and experience of the persons nominated shall be appropriate to discharge their responsibilities; ~~and~~
 - (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 ~~co-ordination~~ ~~coordination~~ within the production organisation in respect of airworthiness, noise, fuel venting and exhaust emission data matters;
- (d) with regard to certifying staff, authorised by the production organisation to sign the documents issued under point 21.A.163 under the scope or terms of approval:
- (1) the knowledge, background (including other functions in the organisation), and



experience of the certifying staff are appropriate to discharge their allocated responsibilities;
and

~~(2) — the production organisation maintains a record of all certifying staff which shall include details of the scope of their authorisation;~~

- (2) certifying staff are provided with evidence of the scope of their authorisation.

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PART TWO OF FIVE (CONTINUED):**SURVEY REFERENCE:****21.A.147 Changes to the approved production management system organisation**

- After the issue of a production organisation approval, each change to the approved production management system organisation that is significant to the showing demonstration of conformity or to the airworthiness and characteristics of noise, fuel venting and exhaust emissions of the product, part or appliance, particularly changes to the quality system, shall be approved by the competent authority before being implemented. Before the implementation of the change, an application for approval shall be submitted in writing to the competent authority, and the organisation shall demonstrate, to the competent authority before implementation of the change, that it will continue to comply with this Subpart Annex after the implementation.

~~The competent authority shall establish the conditions under which a production organisation approved under this Subpart may operate during such changes unless the competent authority determines that the approval should be suspended.~~

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.157 Investigations

~~A production organisation shall make arrangements that allow the competent authority to make any investigations, including investigations of partners and sub-contractors, necessary to determine compliance and continued compliance 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; ~~(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) under point 21.A.307 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).

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PART TWO OF FIVE (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 in a condition for safe operation, ~~and additionally in the case of engines, determine according to data provided by the engine type-certificate holder that each completed engine is in compliance with the applicable emissions requirements as defined in point 21.A.18(b), current at the date of manufacture of the engine, to certify emissions compliance; or~~
 - (3) additionally, in the case of engines, determine that the completed engine is in compliance with the applicable emissions requirements on the date of manufacture of the engine;
 - (4) determine that other products, parts or appliances conform to the applicable data before issuing EASA Form 1 as a conformity certificate;
- (d) comply with Subpart A of this Annex ~~record all details of work carried out;~~
- ~~(e) establish and maintain an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of occurrence reports in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include evaluation of relevant information relating to occurrences and the promulgation of related information;~~
- ~~(f)

 - (1) report to the holder of the type certificate or design approval, all cases where products, parts or appliances have been released by the production organisation and subsequently identified to have possible deviations from the applicable design data, and investigate with the holder of the type certificate or design approval in order to identify those deviations which could lead to an unsafe condition;
 - (2) report to the Agency and the competent authority of the Member State, or both, the deviations which could lead to an unsafe condition identified according to point (1). Such reports shall be made in a form and manner established by the Agency under point 21.A.3A(b)(2) or accepted by the competent authority of the Member State;
 - (3) where the holder of the production organisation approval is acting as a supplier to another production organisation, report also to that other organisation all cases where it has released products, parts or appliances to that organisation and subsequently identified them to have possible deviations from the applicable design data;~~
- (e) provide assistance to the holder of the ~~type certificate~~ 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;
- ~~(h) establish an archiving system incorporating requirements imposed on its partners, suppliers and sub-contractors, ensuring conservation of the data used to justify conformity of the products, parts~~



~~or appliances. Such data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances;~~

- (f) where, under its terms of approval, the holder issues a certificate of release to service, determine that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation, prior to issuing the certificate;
- (g) where applicable, under the privilege of point 21.A.163(e), determine the conditions under which a permit to fly can be issued;
- (h) where applicable, under the privilege of point 21.A.163(e), establish compliance with points 21.A.711(c) and (e) before issuing a permit to fly to an aircraft;-
- (i)- comply with Subpart A of this Annex.

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**Competent authority
of an EU Member State or
EASA**

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART THREE OF FIVE PARTS: 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 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.143(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 Subpart 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 accountabilities 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 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 general description of man-power resources;

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PART THREE OF FIVE (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 quality production management system and the policy, processes and the procedures as required by point 21.A.139(b)(1);	
(12) a list of those outside parties referred to in point 21.A.139 (a) (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.	

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**Competent authority
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RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART FOUR OF FIVE PARTS: FINDINGS ON Part 21 SUBPART G COMPLIANCE STATUS

Name of organisation:

Approval reference: _____ Survey reference: _____

Note A: Each finding must be identified by 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:

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PART FOUR OF FIVE (CONTINUED): Sheet ___ of ___
 SURVEY REFERENCE:

NO:	FINDING	LEVEL	OUTSTANDING ACTION	CLEARANCE	
				DATE	REP.REF.

NAME & SIGNATURE OF INSPECTOR: Date:

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**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 FIVE OF FIVE PARTS: 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:

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— [21.B.220 Initial certification procedure](#)



GM2 No 3 to 21.B.220(c) Initial certification procedure - Procedures for investigation – POA applications received from organisations with facilities/partners/suppliers/sub-contractors located in a third country

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 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) include the facilities outside the Member States fully in their investigation and surveillance activities for the applicant for, or holder of, the POA;
- (b) include the facilities outside the Member States in the terms of approval of the EASA Form 55 (see Annex I Part 21 Appendix X) when issuing the POA.

Partners/suppliers/subcontractors sub-contractors located in a third country

The competent authority should define on the basis of Part 21 and, its associated CS and GM, a clear procedure on supplier control. This procedure should include the control of partners/suppliers/subcontractors sub-contractors 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 sub-contractors 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 competent authority procedure, assess the necessary level of surveillance to be exercised by the production organisation on partners / suppliers / subcontractors sub-contractors and check the audit plan of the production organisation against this level.

The level of ~~co-operation~~ cooperation between the competent authority and the competent authority of the third country where a partner/supplier/subcontractor sub-contractors or of the production organisation is located may influence the authorities' activities concerning this partner/supplier/ subcontractor sub-contractors. ~~Co-operation~~ 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/~~sub contractors~~ ~~sub-contractors~~ will be based on the following principles:

- (a) ~~When~~ a recognition agreement under Article 68 of Regulation (EU) 2018/1139 covering production subjects has been concluded:
- a(1) The competent authority in accordance with GM1 ~~№ 2 to 21.A.139(a)~~ (d)(1) may decide that direct surveillance of the POA holder activities at the foreign location may not be necessary.
 - b(2) In any other case, ~~the~~ 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, ~~the Agency EASA~~, and the competent authority of a third country enter into a specific working arrangement addressing the following matters:
- a(1) acceptance by the competent authority of the third country of conducting manufacturing surveillance of the relevant production activities on behalf of the competent authority, under the respective quality standards defined by the competent authority;
 - b(2) tasks to be performed; and
 - c(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 in case that~~ 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.

- [21.B.220 Initial certification procedure](#)

~~GM3 No 4 to 21.B.220(c)~~ Initial certification procedure **Procedures for investigation — Competent authority surveillance of suppliers of a POA holder located in other Member States**

COMPETENT AUTHORITY SURVEILLANCE OF SUPPLIERS OF A POA HOLDER LOCATED IN OTHER MEMBER STATES

- (a)1. 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 ~~the~~ EASA Form 1 -



Authorised Release Certificate will identify those countries as the ~~locations~~ ~~location~~ 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 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~~ ~~chain~~ of responsibilities ~~chain~~ so that no separate technical agreement between these national authorities is necessary, and when necessary, to establish a means of communication between the involved competent authorities of the Member States.

(b)2. Principle to organise competent authority supplier surveillance between Member States.:

In order to avoid duplication and to take the best advantage of Regulation (EC) No 216/2008 that establishes under Article 11 mutual recognition of certificates issued by production organisations approved in accordance with Part 21 Section A Subpart G by a ~~an~~ 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 ~~activity~~ ~~activities~~ to the other competent authority of the supplier.

This applies between Member States and ~~for~~ ~~to~~ 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 ~~POA~~ contractor always retains the right of direct supervision at the supplier location, especially when serious quality problems are encountered. In such a case, ~~co-ordination~~ there will be ~~coordination~~ ~~will be organised~~ 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 an EASA 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:

2.(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 ~~sub-contractor~~ ~~subcontractor~~ ~~with~~ of the following:

(i)a. ~~The identification~~ ~~identification~~ (and location) of the contractor;



- (ii) ~~b.~~ The identification ~~identification~~ (and location) of the ~~sub-contractor~~ subcontractor;
- (iii) ~~e.~~ The identification ~~identification~~ of the subcontracting (parts, contract No ~~N°~~, etc.);
- (iv) ~~d.~~ Reference ~~A reference~~ to the quality requirements attached to the contract;
- (v) ~~e.~~ The name ~~Name~~ and address of the competent authority office/person in charge of the POA;
- (vi) ~~f.~~ Whether ~~Direct Delivery~~ Authorisation (DDA) applies;
- (vii) ~~g.~~ Any specific action item/requirement from the competent authority; and
- (viii) ~~h.~~ Request ~~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 ~~that~~ the contract/order from the contractor to the ~~sub-contractor~~ subcontractor ~~should 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.(2) Tasks of the competent authority of the supplier (~~sub-contractor~~ subcontractor)

On receipt of the information from the competent authority of the contractor, the competent authority of the ~~sub-contractor~~ subcontractor should:

- (i) ~~V~~erify that the scope of work of the POA of the supplier covers the intended supply (or envisage ~~to extend~~ extending it in liaison with the supplier);
- (ii) ~~V~~erify that the specific quality requirements for the parts have been introduced ~~in~~ into the quality system of the supplier;
- (iii) ~~C~~onfirm 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) ~~I~~ndicate the name and address of the competent authorities 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.

2.(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 at a given date in order to guarantee proper ~~on-going~~ ~~ongoing~~ control of the subcontract by both competent authorities.

This information should cover in a concise form:

a(i) For the competent authority of the contractor:

- A ~~a résumé~~ ~~resume~~ of the quality problems encountered by the contractor, on receipt inspection, on installation on aircraft or on in service aircraft; and
- A ~~a~~ status of the reference documents.

b(ii) For the competent authority of the ~~sub-contractor~~ ~~subcontractor~~:

A ~~résumé~~ ~~resume~~ of at least the following subjects:

- ~~Changes in organisation and qualification of the~~ ~~sub-contractor~~ ~~subcontractor~~ (in case of impact on the procurement);
- Quality problems encountered during manufacture;
- Corrective actions following problems encountered earlier on ~~in~~ the procurement;
- Findings from national authorities' surveillance that may have an impact on the procurement; and,
- Quality problems related to the contractor procurement (materials, documentation, procedures, processes).

~~Any exchange~~ ~~Exchange~~ of information between ~~competent~~ ~~national~~ 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 ~~competent~~ ~~national~~ 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~~ ~~Release~~ of parts by the POA ~~sub-contractor~~ ~~subcontractor~~ to the contractor will be accompanied by an « 'Authorised Release Certificate EASA Form 1» issued for «'Airworthiness» or for «'Conformity» as appropriate.

b) ~~Sub-subcontracting~~ ~~Subsubcontracting~~

If the ~~sub-contractor~~ ~~subcontractor~~ wants itself to subcontract, it is up to the competent authority of the ~~sub-contractor~~ ~~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.



<p>Competent authority of an EU Member State or EASA</p> <p>REQUEST FOR REPORTING ON SUB-CONTRACTOR SUBCONTRACTOR SURVEILLANCE</p>	
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:	<SUB-CONTRACTOR COMPANY>
With approval reference:	<SUB-CONTRACTOR POA REF.NO.>
Which is situated in:	<COUNTRY OF SUB-CONTRACTOR COMPANY>
As part of the surveillance as required for the Part 21 Section A Subpart G approved production organisation, according to GM3 No. 4 to 21.B.220(e), the competent authority of the sub-contractor subcontractor is requested to perform authority surveillance on the specific sub-assembly sub-assembly 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 sub-contractor subcontractor:	
Name and address of the requesting competent authority office/person in charge of the POA:	
Direct Delivery Authorisation (DDA) applies:	<input type="checkbox"/> Yes <input type="checkbox"/> 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 No. 4 to 21.B.220(e) (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 ~~sub-contractor~~ subcontractor surveillance, Page x of x



<p>Competent authority of an EU Member State or EASA</p> <p>REPORT ON SUB-CONTRACTOR SUBCONTRACTOR SURVEILLANCE</p>	
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:	<SUB-CONTRACTOR COMPANY>
With approval reference:	<SUB-CONTRACTOR 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 GM3 No. 4 to 21.B.220(e) 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., etc. ...):	
Identification of attachments to this report (if needed):	
Date and identification of the previous report:	
Resume of surveillance results:	
Changes in organisation and qualification of the sub-contractor subcontractor (in case of impact on the procurement):	
Quality problems encountered during manufacture:	
Corrective actions following problems encountered earlier on 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 Exchange of information between national 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 sub-contractor subcontractor surveillance, Page x of x

– [21.B.220 Initial certification procedure](#)



AMC1 21.B.220(d)(1) Initial certification procedure

ISSUE OF THE CERTIFICATE

- (a) The competent authority should base its decision to issue or amend 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) In some cases, it may be acceptable for some findings to not be fully closed because corrective actions are still in progress. The competent authority may decide according to the following principles:
 - (1) Findings should be equivalent to level 2, which do not need to be rectified as a matter of urgency within less than 3 months, and should normally not exceed three in number.
 - (2) A corrective action plan, including timescales, should have been accepted and should not require an additional and specific follow-up audit by the competent authority.
- (d) 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.220 Initial certification procedure](#)

AMC1 21.B.221(a), (b) and (c) Oversight principles

MANAGEMENT SYSTEM ASSESSMENT

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.

As part of the continuing oversight, the competent authority should remain satisfied as to the presence of the required enablers, and assess the effectiveness of the organisation's management system and its processes.

When significant changes take place in the organisation, the competent authority should determine whether the existing assessment needs to be reviewed to ensure that it is still appropriate.

– [21.B.221 Oversight principles](#)

AMC1 21.B.222 and 21.B.432 Oversight programme

ANNUAL REVIEW

- (a) 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 safety performance of the organisation.

(b) When reviewing the oversight programme and the oversight planning cycle, the competent authority should also consider any relevant information collected in accordance with points 21.A.3A and 21.B.215(d) for production organisations or point 21.B.431(d) for design organisations.

– [21.B.222 Oversight programme](#)

GM1 21.B.222(a) Oversight programme

MAINTENANCE OF THE POA — WORK ALLOCATION WITHIN THE COMPETENT AUTHORITY

After the issue of the approval, the competent authority should appoint a suitable member of its technical staff as the POATL to be in charge of the approval for the purpose of continued surveillance.

Where the POA holder facilities are located in more than one Member State, the competent authority of the State of manufacture will liaise with the competent authorities of the various members to ensure appropriate continued surveillance.

– [21.B.222 Oversight programme](#)

AMC1 21.B.222(b) and 21.B.432(b) Oversight programme

SPECIFIC NATURE AND COMPLEXITY OF THE ORGANISATION — RESULTS OF PAST OVERSIGHT

When determining the oversight programme, including the relevant sample of product, parts and appliances under the scope of the organisation as the 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) 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 type of any subcontractors who perform production or design tasks as appropriate; and
- (f) the volume of activity for each product, parts or appliance.

– [21.B.222 Oversight programme](#)

AMC2 21.B.222(b) and 21.B.432(b) Oversight programme

SUBCONTRACTED ACTIVITIES

If a Part 21 organisation subcontracts some tasks, the competent authority should determine whether the subcontracted organisations needs 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 organisation approved according to Subparts G or J, and based on the assessment of the associated risks.

For such an audit, the competent authority inspector should ensure that he or she is accompanied throughout the audit by a senior technical member of the Part 21 organisation.

- [21.B.222 Oversight programme](#)

GM1 21.B.222(b) Oversight programme

The oversight programme consists of:

- planned continued surveillance, in which the total surveillance actions are split into several audits, which are carried out at planned intervals during the validity period of the production organisation approval. Within the continued surveillance, one aspect may be audited once or several times, depending upon its importance; and
- unplanned POA reviews, which are specific additional investigations of a POA holder 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 product.

- [21.B.222 Oversight programme](#)

AMC1 21.B.222(b)(1) Oversight programme

AUDIT

- The oversight programme should indicate which aspects of the certificate will be covered by each audit.
- A part of each audit should concentrate on the organisation's audit reports produced by the compliance monitoring function to determine whether the organisation is identifying and correcting its problems.
- At the conclusion of the audit, an audit report should be completed by the auditing inspector, identifying the areas and processes that were audited and including all the findings that were raised.
- 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.

- [21.B.222 Oversight programme](#)

GM1 21.B.222(b)(1)(ii) Oversight programme

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.
- (c) The sampling plan should be flexible so as to:
- (1) accommodate changes in the production rate;
 - (2) make use of the results from other samples;
 - (3) make use of the results from other POA investigations; and
 - (4) provide the competent authorities with the maximum degree of confidence.
- (d) To be effective, this product sample requires that the individual investigator(s):
- (1) have a good practical knowledge of the product, part or appliance;
 - (2) have a good practical knowledge of the manufacturing processes;
 - (3) have up-to-date knowledge of the production organisation's production programme;
 - (4) use an appropriate and up-to-date sample plan and compliance checklists;
 - (5) have a suitable recording system for the results;
 - (6) have a properly operating system to provide feedback to their competent authority's organisation for the POA and the production organisation;
 - (7) maintain an effective working relationship with the production organisation and its staff; and
 - (8) be able to communicate effectively.

– [21.B.222 Oversight programme](#)



AMC1 21.B.222(c) Oversight programme

OVERSIGHT PLANNING CYCLE AUDIT AND INSPECTION

- (a) When determining the oversight planning cycle and defining the oversight programme, the competent authority should assess the risks related to the activity 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 audits and inspections that is appropriate to each organisation. The planning of 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.

– [21.B.222 Oversight programme](#)

AMC1 21.B.222(c) and 21.B.432(c) Oversight programme

OVERSIGHT PLANNING CYCLE — AUDIT

- (a) For each organisation approved by the competent authority, all the processes should be completely 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) Audits should include at least one on-site audit within each oversight planning cycle. For organisations that exercise their regular activity at more than one site, the determination of the sites to be audited should consider the results of past oversight, the volume of activity at each site, as well as the main risk areas identified.
- (c) For organisations that hold more than one approval, 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, subject to the following conditions:
 - (1) the specific audit item should be the same for all the approvals under consideration;
 - (2) there should be 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;
 - (3) the competent authority should be satisfied that there is no evidence that standards have deteriorated in respect of those specific audit items for which credit is granted;
and



(4) the interval between two audits for the specific item for which credit is granted should not exceed the applicable oversight planning cycle.

– [21.B.222 Oversight programme.](#)

AMC1 21.B.222(d) Oversight programme

EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS

(a) If the competent authority applies an oversight planning cycle that exceeds 24 months, it should perform, at a minimum, one inspection of the organisation within each 12-month segment of the applicable oversight planning cycle to validate the oversight programme.

(b) If the results of this 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 determine the format and contents of the regular reports to be made by the organisation on its safety performance.

(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.

– [21.B.222 Oversight programme](#)

GM1 ~~21.B.225(a)~~ 21.B.125(b), 21.B.225(b) and 21.B.430(b) Findings and corrective actions **Objective evidence**

OBJECTIVE EVIDENCE

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; and
- (c) information from interview questions and observations of POA an organisation's activities.

– [21.B.225 Findings and corrective actions](#)

GM1 21.B.125(b)(1) and 21.B.225(b)(1) Findings and corrective actions

UNCONTROLLED NON-COMPLIANCE WITH APPLICABLE DESIGN DATA

An uncontrolled non-compliance with applicable design data is a non-compliance that:

- (a) cannot be discovered through systematic analysis; or
- (b) prevents the identification of the affected products, parts, appliances, or material.

– [21.B.225 Findings and corrective actions](#)



~~AMC 1 21.B.225(d)(a) Findings and corrective actions Notification of findings~~

~~NOTIFICATION OF FINDINGS~~

~~In case of a level 1 one finding, confirmation must should be obtained in a timely manner that the accountable manager has taken note of the finding and its details received the letter containing details of the level one finding and the approval suspension details.~~

~~A level two finding requires timely and effective handling oversight by the competent authority to ensure the completion of the corrective action. This oversight may includes intermediate communication, including reminding letters as necessary, with to remind the POA approval holder to verify that the corrective action plan is followed.~~

~~The competent authority should grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, which should not in any case be more than 21 working days, commencing from the date of the written communication of the finding to the organisation, requesting corrective action to address the non-compliance identified.~~

- ~~– [21.B.225 Findings and corrective actions](#)~~

~~AMC No 1 to 21.B.230 Issue of the certificate~~

~~The competent authority should base its decision to issue or amend a POA on the recommendation report (EASA Form 56, see [GM No 2 to 21.B.220\(c\)](#)) of the POAT submitted by the POA team leader. The EASA Form 56 includes a proposal by the POAT for the scope and terms of approval defining the products, parts and appliances for which the approval is to be granted, with appropriate limitations.~~

~~When the competent authority issues the approval a final controlled copy of an acceptable exposition for the organisation should have been supplied to the competent authority.~~

~~In some cases it may be accepted that some findings are not fully closed because corrective actions are still in progress. The competent authority may decide according to the following principles:~~

- ~~1) Findings should be equivalent to level two, which do not need to be rectified as a matter of urgency within less than three months, and should normally not exceed three in number.~~
- ~~2) Corrective action plan, including timescales, should have been accepted and should not require an additional and specific follow-up audit by the competent authority.~~

~~A record should be kept by the competent authority and should be brought to the attention of the Agency on request for standardisation purposes.~~

~~GM 21.B.235(a)(4) Guide to the conduct of monitoring production standards.~~

- ~~1. [21.B.235\(a\)\(4\)](#) identifies a need for a sample investigation of products, parts or appliances, their associated conformity determinations and 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 appropriate to the scope and size of the relevant applicant.~~

2. The sampling plan could, for example, investigate:

- (a) a modification (or change)
- (b) the installation, testing, or operation of a major part or system
- (c) the accuracy and generation of the Flight Test report data
- (d) the accuracy and generation of the Weighing report data
- (e) an engine test bed run
- (f) records traceability
- (g) the accuracy and generation of the Statement of Conformity data and the associated safe operation determination
- (h) the accuracy and generation of EASA Form 1 data.

The sampling plan should be flexible so as to:

- (i) accommodate changes in production rate
- (j) make use of results from other samples
- (k) make use of results from other POA Investigations
- (l) provide the maximum national authorities confidence

To be effective this product sample requires that the individual investigator(s):

- (m) have a good practical knowledge of the product, part or appliance
- (n) have a good practical knowledge of the manufacturing processes
- (o) have an up to date knowledge of the manufacturers production programme
- (p) use an appropriate and up to date sample plan and compliance check lists
- (q) have a suitable recording system for the results
- (r) have a properly operating feedback system to their national authorities organisation for POA and the manufacturer
- (s) maintain an effective working relationship with the manufacturer and his staff
- (t) be able to communicate effectively

GM 21.B.235(b) Maintenance of the POA – Work allocation within the competent authority

After issue of the approval the competent authority should appoint a suitable member of its technical staff as the POATL to be in charge of the approval for the purpose of continued surveillance.

Where the POA holder facilities are located in more than one Member State the competent authority of the State of manufacture will liaise with the competent authorities of the various partners/members to ensure appropriate continued surveillance.



GM 21.B.235(b) and (c) Continued surveillance

Continued surveillance consists of:

1. ~~Planned continued surveillance, in which the total surveillance actions are split into several audits, which are carried out at planned intervals during the validity period of the production organisation approval. Within the continued surveillance one aspect may be audited once or several times depending upon its importance.~~
2. ~~Unplanned POA reviews, which are specific additional investigation of a POA holder related to surveillance findings or external needs. The competent authority is responsible for deciding when a review is necessary taking into account changes in the scope of work, changes in personnel, reports on the organisation performance submitted by other EASA or national authorities teams, reports on the in service product.~~

AMC 21.B.235(c) Continuation of POA

~~At the end of the 24 months continued surveillance cycle the POATL responsible for the POA should complete an EASA Form 56 (see GM No 2 to 21.B.220(c)) as a summary report for the continued surveillance including the recommendation for continuation of the POA as applicable. The EASA Form 56 should be countersigned by the person responsible within the competent authority for his acceptance. At this stage there is no limitation to the number of level two findings that may be open, provided they are within the time limits of the respective corrective action plans.~~

AMC1 No 1 to 21.B.240 Changes to a production organisation approval Application for significant changes or variation of scope and terms of the POA

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 (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 (2), the competent authority may require the organisation to produce a written résumé of the proposed person's qualifications. The competent authority should reserve the right to interview the nominee or call for additional evidence of his or her suitability before deciding upon his or her acceptability.
- (c) For changes that require 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 a safety risk assessment is deemed necessary, the competent authority should inform the organisation accordingly.

- (e) If the competent authority considers that it is necessary to review the safety risk assessment performed by the organisation, it should request the assessment from the organisation and assess its results.
- (f) If required for verification, the audit may conduct interviews and inspections carried out at the organisation's facilities.
- (g) The competent authority should receive an application for any significant changes or for a change to the terms of approval of the DOA on an EASA Form 51 completed by the applicant.

~~The competent authority must receive an application for significant changes or variation of scope and terms of the POA on an EASA Form 51 (see below) completed by the applicant.~~

- [21.B.240 Changes to a production organisation approval](#)



EASA Form 51	
Application for significant changes or variation of scope and terms of Part 21 POA	
<i>Competent authority of an EU Member State or EASA</i>	
1. Name and address of the POA holder:	
2. Approval reference number:	
3. Locations for which changes in the terms of approval are requested:	
4. Brief summary of 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 must be entered as written on the current approval certificate. Where 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 must 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 locations for which changes in the terms of approval are requested or state 'not applicable' if no change is to be anticipated here.

Block 4: This Block should include further details for the variation of the scope of approval for the addresses indicated in Block 3. The Block 'General' must include overall information for the change (including



changes e.g. in workforce, facilities etc.), while the Block 'Scope of approval' must address the change in the scope of work and products/categories following the principles laid down in the GM 21.A.151. The Block 'nature of privileges' must indicate a change in the privileges as defined in 21.A.163(b) (d). State 'not applicable' if no change is anticipated here.

~~Block 5: This Block must state the changes to the organisation as defined in the current production organisation exposition, including changes the organisational structure, functions and responsibilities. This Block must therefore also be used to indicate a change in the accountable manager in accordance with 21.A.145(c)(1) or a change in the nomination of the responsible managers in accordance with 21.A.145(c)(2). A change in the nomination of responsible managers must be accompanied by the corresponding EASA Forms 4. State 'not applicable' if no change is anticipated here.~~

~~Block 6: State the position and name of the accountable manager here. Where there is a change in the nomination of the accountable manager, the information must refer to the nominee for this position. State 'not applicable' if no change is anticipated here.~~

~~In case of an application for a change of the accountable manager the EASA Form 51 must be signed by the new nominee for this position. In all other cases the EASA Form 51 must be signed by the accountable manager.~~

GM 21.B.245 Continued validity

1. GENERAL

~~Decisions on restriction, surrender, suspension or revocation of POA will always be actioned in such a way as to comply with any applicable national laws or regulations relating to appeal rights and the conduct of appeals, unless the decision has been taken by the Agency. In such case, the Agency appeal procedures will apply.~~

~~2. RESTRICTION is temporary withdrawal of some of the privileges of a POA under 21.A.163.~~

~~3. SURRENDER is a permanent cancellation of a production organisation approval by the competent authority upon formal written request by the accountable manager of the organisation concerned. The organisation effectively relinquishes its rights and privileges granted under the approval and, after cancellation, may not make certifications invoking the approval and must remove all references to the approval from its company documentation.~~

~~4. SUSPENSION is temporary withdrawal of all the privileges of a production organisation approval under 21.A.163. The approval remains valid but no certifications invoking the approval may be made while the suspension is in force. Approval privileges may be re-instated when the circumstances causing the suspension are corrected and the organisation once again can demonstrate full compliance with the Requirements.~~

~~5. REVOCATION is a permanent and enforced cancellation of the whole of an approval by the competent authority. All rights and privileges of the organisation under the approval are withdrawn and, after revocation, the organisation may not make any certifications or other statements invoking the approval and must remove all references to the approval from its company documentation.~~

AMC 21.B.245 Corrective action plan

It is expected that any established POA holder will move quickly to re-establish compliance with Part 21 and not risk the possibility of approval suspension. Therefore, the corrective action period granted by the competent authority must be appropriate to the nature of the finding but in any case initially must not be more than six months. In certain circumstances and subject to the nature of the finding the competent authority can vary the six months period subject to a satisfactory corrective action plan agreed by the competent authority.

Failure to comply within time scale agreed by the competent authority means that provisional suspension of the POA in whole or in part must proceed.



SUBPART J — DESIGN ORGANISATION APPROVAL

AMC1 21.B.220 and 21.B.430 Initial certification procedure

VERIFICATION OF COMPLIANCE

- (a) In order to verify the organisation's compliance with the applicable requirements, the competent authority should conduct an audit of the organisation, including interviews of the personnel, and inspections 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 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 law.
- [21.B.430 Initial certification procedure](#)

AMC1 21.B.430 and 21.B.431 Initial certification procedure

INVESTIGATION TEAM

- (a) The competent authority should appoint a design organisation investigation team for each applicant for, or each holder of, a design 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(c).
- (b) The competent authority should perform sufficient investigation activities for an applicant for, or a holder of, a DOA to justify the recommendations for the issuance, maintenance, amendment, suspension or revocation of the approval.
- (c) The competent authority should prepare procedures for the investigation of a DOA as part of the documented procedures that cover at least the following elements:
 - (1) the evaluation of the applications received;
 - (2) the appointment of the organisation approval team;
 - (3) the preparation and planning of the investigation;



- (4) the evaluation of the documentation (design organisation handbook, procedures, etc.);
- (5) the auditing;
- (6) the follow-up of corrective actions;
- (7) any recommendation for the issuance, amendment, suspension or revocation of a design organisation approval; and
- (8) continued surveillance.

– [21.B.430 Initial certification procedure](#)

AMC1 21.B.430(a) Initial certification procedure

ORGANISATION APPROVAL TEAM

(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 approval team investigations (not necessarily only Part 21 Section A Subpart J); and
- (4) relevant knowledge of the design management system.

(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, which is mandatory, for Part 21 Section A, Subparts A and J, and Section B, Subparts A and J;
- (2) education and experience, to cover the 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.

– [21.B.430 Initial certification procedure](#)

AMC1 21.B.430(d)(1) Initial certification procedure

ISSUE OF THE CERTIFICATE

- (a) The competent authority should base its decision to issue or amend a DOA on the recommendation in the DOA investigation report (for an initial investigation) or the significant change report (for significant changes) submitted by the DOA team leader. The report includes a proposal by the DOAT for the 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.
 - (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) The findings should be of level 2 or 3, which do not need to be rectified as a matter of urgency within less than 3 months, and should normally not exceed three in number.
 - (2) A corrective action plan, including timescales, should have been accepted, and should not require an additional specific follow-up audit by the competent authority.
- [21.B.430 Initial certification procedure](#)

AMC1 21.B.431(a), (b) and (c) Oversight principles

MANAGEMENT SYSTEM ASSESSMENT

As part of the initial certification of an organisation in accordance with point 21.B.430, 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.

As part of their continuing oversight, the competent authority should remain satisfied as to the presence of the required enablers, and assess the effectiveness of the organisation's management system and processes.

When significant changes take place in the organisation, the competent authority should decide whether it needs to review the existing assessment to ensure it is still appropriate.

- [21.B.431 Oversight principles](#)

AMC1 21.B.222 and 21.B.432 Oversight programme

ANNUAL REVIEW

- (a) 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 safety performance of the organisation.
- (b) When reviewing the oversight programme and the oversight planning cycle, the competent authority should also consider any relevant information collected in accordance with points 21.A.3A and 21.B.215(d) for production organisations, or point 21.B.431(d) for design organisations.

- [21.B.432 Oversight programme](#)

AMC1 21.B.222(b) and 21.B.432(b) Oversight programme

SPECIFIC NATURE AND COMPLEXITY OF THE ORGANISATION — RESULTS OF PAST OVERSIGHT

When determining the oversight programme, including the 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) any specific procedures implemented by the organisation that are related to any alternative means of compliance used;
- (d) the number of locations and the activities performed at each location;
- (e) the number and type of subcontractors who perform production or design activities as appropriate; and
- (f) the volume of activity for each product, parts or appliance.

– [21.B.432 Oversight programme](#)

AMC2 21.B.222(b) and 21.B.432(b) Oversight programme

SUBCONTRACTED ACTIVITIES

If a Part 21 organisation subcontracts some activities, the competent authority should determine whether the Part 21 organisation needs to be audited on how they control particular subcontracted activities 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 organisation approved according to Subparts G or J, and based on the assessment of the associated risks.

For such an audit, the competent authority inspector should ensure that he or she is accompanied throughout the audit by a senior technical member of the Part 21 organisation.

– [21.B.432 Oversight programme](#)

AMC1 21.B.432(b)(1) Oversight programme

AUDIT

- (a) The oversight programme should indicate which aspects of the terms of approval will be covered by each audit.
- (b) Audits may be complemented by a review of the compliance monitoring results particular to the topics of the audit to determine if the organisation is identifying and correcting its problems.
- (c) At the conclusion of the audit, the auditing inspector should complete an audit report that identifies the areas and processes that were audited and includes all the findings that were raised.

– [21.B.432 Oversight programme](#)

AMC1 21.B.432(c) Oversight programme

OVERSIGHT PLANNING CYCLE AUDIT AND INSPECTION



- (a) When determining the oversight planning cycle and defining the oversight programme, the competent authority should assess the risks related to the activity 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 audits and inspections that is appropriate to each organisation. The planning of 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.
 - (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 aspects of the organisation's activity are audited and inspected within the applicable oversight planning cycle.
- [21.B.432 Oversight programme](#)

AMC2 21.B.222(c) and 21.B.432(c) Oversight programme

OVERSIGHT PLANNING CYCLE — AUDIT

- (a) For each organisation approved by the competent authority, all the processes should be completely 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) Audits should include at least one on-site audit within each oversight planning cycle. For organisations that exercise their regular activity at more than one site, the determination of the sites to be audited should consider the results of past oversight, the volume of activity at each site, as well as the main risk areas identified.
- (c) For organisations that hold more than one approval, 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, subject to the following conditions:
 - (1) the specific audit item should be the same for all the approvals under consideration;
 - (2) there should be 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;
 - (3) the competent authority should be satisfied that there is no evidence that standards have deteriorated in respect of those specific audit items for which credit is granted; and
 - (4) the interval between two audits for the specific item for which credit is granted should not exceed the applicable oversight planning cycle.

- [21.B.432 Oversight programme](#)



AMC1 21.B.432(d) Oversight programme

EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS

- (a) If the during an inspection the competent authority finds 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.
- (b) In order to be able to apply an oversight planning cycle of up to 36 months, the competent authority should determine the format and contents of the regular reports to be made by the organisation on its safety performance.
- (c) 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.

– [21.B.432 Oversight programme](#)

GM1 21.B.125(b), 21.B.225(b) and 21.B.430(b) Findings and corrective actions

OBJECTIVE EVIDENCE

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; and
- (c) information from interview questions and observations of organisation activities.

– [21.B.433 Findings and corrective actions](#)

AMC1 21.B.433(d) Findings and corrective actions

NOTIFICATION OF FINDINGS

In the case of a level 1 finding, confirmation should be obtained in a timely manner that the head of the design organisation has taken note of the finding and its details.

A finding requires timely and effective oversight by the competent authority to ensure the completion of the corrective action. This oversight may include intermediate communication, including letters as necessary, to remind the approval holder to verify that the corrective action plan is followed.

The competent authority should grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, which should not in any case be more than 21 working days, commencing from the date of the written communication of the finding to the organisation, requesting corrective action to address the non-compliance identified.

– [21.B.433 Findings and corrective actions](#)

AMC1 21.B.435 Changes to a design organisation approval

APPLICATION FOR SIGNIFICANT CHANGES OR VARIATION OF SCOPE AND TERMS OF THE DOA

- (a) The competent authority should have adequate control over any changes in the personnel specified in points 21.A.245(a) and (b). Such changes in personnel will require an amendment to the handbook.
- (b) When an organisation submits the name of a new nominee for any of the personnel positions specified in points 21.A.245(a) and (b), the competent authority may require the organisation to produce a written résumé of the proposed person's qualifications. The competent authority should reserve the right to interview the nominee or call for additional evidence of his or her suitability before deciding upon his or her acceptability.
- (c) For changes that require 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 a safety risk assessment is deemed necessary, the competent authority should inform the organisation accordingly.
- (e) If the competent authority considers that it is necessary to review the safety risk assessment performed by the organisation, it should request the assessment from the organisation and assess its results.
- (f) If required for verification, the audit may include interviews and inspections carried out at the organisation's facilities.
- (g) The competent authority should receive an application for any significant changes or for a change to the terms of approval of the DOA on an EASA Form 82 completed by the applicant.

– [21.B.435 Changes to a design organisation approval](#)

