

*eRules*

# ATM/ANS — EQUIPMENT

(IR + AMC/GM)



# Easy Access Rules for ATM /ANS - Equipment (Regulation (EU) 2023/1769 & Regulation (EU) 2023/1768)

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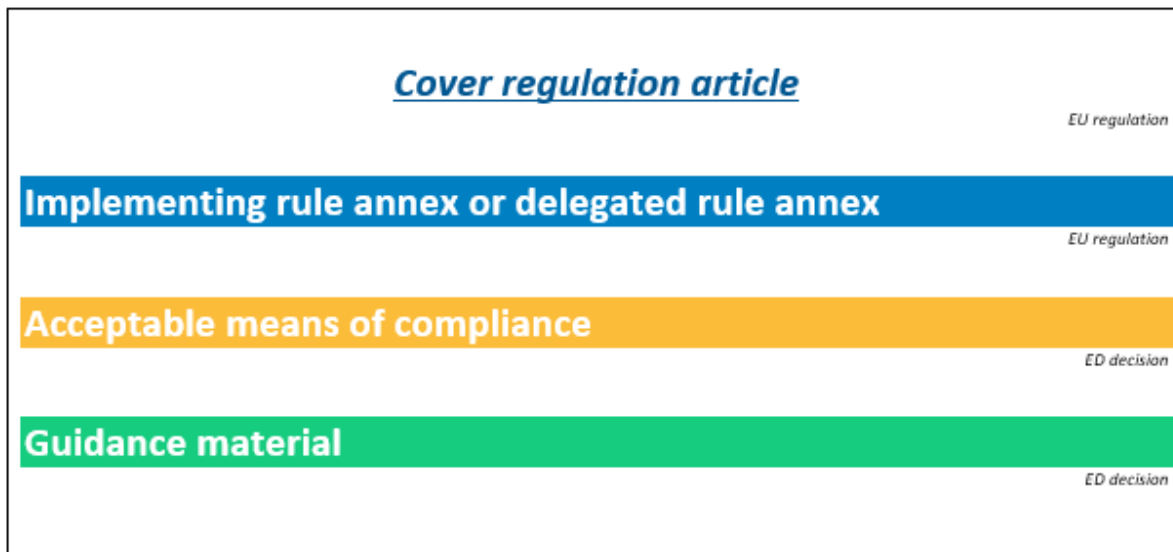
## LIST OF REVISIONS

Published	Reason for revision
November 2024	<p>First Easy Access Rules document powered by eRules.</p> <p>The EAR incorporate:</p> <ul style="list-style-type: none"><li>- Implementing Regulation (EU) 2023/1769</li><li>- ED Decision 2024/002/R</li><li>- Delegated Regulation (EU) 2023/1768</li><li>- ED Decision 2023/016/R</li><li>- ED Decision 2024/001/R</li></ul>

## NOTE FROM THE EDITOR

The content of this document is arranged as follows: the cover regulation (recitals and articles) of the implementing rule (IR) or delegated rule (DR) appears first, then the IR or DR annex points, followed by the related acceptable means of compliance (AMC) and guidance material (GM).

All elements (i.e. articles, IRs, DRs, AMC, CSs, and GM) are colour-coded and can be identified according to the illustration below. The EU regulation or EASA Executive Director (ED) decision through which the article, IR, DR, CS, AMC, or GM was introduced or last amended is indicated below the article, IR, DR, CS, AMC, or GM title in *italics*.



This document will be updated regularly to incorporate further amendments.

The format of this document has been adjusted to make it user-friendly and for reference purposes. Any comments should be sent to [erules@easa.europa.eu](mailto:erules@easa.europa.eu).

## INCORPORATED AMENDMENTS

### COMMISSION IMPLEMENTING REGULATIONS

Incorporated Commission Regulation	Affected Part	Regulation amendment	Applicability date <sup>1</sup>
<a href="#">Regulation (EU) 2023/1769</a>	Cover regulation	Initial issue	5/10/2023
	Annex I (Part-DPO.AR)		
	Annex II (Part-DPO.OR)		

### COMMISSION DELEGATED REGULATIONS

Incorporated Commission Regulation	Affected Part	Regulation amendment	Applicability date <sup>1</sup>
<a href="#">Regulation (EU) 2023/1768</a>	Cover regulation	Initial issue	5/10/2023
	Annex I (Part-ATM/ANS.EQMT.AR)		
	Annex II (Part-ATM/ANS.EQMT.CERT)		
	Annex III (Part-ATM/ANS.EQMT.DEC)		

### ED DECISIONS (AMC & GM TO COMMISSION IMPLEMENTING REGULATIONS)

Incorporated ED Decision	Affected Part	Regulation amendment	Applicability date <sup>1</sup>
<a href="#">ED Decision 2024/002/R</a>	Annex II (Part-DPO.OR)	Issue 1	23/3/2024

### ED DECISIONS (AMC & GM TO COMMISSION DELEGATED REGULATIONS)

Incorporated Commission Regulation	Affected Part	Regulation amendment	Applicability date <sup>1</sup>
<a href="#">ED Decision 2023/016/R</a>	Cover regulation	Issue 1	27/10/2023
<a href="#">ED Decision 2024/001/R</a>	Cover regulation	Issue 1, Amendment 1	23/3/2024
	Annex I (Part-ATM/ANS.EQMT.AR)	Issue 1	
	Annex II (Part-ATM/ANS.EQMT.CERT)	Issue 1	

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

<sup>1</sup> This is the date of application (i.e. the date from which an act or a provision in an act produces its full legal effects) as defined in the relevant cover regulation article. Some provisions of the regulations though may be applicable at a later date (deferred applicability). Besides, there may be some opt-outs (derogations from certain provisions) notified by the Member States.

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# IMPLEMENTING REGULATION (EU) 2023/1769

## COVER REGULATION TO IMPLEMENTING REGULATION (EU) 2023/1769

Commission Implementing Regulation (EU) 2023/1769 laying down technical requirements and administrative procedures for the approval of organisations involved in the design or production of air traffic management/air navigation services systems and constituents and amending Implementing Regulation (EU) 2023/203

### *Powers and recitals*

*Regulation (EU) 2023/1769*

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 <sup>(1)</sup>, and in particular Article 43(1) and Article 62(15), point (c) thereof,

Whereas:

- (1) Taking into account the objectives and principles set out in Articles 1 and 4 to Regulation (EU) 2018/1139, and in particular the nature and risk of the activity concerned, organisations involved in the design or production of air traffic management/air navigation service (ATM/ANS) systems and ATM/ANS constituents, should be required to hold a certificate.
- (2) In order to ensure the uniform implementation of and compliance with the essential requirements referred to in Article 40 of Regulation (EU) 2018/1139, for the provision of ATM/ANS this Regulation should lay down rules and procedures for issuing, maintaining, amending, limiting, suspending or revoking the certificates for organisations involved in the design or production of ATM/ANS systems and ATM/ANS constituents, as well as the privileges and responsibilities of the holders of certificates.
- (3) The conformity assessment of ATM/ANS equipment laid down in Commission Delegated Regulation (EU) 2023/ 1768 <sup>(2)</sup> depends on the nature and the risk of the ATM/ANS service, or on the functionality of a particular ATM/ANS equipment and is based on the existing methodologies and best practices. That Regulation establishes three different types of conformity assessment, in particular: a certification by the Agency of certain ATM/ANS equipment; a declaration by an approved organisation involved in the design or production of

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<sup>1</sup> OJ L 212, 22.08.2018, p. 1.

<sup>2</sup> Commission Delegated Regulation (EU) 2023/1768 of 14 July 2023 laying down detailed rules for the certification and declaration of air traffic management/air navigation services systems and air traffic management/air navigation services constituents (see page 1 of this Official Journal).

ATM/ANS equipment; and a statement of compliance by the ATM/ANS provider or by an approved organisation involved in the design or production of ATM/ANS equipment.

- (4) The typical life cycle of ATM/ANS equipment consists of various phases: design, production, installation, operation, maintenance, and decommission. The ATM/ANS provider is usually responsible for some of those phases, while for other phases the organisations involved in the design or production of ATM/ANS equipment are responsible. Therefore, common requirements should be established for the approval and oversight of organisations involved in the design or production of certain ATM/ANS equipment used in the provision of ATM/ANS, in particular those referred to in point 3.1 of Annex VIII to Regulation (EU) 2018/1139.
- (5) The European Union Aviation Safety Agency ('the Agency') is responsible for all competent authority tasks related to certificates and declarations for ATM/ANS systems and ATM/ANS constituents ('ATM/ANS equipment'), including oversight and enforcement. To ensure consistency and risk-based assessment and, amongst others, to avoid duplication and administrative burdens, as well as to promote effectiveness in certification and oversight processes, those oversight and enforcement functions should be exercised by the Agency. For the purpose of certification or review of declarations of ATM/ANS equipment, it is necessary that the Agency also oversees the processes established by design and production organisations, including, where necessary, the certification of those organisations. Therefore, the Agency should be responsible for the approval of the organisations involved in the design or production of ATM/ANS equipment and at the same time for the attestation of ATM/ANS equipment.
- (6) The competency of the Agency to certify design or production organisations should allow also for a non-discriminatory and harmonised approach towards all design or production organisations applying for a certificate under this Regulation. ATM/ANS equipment put on the market in the Union can be used in all Member States and for all kind of services, no matter whether it is used by ATM/ANS providers active in one or more Member States. It is not possible to categorise the organisations involved in the design and production based on their future catalogue of equipment to be used on a local or Union level. The same principle is to be observed when the Agency is allocating certification and oversight tasks.
- (7) In accordance with Article 29(2), point (a), of Regulation (EU) 2021/696 <sup>(1)</sup> of the European Parliament and of the Council, the European Union Agency for the Space Programme (EUSPA) has been entrusted with the task of managing the exploitation of the European Geostationary Navigation Overlay Service (EGNOS), as provided for in Article 44 of that Regulation. The exploitation of EGNOS covers, amongst other actions, the support to certification and standardisation activities. EUSPA does not perform alone all the tasks relating to the exploitation of EGNOS and instead relies on the expertise of other entities, in particular the European Space Agency (ESA), on activities related to system evolution, design and development of parts of the ground segment. Hence EUSPA should be considered as equivalent to a design or production organisation in the context of this Regulation.
- (8) According to the roles and responsibilities defined in Regulation (EU) 2021/696 for EUSPA and ESA, there is not one unique entity responsible for the design of the EGNOS system and its equipment and therefore there is not a single Design and Production Organisation that could be approved by EASA.

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<sup>1</sup> Regulation (EU) 2021/696 of the European Parliament and of the Council of 28 April 2021 establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013 and (EU) No 377/2014 and Decision No 541/2014/EU (OJ L 170, 12.5.2021, p. 69).

- (9) Consequently, the specificities of the set-up for the design of the EGNOS system require specific means for the demonstration of compliance with the essential requirements laid down in Regulation (EU) 2018/1139, taking into account that EGNOS is a multimodal service, which should also comply with relevant regulatory requirements for other sectors.
- (10) Both agencies should cooperate to assure compliance of the EGNOS system with the relevant ICAO standards so that respective arrangements ensure a level of safety and interoperability equivalent to that resulting from the full application of the requirements for design and production in this Regulation. The cooperation will also include the consultation of EUSPA in the development of detailed specifications.
- (11) This Regulation has taken due account of the content of the ATM Master Plan and technological capabilities contained in it.
- (12) The Agency has prepared draft implementing rules and submitted them to the Commission with Opinion No 01/2023 in accordance with Article 75(2), points (b) and (c), and Article 76(1) of Regulation (EU) 2018/1139.
- (13) In order to make optimal use of existing resources and expertise, the Agency may seek administrative support when executing its certification, oversight and enforcement tasks under this Regulation from national competent authorities. This administrative support should not constitute any delegation of powers or responsibilities of tasks.
- (14) In order to include design or production organisations of ATM/ANS equipment in the scope of the management of information security risks with a potential impact on aviation safety Implementing Regulation (EU) 2023/203 should be amended.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 127(1) of Regulation (EU) 2018/1139.

HAS ADOPTED THIS REGULATION:

## **Article 1 - Subject matter**

*Regulation (EU) 2023/1769*

This Regulation lays down technical requirements and administrative procedures for the approval of organisations involved in the design or production of ATM/ANS systems and ATM/ANS constituents subject to certification in accordance with [Article 4](#) of Delegated Regulation (EU) 2023/1768 or declaration of design compliance in accordance with [Article 5](#) of that Regulation.

## **Article 2 - Definitions**

*Regulation (EU) 2023/1769*

For the purpose of this Regulation the following definitions apply:

- (1) 'ATM/ANS equipment' means ATM/ANS constituents as defined by Article 3(6) of Regulation (EU) 2018/1139 and ATM/ANS systems as defined by Article 3(7) of that Regulation, excluding airborne constituents, which are subject to Commission Regulation (EU) No 748/2012 <sup>(1)</sup>;
- (2) 'ATM/ANS equipment directive' means a document issued by the Agency which mandates actions to be performed by ATM/ANS providers on ATM/ANS equipment to address an unsafe and/or insecure condition that has been identified and restore the performance and

<sup>1</sup> Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1).

interoperability of that ATM/ANS equipment when evidence shows that the safety, security, performance or interoperability of that particular equipment may otherwise be compromised.

### **Article 3 - Competent authority requirements**

*Regulation (EU) 2023/1769*

1. For the purposes of this Regulation, the competent authority responsible for the issue of approvals to organisations involved in the design or production of ATM/ANS equipment and for the oversight and enforcement in respect of those organisations, shall be the Agency.
2. The Agency shall fulfil the detailed requirements laid down in [Annex I](#) (Part-DPO.AR) when conducting certification, investigations, inspections, audits and other monitoring activities necessary to ensure the effective oversight of organisations involved in the design or production of ATM/ANS equipment subject to this Regulation. The Agency may seek administrative support from national competent authorities for the performance of its tasks related to certification, oversight and enforcement when executing its functions under this Regulation.

### **Article 4 - Organisations involved in the design, or production of ATM/ANS equipment**

*Regulation (EU) 2023/1769*

1. An organisation involved in the design or production of ATM/ANS equipment subject to certification in accordance with [Article 4](#) of Delegated Regulation (EU) 2023/1768 or declaration of design compliance in accordance with [Article 5](#) of that Regulation shall demonstrate its capability as a design or production organisation for ATM/ANS equipment in accordance with [Annex II](#) (Part-DPO.OR).
2. Organisations involved in the design or production of the ATM/ANS equipment of the European Geostationary Navigation Overlay Service (EGNOS) shall be deemed to comply with the requirements of [Annex II](#) to this Regulation by demonstrating their compliance with Regulation (EU) 2021/696 and with the management, design and quality standards applicable to EGNOS under that Regulation. Such organisations shall not be required to be approved by the Agency.

The European Union Agency for the Space Programme shall ensure in its role of a design or production organisation that the other organisations involved in the design or production of the equipment of EGNOS follow design and production processes resulting in the level of safety and interoperability equivalent to [Annex II](#) (Part-DPO.OR).



## **Article 5 - Amendments to Implementing Regulation (EU) 2023/203**

**(1)**

*Regulation (EU) 2023/1769*

Implementing Regulation (EU) 2023/203 is amended as follows:

- (1) in Article 2(1), the following point (j) is added:
  - (j) approved organisations involved in the design or production of ATM/ANS systems and ATM/ANS constituents subject to Commission Implementing Regulation (EU) 2023/1769<sup>(2)</sup>.
- (2) in Article 6(1), the following point (h) is added:
  - (h) with regard to organisations referred to in Article 2(1), point (j), the competent authority designated in accordance with Article 3(1) of Implementing Regulation (EU) 2023/1769.’.

## **Article 6 - Entry into force**

*Regulation (EU) 2023/1769*

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

## **Signature**

*Regulation (EU) 2023/1769*

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

Done at Brussels, 12 September 2023.

*For the Commission*

*The President*

**Ursula VON DER LEYEN**

<sup>1</sup> Commission Implementing Regulation (EU) 2023/203 of 27 October 2022 laying down rules for the application of Regulation (EU) 2018/1139 of the European Parliament and of the Council, as regards requirements for the management of information security risks with a potential impact on aviation safety for organisations covered by Commission Regulations (EU) No 1321/2014, (EU) No 965/2012, (EU) No 1178/2011, (EU) 2015/340, Commission Implementing Regulations (EU) 2017/373 and (EU) No 2021/664, and for competent authorities covered by Commission Regulations (EU) No 748/2012, (EU) No 1321/2014, (EU) No 965/2012, (EU) No 1178/2011, (EU) 2015/340 and (EU) No 139/2014, Commission Implementing Regulations (EU) 2017/373 and (EU) No 2021/664 and amending Commission Regulations (EU) No 1178/2011, (EU) No 748/2012, (EU) No 965/2012, (EU) No 139/2014, (EU) No 1321/2014, (EU) 2015/340, and Commission Implementing Regulations (EU) 2017/373 and (EU) No 2021/664 (OJ L 31, 2.2.2023, p. 1).

<sup>2</sup> Commission Implementing Regulation (EU) 2023/1769 of 12 September 2023 laying down technical requirements and administrative procedures for the approval of organisations involved in the design or production of air traffic management/air navigation services systems and constituents and amending Implementing Regulation (EU) 2023/203 (OJ L 228, XX.9.2023, p. 19).’

## ANNEX I - REQUIREMENTS FOR THE AGENCY - (PART-DPO.AR)

### SUBPART A - GENERAL REQUIREMENTS (DPO.AR.A)

#### DPO.AR.A.001 Scope

Regulation (EU) 2023/1769

This Annex establishes the requirements for the administration and management systems of the Agency for the certification, oversight and enforcement tasks of design or production organisations when the Agency exercises its tasks and responsibilities.

#### DPO.AR.A.010 Immediate reaction to a safety, security and interoperability problem

Regulation (EU) 2023/1769

- (a) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council <sup>(1)</sup>, and the delegated and implementing acts adopted on the basis thereof, the Agency shall implement a system to appropriately collect, analyse, and disseminate safety, security and interoperability information.
- (b) Upon receiving the information referred to in point (a), the Agency shall take appropriate measures to address any identified safety, security, or interoperability problem, including the issuing of ATM/ANS equipment directives in accordance with point [ATM/ANS.EQMT.AR.A.030](#) of [Annex I](#) to Delegated Regulation (EU) 2023/1768.
- (c) The measures taken under point (b) shall immediately be notified to the organisation concerned, who is obliged to comply with them, in accordance with point [DPO.OR.A.035](#). The competent authorities of the ATM/ANS providers concerned shall also be notified.

#### DPO.AR.A.015 Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

Regulation (EU) 2023/1769

- (a) The Agency shall implement a system to appropriately collect, analyse, and disseminate information related to information security incidents and vulnerabilities with a potential impact on aviation safety that are reported by organisations. This shall be done in coordination with any other relevant authorities responsible for information security or cybersecurity within the Member State to increase the coordination and compatibility of reporting schemes.
- (b) Upon receiving the information referred to in point (a), the Agency shall take adequate measures to address the potential impact on aviation safety of the information security incident or vulnerability.

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

- (c) Measures taken in accordance with point (b) shall immediately be notified to all persons or organisations that shall comply with them under Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis. The Agency shall also notify those measures to the competent authorities of the Member States concerned.

## **SUBPART B - MANAGEMENT (DPO.AR.B)**

### **DPO.AR.B.001 Management system**

*Regulation (EU) 2023/1769*

- (a) The Agency shall establish and maintain a management system, including, as a minimum, the following elements:
- (1) documented policies and procedures to describe its organisation, means and methods to establish compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on their bases, as necessary, for the exercise of its certification, oversight and enforcement tasks; the procedures shall be kept up to date and serve as the basic working documents within the Agency for all related tasks;
  - (2) a sufficient number of personnel to perform its tasks and discharge its responsibilities under this Regulation; a system shall be in place to plan the availability of personnel in order to ensure the proper completion of all related tasks;
  - (3) personnel that are qualified to perform their allocated tasks and have the necessary knowledge and experience, and have received initial and recurrent training to ensure their continuing competence;
  - (4) adequate facilities and offices to perform the allocated tasks;
  - (5) a function to monitor the compliance of the management system with the relevant requirements and the adequacy of the procedures, including the establishment of an internal audit process and a safety risk management process; the compliance-monitoring function shall include a system to provide feedback about audit findings to the senior management of the Agency to ensure the implementation of corrective actions as necessary;
  - (6) a person or group of persons ultimately responsible to the senior management of the Agency for the compliance- monitoring function.
- (b) The Agency shall, for each field of activity included in the management system, appoint one or more persons with the overall responsibility for the management of the relevant task(s).
- (c) The Agency shall establish procedures for its participation in a mutual exchange of all the necessary information with any other competent authority(ies) referred to in Article 4 of Commission Implementing Regulation (EU) 2017/373 <sup>(1)</sup> and provide them with assistance or request assistance from them, including any information that stems from mandatory and voluntary occurrence reporting as required by point DPO.OR.A.045.
- (d) The management system established and maintained by the Agency shall comply with Annex I (Part-IS.AR) of Implementing Regulation (EU) 2023/203 in order to ensure the proper management of information security risks which may have an impact on aviation safety.

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<sup>1</sup> Commission Implementing Regulation (EU) 2017/373 of 1 March 2017 laying down common requirements for providers of air traffic management/air navigation services and other air traffic management network functions and their oversight, repealing Regulation (EC) No 482/2008, Implementing Regulations (EU) No 1034/2011, (EU) No 1035/2011 and (EU) 2016/1377 and amending Regulation (EU) No 677/2011 (OJ L 62, 8.3.2017, p. 1).

## **DPO.AR.B.010 Changes in the management system**

*Regulation (EU) 2023/1769*

- (a) The Agency shall have a system in place to identify those changes that affect its capability to perform its tasks and discharge its responsibilities as set out in Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof. That system shall enable the Agency to take action, as appropriate, to ensure that the management system remains adequate and effective.
- (b) The Agency shall update its management system to reflect any changes to Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, in a timely manner, so as to ensure the effective implementation of its management system.

## **DPO.AR.B.015 Record-keeping**

*Regulation (EU) 2023/1769*

- (a) The Agency shall establish and maintain a record-keeping system that provides for adequate storage, accessibility, and reliable traceability of:
  - (1) the management system's documented policies and procedures;
  - (2) the training, qualifications, and authorisation of personnel as required by point [DPO.AR.B.001](#) (a)(3);
  - (3) the allocation of tasks, covering the elements required by point [ATM/ANS.EQMT.AR.A.020](#) of [Annex I](#) to Delegated Regulation (EU) 2023/1768, as well as the details of the allocated tasks;
  - (4) the approval process as regards organisations involved in the design or production of ATM/ANS equipment, the certification process, and the registration of declarations of design compliance for ATM/ANS equipment and the continuing oversight, including:
    - (i) applications for the issue of approvals;
    - (ii) approvals issued to organisations involved in the design or production of ATM/ANS equipment, including the associated privileges and any changes to them;
    - (iii) ATM/ANS equipment certificates issued, including any changes to them that it has issued;
    - (iv) all valid declarations of design compliance of ATM/ANS equipment that it has registered;
    - (v) the Agency's continuing oversight programme, including all assessment, audit and inspection records;
    - (vi) a copy of the oversight programme listing the dates when audits are due and when audits were carried out;
    - (vii) copies of all formal correspondence;
    - (viii) recommendations for the issue or continuation of a certificate or continuation of the registration of a declaration, details of findings, and actions taken by the organisations to close them, including the date of closure of each item, enforcement actions, and observations;
    - (ix) any assessment, audit or inspection report;

- (x) copies of all organisation handbooks, procedures and processes or manuals and amendments to them;
- (xi) copies of any other documents approved by the Agency;
- (5) the notification and evaluation of the alternative means of compliance proposed by organisations involved in the design or production of ATM/ANS equipment and the assessment of these alternative means of compliance;
- (6) safety information, ATM/ANS equipment directives, and follow-up measures;
- (7) the use of flexibility provisions pursuant to Article 76(4) of Regulation (EU) 2018/1139.
- (b) The Agency shall maintain a list of all the certificates it has issued and of any declarations it has registered.
- (c) All the records referred to in points (a) and (b) shall be stored in a manner that ensures protection against damage, alteration and theft and kept for a minimum period of five years after the approvals and certificates cease to be valid or the declarations are withdrawn, subject to the applicable data protection law.

## SUBPART C - CERTIFICATION, OVERSIGHT, AND ENFORCEMENT (DPO.AR.C)

### DPO.AR.C.001 Issue of approvals to organisations involved in the design or production of ATM/ANS equipment

Regulation (EU) 2023/1769

- (a) Upon receiving an application for the issue of an approval to an organisation involved in the design or production of ATM/ANS equipment, the Agency shall verify the organisation's compliance with the requirements laid down in [Annexes II](#) and [III](#) of Delegated Regulation (EU) 2023/1768 and in [Annex II](#) to this Regulation.
- (b) The Agency may request any audits, inspections or assessments it finds necessary before issuing the approval with all the relevant information set out in [Appendix 1](#) to this Annex.
- (c) The approval shall be issued for an unlimited duration. The privileges as regards the activities the organisation is approved to conduct shall be specified in the conditions attached to the approval.
  - (1) With regard to an organisation involved in the design of ATM/ANS equipment, the conditions shall specify the type of design work and the categories of ATM/ANS equipment for which the organisation holds an approval, and the privileges the organisation is approved to exercise.
  - (2) With regard to an organisation involved in the production of ATM/ANS equipment, the conditions shall specify the scope of work and the ATM/ANS equipment or the equipment categories, or both, for which the approval holder is entitled to exercise the privileges.
- (d) The approval shall not be issued where a level 1 finding referred to in [DPO.AR.C.015](#) remains open. In exceptional circumstances, finding(s) other than level 1 shall be assessed and mitigated as necessary by the organisation and a corrective action plan for closing the finding(s) shall be approved by the Agency prior to the issue of the approval.
- (e) Each change to the approval and to its conditions shall be approved by the Agency.

### DPO.AR.C.005 Oversight programme

Regulation (EU) 2023/1769

- (a) The Agency shall establish and update annually an oversight programme taking into account the specific nature of the organisations it oversees, the complexity of their activities, and the results of past certification or oversight activities, and shall base it on the assessment of the associated risks. The oversight programme shall include audits, which shall:
  - (1) cover all the areas of potential concern, with a focus on those areas where problems have been identified in the past;
  - (2) cover all the organisations, certificates and declarations under the Agency's oversight;
  - (3) cover the means implemented by the organisations to ensure the competence of their personnel;
  - (4) ensure that audits are conducted in a manner commensurate with the level of the risk posed by the organisation's activities;

- (5) ensure that for organisations under its supervision, an oversight planning cycle not exceeding 24 months is applied.

The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

The oversight planning cycle may be extended to a maximum of 36 months if the Agency has established that during the previous 24 months:

- (i) the organisation has continuously demonstrated compliance with the change management requirements under point [DPO.OR.B.005](#);
- (ii) no level 1 findings referred to in [DPO.AR.C.015](#) have been issued;
- (iii) all corrective actions referred to in [DPO.AR.C.015](#) have been implemented within the time period accepted or extended by the Agency as defined in point [DPO.AR.C.015](#).

If, in addition to points (i), (ii) and (iii), the organisation has established an effective continuous reporting system to the Agency as regards its regulatory compliance, which has been approved, the oversight planning cycle may be extended to a maximum of 48 months;

- (6) ensure the follow-up of the implementation of corrective actions referred to in [DPO.AR.C.015](#);
  - (7) be subject to consultation with the organisations concerned and thereafter its notification;
  - (8) indicate the planned intervals of the inspections of the different sites, if necessary.
- (b) The Agency may decide to modify the objectives and the scope of the preplanned audits, including documentary reviews and additional audits, wherever that need arises.
  - (c) The Agency shall decide which arrangements, elements, physical locations, and activities are to be audited within a specified time frame.
  - (d) Audit observations and findings issued in accordance with point [DPO.AR.C.015](#) shall be documented.
  - (e) The findings shall be supported by evidence and identified in terms of applicable requirements and their implementation arrangements against which the audit has been conducted.
  - (f) An audit report, including the details of findings and observations, shall be prepared and communicated to the organisation concerned.



## **DPO.AR.C.010 Changes to the information security management system**

*Regulation (EU) 2023/1769*

- (a) For changes managed and notified to the Agency in accordance with the procedure set out in point IS.I.OR.255(a) of Annex II (Part-IS.I.OR) to Implementing Regulation (EU) 2023/203, the Agency shall include the review of such changes in its continuing oversight programme in accordance with the principles laid down in point [DPO.AR.C.005](#) of this Annex. If any non-compliance is found, the Agency shall notify the organisation thereof, request further changes and act in accordance with point [DPO.AR.C.015](#) of this Annex.
- (b) With regard to other changes requiring an application for approval in accordance with point IS.I.OR.255(b) of Annex II (Part-IS.I.OR) to Implementing Regulation (EU) 2023/203:
  - (1) upon receiving the application for the change, the Agency shall check the organisation's compliance with the applicable requirements before issuing the approval;
  - (2) the Agency shall establish the conditions under which the organisation may operate during the implementation of the change;
  - (3) if it is satisfied that the organisation complies with the applicable requirements, the Agency shall approve the change.

## **DPO.AR.C.015 Findings, corrective actions, and enforcement measures**

*Regulation (EU) 2023/1769*

- (a) When the Agency, during investigation, oversight or by any other means, identifies any non-compliance with the applicable requirements of this Regulation of a procedure or manual required by this Regulation, or of a certificate or declaration issued in accordance with this Regulation, it shall, without prejudice to any additional action required by Regulation (EU) 2018/1139, raise a finding.
- (b) The Agency shall have a system in place to:
  - (1) analyse findings for their safety and interoperability significance;
  - (2) identify appropriate enforcement measures, including the suspension or revocation of approvals and certificates;
  - (3) issue directives on the basis of the risk posed by the organisation's non-compliance.
- (c) A level 1 finding shall be raised by the Agency when it identifies any significant non-compliance with the ATM/ANS certification basis as per point [ATM/ANS.EQMT.AR.B.001](#) of [Annex I](#) to Delegated Regulation (EU) 2023/1768 that may lead to uncontrolled non-compliance and to a potential unwanted condition.

Level 1 findings shall include but are not limited to:

- (1) the promulgation of operational procedures which introduce a significant risk to the organisation's activities;
- (2) the obtainment or maintenance of the validity of the organisation's approval through the submission of falsified documentary evidence;
- (3) evidence of malpractice or fraudulent use of the organisation's approval;

- (4) the lack of an accountable manager.
- (d) A level 2 finding shall be raised by the Agency where non-compliance with any of the following is identified:
- (i) with the applicable requirements of Regulation (EU) 2018/1139;
  - (ii) with the delegated and implementing acts adopted on the basis of Regulation (EU) 2018/1139;
  - (iii) with the procedures and manuals required by Regulation (EU) 2018/1139; or
  - (iv) with the approval issued in accordance with Regulation (EU) 2018/1139, which is not classified as a level 1 finding.
- (e) Where a finding is raised, the Agency shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis, communicate the finding in writing to the organisation concerned and require it to take corrective action to address the non-compliance(s) identified.
- (1) In the case of level 1 findings, the Agency shall immediately take appropriate enforcement measures and may, if appropriate, limit, suspend or revoke in whole or in part the approval until successful corrective action has been taken by the organisation.
  - (2) In the case of level 2 findings, the Agency shall:
    - (i) grant the organisation a corrective action implementation period, as part of an action plan, appropriate to the nature of the finding;
    - (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 2 findings, where the organisation fails to submit a corrective action plan that is acceptable to the Agency in the light of the finding, or where the organisation fails to perform the corrective action within the period of time accepted or extended by the Agency, the finding may be raised to a level 1 finding and action shall be taken in accordance with point (e)(1).
- (f) For those cases where level 1 and level 2 findings are not required, the Agency may issue observations.
- (g) The Agency shall:
- (1) suspend a certificate if it considers that there are reasonable grounds that such action is necessary to prevent a credible threat to the safety, security, performance or interoperability of ATM/ANS equipment;
  - (2) issue an ATM/ANS equipment directive under the conditions of point [ATM/ANS.EQMT.AR.A.030](#) of [Annex I](#) to Delegated Regulation (EU) 2023/1768;
  - (3) suspend, revoke or limit a certificate if such action is required in accordance with point (c);
  - (4) take immediate and appropriate action that is necessary to limit or prohibit the activities of an organisation or a natural or legal person if it considers that there are reasonable grounds that such action is necessary to prevent a credible threat to ATM/ANS equipment;

- (5) register a declaration of design compliance only after all the findings from the initial oversight investigation have been resolved;
  - (6) temporarily or permanently deregister a declaration of design compliance if it considers that there are reasonable grounds that such action is necessary to prevent a credible threat to the safety, security, performance or interoperability of ATM/ANS equipment;
  - (7) take any further enforcement measures which are necessary to ensure that any non-compliance with the essential requirements of Annex VIII and, if applicable, Annex VII to Regulation (EU) 2018/1139 and with this Annex, is rectified and, where necessary, mitigate its consequences.
- (h) Upon taking enforcement measures in accordance with point (g), the Agency shall notify them to the addressee, state the reasons for them, and inform the addressee of its right to appeal.

## **Appendix 1 - SPECIFICATIONS OF THE APPROVAL OF AN ORGANISATION INVOLVED IN THE DESIGN OR PRODUCTION OF ATM/ANS EQUIPMENT**

*Regulation (EU) 2023/1769*

The approval shall specify:

- (a) the Agency as the competent authority that issues the approval;
- (b) the applicant's name and postal address;
- (c) the applicant's scope of work;
- (d) the location where the activities are to be performed;
- (e) the associated privileges for which the applicant has been approved;
- (f) a statement of the applicant's conformity and compliance with the applicable requirements;
- (g) the date of issue and the validity of the approval;
- (h) the additional conditions or limitations attached to it.

# ANNEX II - REQUIREMENTS FOR ORGANISATIONS INVOLVED IN THE DESIGN OR PRODUCTION OF ATM/ANS EQUIPMENT - (PART-DPO.OR)

## SUBPART A - GENERAL REQUIREMENTS (DPO.OR.A)

### DPO.OR.A.001 Scope

Regulation (EU) 2023/1769

This Annex establishes the common requirements as regards the rights and obligations of an applicant for, and a holder of, an organisation approval for the design or production of ATM/ANS equipment.

### DPO.OR.A.005 Eligibility

Regulation (EU) 2023/1769

Any natural or legal person who has demonstrated, or is set to demonstrate, their capability to design or produce ATM/ANS equipment in accordance with point [DPO.OR.A.010](#), may apply for a design or production organisation approval under the conditions laid down in this Annex.

### DPO.OR.A.010 Application for a design or production organisation approval and demonstration of capability

Regulation (EU) 2023/1769

- (a) An application for a design or production organisation approval shall be made in a form and manner established by the Agency.
- (b) In order to obtain an approval, an organisation involved in the design or production of ATM/ANS equipment shall comply with the requirements set out in this Regulation where those requirements are applicable to the design or production of ATM/ANS systems and ATM/ANS constituents that the organisation performs or intends to perform.

### AMC1 DPO.OR.A.010(a) Application for a design or production organisation approval and demonstration of capability

ED Decision 2024/002/R

#### FORM

The dedicated EASA application form (FO.AOA.00085) should be obtained from the EASA website<sup>1</sup> and completed and signed by the accountable manager of the design or production organisation (DPO). The completed form should be submitted to EASA, accompanied by a copy of the organisation exposition and the company's registration, in accordance with the instructions included in the form.

<sup>1</sup> <https://www.easa.europa.eu/en/document-library/application-forms/foaoa00085>

## **DPO.OR.A.015 Organisation exposition**

*Regulation (EU) 2023/1769*

- (a) An organisation involved in the design or production of ATM/ANS equipment shall establish and maintain an organisation exposition, which provides the following information:
- (1) a statement signed by the accountable manager confirming that the organisation exposition and any associated manuals, which define the organisation's compliance with the requirements will be complied with at all times;
  - (2) the title(s) and name(s) of the key manager(s) as referred to in point [DPO.OR.B.020](#);
  - (3) the duties and responsibilities of the manager(s), including matters for which they may deal directly with the Agency on behalf of the organisation;
  - (4) an organisational chart showing lines of responsibility and accountability of the managers throughout the organisation, including a direct accountability of the accountable manager;
  - (5) a general description of the organisation's manpower resources;
  - (6) a general description of the facilities located at each location specified in the organisation's approval;
  - (7) a general description of the organisation's scope of work relevant to the terms of approval;
  - (8) the procedure(s) for the verification and demonstration that the design of ATM/ANS equipment, or changes to it, complies with the applicable detailed specifications and requirements as established by Delegated Regulation (EU) 2023/1768 and has no unsafe or insecure features, as applicable;
  - (9) the procedure for the preparation and maintenance of the technical data and records, for each model of each piece of ATM/ANS equipment for which a certificate or declaration of design compliance has been issued in accordance with Delegated Regulation (EU) 2023/1768, as applicable;
  - (10) the procedure(s) for the notification of organisational changes to the Agency;
  - (11) the amendment procedure for the organisation's exposition;
  - (12) a description, direct or by cross reference, of the organisation's management system and procedure(s);
  - (13) a description, direct or by cross reference, of the contractors' management and procedure(s) of supervision referred to in point [DPO.OR.B.015](#) of this Annex.
- (b) The organisation exposition shall be amended as necessary to remain an up-to-date description of the organisation, and a copy of it, including its amendments, shall be supplied to the Agency.
- (c) An application for a change approval referred to in point [DPO.OR.B.005](#) of this Annex shall be based on the submission of the proposed changes to the organisation exposition.

## **DPO.OR.A.025 Duration, continued validity and privileges of an organisation approval**

*Regulation (EU) 2023/1769*

- (a) An organisation's approval shall remain valid for an unlimited period of time provided that:
  - (1) the organisation remains compliant with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis;
  - (2) the approval has not been surrendered by the organisation or suspended or revoked by the Agency.
- (b) Upon revocation or surrender of the approval, if issued in a paper format, it shall be returned to the Agency without delay.
- (c) The holder of an organisation approval shall be entitled, within the scope of its terms of approval and under the relevant procedures of the design management system:
  - (1) to classify changes to an ATM/ANS equipment as 'major' or 'minor';
  - (2) to approve minor changes to an ATM/ANS equipment certificate(s) and/or declaration(s) issued under Delegated Regulation (EU) 2023/1768;
  - (3) to approve certain major changes to an ATM/ANS equipment certificate issued under Delegated Regulation (EU) 2023/1768;
  - (4) to issue declarations of design compliance of ATM/ANS equipment pursuant to [Article 5](#) of Delegated Regulation (EU) 2023/1768; and
  - (5) to issue statements of compliance of ATM/ANS equipment pursuant to [Article 6](#) of Delegated Regulation (EU) 2023/1768.

## **DPO.OR.A.030 Facilitation and cooperation**

*Regulation (EU) 2023/1769*

- (a) An organisation involved in the design or production of ATM/ANS equipment shall facilitate the inspections and audits performed by the Agency or by a qualified entity that acts on its behalf, and it shall cooperate as necessary for the efficient and effective exercise of the powers of the Agency.
- (b) An organisation involved in the design or production of ATM/ANS equipment shall cooperate with and support the ATM/ANS providers using its ATM/ANS equipment in their compliance demonstration process to the competent authorities concerned.

## **DPO.OR.A.035 Findings and corrective actions**

*Regulation (EU) 2023/1769*

Following the receipt of the notification of findings from the Agency, the organisation involved in the design or production of ATM/ANS equipment shall:

- (a) identify the root cause of the non-compliance;
- (b) define a corrective action plan;

- (c) demonstrate the implementation of the corrective action to the satisfaction of the Agency within the time period proposed and approved by the Agency, as defined in point (e)(2) of point [DPO.AR.C.015](#).

## **DPO.OR.A.040 Immediate reaction to a safety, security and interoperability problem**

*Regulation (EU) 2023/1769*

An organisation involved in the design or production of ATM/ANS equipment shall implement any safety and security measures, including ATM/ANS equipment directives, taken by the Agency in accordance with points [DPO.AR.A.010](#) and [DPO.AR.A.015](#).

## **DPO.OR.A.045 Failures, malfunctions, and defects**

*Regulation (EU) 2023/1769*

- (a) The holder of an approval issued in accordance with this Regulation shall:
- (1) establish and maintain a system for collecting, investigating and analysing reports of and information on failures, malfunctions, defects or other occurrences which have caused or might cause adverse effects on the continuing compliance of the ATM/ANS equipment with the applicable requirements;
  - (2) inform all known users of the ATM/ANS equipment concerned and, on request, any person mandated under other associated regulations, about the system established in accordance with point (1) and about how to provide such reports of and information on failures, malfunctions, defects or other occurrences.
- (b) For organisations that have their principal place of business in a Member State, the system established in accordance with point (a)(1) shall include provisions for occurrence reporting and follow-up that meet the requirements of Regulations (EU) No 376/2014 and (EU) No 2018/1139 and the delegated and implementing acts adopted on their basis.
- (c) The approval holder shall report to the Agency any failure, malfunction, defect or other occurrence of which it is aware, and which has resulted or may result in an unsafe, insecure, or under-performing condition.
- (d) For approval holders that do not have their principal place of business in a Member State, reports shall be made in a form and manner established by the Agency, as soon as practicable and in any case submitted not later than 72 hours after the person or organisation has become aware of the particular occurrence, unless exceptional circumstances prevent this.
- (e) The approval holder shall investigate an occurrence that has been reported under point (c), including the deficiencies that have led to that occurrence, and report to the Agency the results of its investigation and any action it intends to take or proposes to take to correct these deficiencies.



## **AMC1 DPO.OR.A.045(a)(1) Failures, malfunctions, and defects**

*ED Decision 2024/002/R*

### **COLLECTION, INVESTIGATION AND ANALYSIS OF OCCURRENCES**

The ‘collection’, ‘investigation’ and ‘analysis’ functions of the DPO’s reporting system should include means to:

- analyse occurrences, and related available information;
- identify adverse trends;
- investigate associated root cause(s); and
- establish any necessary corrective action(s).

## **GM1 DPO.OR.A.045(a)(1) Failures, malfunctions, and defects**

*ED Decision 2024/002/R*

### **COLLECTION FUNCTION**

The word ‘collection’ refers to the setting up of procedures which will enable relevant failures, malfunctions and defects or other occurrences to be properly collected when they occur.

As the collection system needs to accept reports that originate outside the organisation (from ATM/ANS providers, suppliers, etc.), it is necessary to inform possible reporters of the existence of the DPO’s reporting system and the appropriate means to submit reports into it. This does not presume that direct access to the system is to be granted if other mechanisms are more appropriate.

## **GM1 DPO.OR.A.045(c) Failures, malfunctions, and defects**

*ED Decision 2024/002/R*

### **REPORTING TO EASA**

The reporting process could include:

- a description of the applicable requirements for the reporting;
- a description of the reporting mechanism, including forms, means and deadlines;
- the personnel responsible for reporting.

## **GM1 DPO.OR.A.045(c);(d) Failures, malfunctions and defects**

*ED Decision 2024/002/R*

### **REPORTING TO EASA — ‘AWARE’**

The reference to being ‘aware’ of an occurrence implies that the organisation identifies the event as one that falls into the category of occurrences to be reported. The 72-hour period starts when the possible unsafe condition is identified by the DPO.

## AMC1 DPO.OR.A.045(e) Failures, malfunctions and defects

*ED Decision 2024/002/R*

### FOLLOW-UP AND CLOSURE OF REPORTED OCCURRENCES

- (a) The organisation should transmit the following information to EASA within 30 days from the date of notification of the occurrence to EASA:
- (1) the latest position of the organisation responsible for design as to whether an unsafe, insecure or under-performing condition is confirmed;
  - (2) the results of the occurrence analysis and of the first investigation — including the cause(s) of the occurrence and missing information, if known; and
  - (3) the measures it has taken, intends to take or proposes to take, including an assessment evaluating whether the product can be operated safely until the corrective action is defined and implemented, or that immediate mitigation measures need to be implemented until a more refined assessment can be provided.
- (b) The final (close-out) report, as soon as available and, in principle, no later than 3 months after the occurrence notification, should include:
- the final position of the organisation involved in the design as to whether an unsafe, insecure or under-performing condition exists;
  - the results of the occurrence analysis and of the final investigation — including the cause(s) of the occurrence and missing information;
  - any corrective and preventive measures taken by the reporting organisation; and
  - an assessment evaluating whether these corrective and preventive measures allow the product to be operated as intended.
- (c) Notwithstanding point (a), when the organisation identifies that no unsafe, insecure or under-performing condition exists as a result of their analysis of a voluntarily reported occurrence, it can delay further communication to EASA up to the issuance of the final report and report the occurrence as closed upon issue (data exchange). In such cases, no follow-up report should be submitted. The final report to EASA should include confirmation and justification that no unsafe, insecure or under-performing condition exists. The organisation is requested to provide information on the cause(s) of the occurrence and on the corrective or preventive measures that were taken by the organisation.

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

## DPO.OR.A.050 Approval transferability

*Regulation (EU) 2023/1769*

An organisation approval is not transferable, except as a result of a change in the ownership of the organisation.

## SUBPART B - MANAGEMENT (DPO.OR.B)

### DPO.OR.B.001 Management system

*Regulation (EU) 2023/1769*

- (a) An organisation involved in the design or production of ATM/ANS equipment shall implement and maintain a management system that includes the following:
- (1) clearly defined lines of responsibility and accountability throughout its organisation, including direct accountability of the accountable manager;
  - (2) a description of the overall philosophy and principles of the organisation, collectively constituting a policy, signed by the accountable manager;
  - (3) the means to verify the performance of the organisation in the light of the performance indicators and performance targets of the management system;
  - (4) a process to identify changes within the organisation and the context in which it operates, which may affect established processes, procedures and products and, where necessary, change the management system to accommodate those changes;
  - (5) a process to identify the scope of changes to the ATM/ANS equipment and the associated risk;
  - (6) a process to review the management system, identify the causes of substandard performance of the management system, determine the implications of such substandard performance, and eliminate or mitigate such causes;
  - (7) a process to ensure that the personnel of the organisation are trained and competent to perform their duties in a safe, efficient, continuous and sustainable manner; in this context, the organisation shall establish policies for the recruitment and training of its personnel;
  - (8) a formal means for communication which ensures that all personnel of the organisation are fully aware of the management system that allows critical information to be communicated and that makes it possible to explain why particular actions are taken and why procedures are introduced or changed;
  - (9) as regards design activities, procedures for:
    - (i) the design of ATM/ANS equipment, and for changes to its design;
    - (ii) the assurance that the design of ATM/ANS equipment, or the changes to its design, comply with the applicable specifications, including independent checking function of the demonstration of compliance on the basis of which the organisation submits compliance statements and associated documentation to the Agency;
    - (iii) the verification of the acceptability of the elements of the ATM/ANS equipment designed, or the tasks performed, by the contracted organisations referred to in point [DPO.OR.B.015](#);
    - (iv) the assurance that staff involved in the design of ATM/ANS equipment are of sufficient numbers and are trained and competent, and have been authorised to discharge their allocated responsibilities;

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- (v) close and efficient coordination between departments and within departments;
- (10) as regards production activities, procedures for:
- (i) the issue and approval of documents, or changes to them;
  - (ii) assessment audits and the control of contracted organisations referred to in point [DPO.OR.B.015](#);
  - (iii) verifying that incoming materials and equipment, including the supply of new items or items used by ATM/ANS equipment buyers, are as specified in the applicable design data;
  - (iv) verifying that ATM/ANS equipment conforms to the applicable design data;
  - (v) identification and traceability;
  - (vi) organisation processes;
  - (vii) inspection and testing;
  - (viii) calibration of tools and test equipment;
  - (ix) the control of non-conforming items;
  - (x) the coordination with the applicant for, or holder of, the design approval;
  - (xi) the completion and retention of records of work carried out;
  - (xii) the issue of release documents;
  - (xiii) the handling, storage and packing of ATM/ANS equipment.
- (b) An organisation involved in the design or production of ATM/ANS equipment shall document all key management system processes, including a process for making personnel aware of their responsibilities, and the procedure for amending those processes.
- (c) An organisation involved in the design or production of ATM/ANS equipment shall establish a function within its management system to monitor its compliance with the applicable requirements and the adequacy of the established procedures. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure the effective implementation of corrective actions, as necessary.
- (d) The management system shall be proportionate to the size of the organisation involved in the design or production of ATM/ANS equipment and the complexity of its activities, taking into account the hazards and associated risks inherent in those activities.
- (e) In addition to the management system referred to in point (a), the organisation involved in the design or production of ATM/ANS equipment shall establish, implement and maintain an information security management system in accordance with Implementing Regulation (EU) 2023/203 in order to ensure the proper management of information security risks which may have an impact on aviation safety.

## GM1 DPO.OR.B.001 Management system

*ED Decision 2024/002/R*

### QUALITY MANAGEMENT ELEMENTS OF THE MANAGEMENT SYSTEM — ISO 9001 CERTIFICATE

An ISO 9001 certificate, relevant to the scope of the approval being requested, issued by an appropriately accredited organisation, covers some quality management elements of the management system, but it does not address other system engineering and safety processes required by this Regulation. EASA may accept ISO 9001 certificates as evidence during compliance investigations for those elements covered. Other elements required by this Regulation in reference to the management system that are not covered by the ISO 9001 certificate issued by an appropriately accredited organisation will be subject to oversight by EASA.

## GM1 DPO.OR.B.001(a) Management system

*ED Decision 2024/002/R*

The management system should include:

- (a) an organisational structure to:
  - (1) control the design, including demonstration of compliance with the applicable detailed specifications;
  - (2) independently check demonstrations of compliance;
  - (3) liaise with EASA;
  - (4) continuously evaluate the organisation;
  - (5) manage contracted activities;
- (b) procedures and responsibilities associated with the functions listed above, taking due account of the requirements applicable to design and approval of changes to ATM/ANS equipment design.

## AMC1 DPO.OR.B.001(c) Management system

*ED Decision 2024/002/R*

### COMPLIANCE MONITORING

- (a) The monitoring of compliance of the management system with the applicable requirements and the adequacy of the established procedures should be performed by systematic means. These systematic means of compliance monitoring may include structured experience exchanges, regular design meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, or other similar means.
- (b) Audits should be one element of compliance monitoring. When implemented, audits should be conducted as combined process/product (project) audits that focus on the implemented key processes or methods practised. In addition, audits should also allow the design or production organisation to find ways to become more efficient by continuous improvement.

## DPO.OR.B.005 Change management

*Regulation (EU) 2023/1769*

- (a) Following the issue of an organisation's approval, any change to the management system that is significant shall be approved by the Agency before being implemented unless such a change is notified and managed in accordance with a procedure approved by the Agency. The organisation shall submit to the Agency an application for approval demonstrating continuous compliance with the applicable requirements.
- (b) Each change to ATM/ANS equipment shall be notified to and approved by the Agency before being implemented unless such a change is managed in accordance with a change management procedure approved by the Agency. This change management procedure shall define the classification of the changes to the ATM/ANS equipment and describe how such changes will be notified and managed.

## AMC1 DPO.OR.B.005(b) Change management

*ED Decision 2024/002/R*

### PROCEDURE TO MANAGE CHANGES TO ATM/ANS EQUIPMENT

- (a) A procedure should be established for the classification and approval of design changes to the ATM/ANS equipment. The procedure should define criteria for classifying a change as minor or major, taking into account points [ATM/ANS.EQMT.CERT.020](#) and [ATM/ANS.EQMT.DEC.020](#) of Delegated Regulation (EU) 2023/1768, and the following key aspects:
- (b) The change is classified as major when:
  - (1) the change includes one of the following evolutions:
    - (i) new concept of operation of the equipment;
    - (ii) new technologies or techniques used in the ATM/ANS equipment development (e.g. used in design or verification);
    - (iii) changes to the ATM/ANS equipment that could significantly impact its functions and its reverification;
    - (iv) changes to the software that significantly impact a software function and induce subsequent reverification and reinvestigation;
    - (v) changes to the hardware that significantly impact a hardware function and induce subsequent reverification and reinvestigation; or
    - (vi) modified ATM/ANS equipment architecture
  - (2) the change introduces the need to add requirements to or remove requirements from:
    - (i) the previously approved certification basis (for ATM/ANS equipment subject to certification); or
    - (ii) the detailed specifications referred to in the declaration (for ATM/ANS equipment subject to declaration of design compliance); for instance, addition or removal of a function addressed in the detailed specifications;

- (3) the change introduces a new limitation to or a new deviation from:
    - (i) the previously approved certification basis (for ATM/ANS equipment subject to certification); or
    - (ii) the detailed specifications referred to in the declaration (for ATM/ANS equipment subject to declaration of design compliance); and
  - (4) the change introduces a new or modified means of compliance used by the DPO, not previously investigated by EASA, to demonstrate compliance with the certification basis (for ATM/ANS equipment subject to certification) or with detailed specifications referred to in the declaration (for ATM/ANS equipment subject to declaration of design compliance).
- (c) The procedure for change management should be defined in coordination with the procedure for configuration of the ATM/ANS equipment, i.e. the part numbering system of DPO equipment should incorporate how minor changes will be reflected in the configuration of the equipment, and more particularly in the part number structure. In the case of a major change, a new model designation / part number may need to be defined.
- (d) Minor changes should be processed in accordance with the privileges of the approved DPO. For minor changes, the approved DPO should:
- (1) record the change description and the justification for the change classification;
  - (2) update all related technical documents including the user manual;
  - (3) record continuous compliance with the ATM/ANS equipment certificate or ATM/ANS equipment declaration of design compliance;
  - (4) notify EASA of the minor changes. When the change is managed in accordance with the change management procedure approved by EASA, the notification can be sent after the change is introduced.
- (e) Major changes should be notified to EASA prior to their introduction by submission of one of the following:
- (1) an application for the issue of a new certificate, in accordance with point [ATM/ANS.EQMT.CERT.020](#) of Implementing Regulation (EU) 2023/1768, for ATM/ANS equipment subject to [Article 4](#) of that Regulation; or
  - (2) a new declaration of design compliance, in accordance with point [ATM/ANS.EQMT.DEC.020](#)(b) of Implementing Regulation (EU) 2023/1768, for ATM/ANS equipment subject to [Article 5](#) of that Regulation.

## GM1 DPO.OR.B.005(b) Change management

*ED Decision 2024/002/R*

### GENERAL

When performing changes to ATM/ANS equipment, a change impact analysis is performed to assess and document the impact of the change on the requirements, design, verification and its associated life cycle data, used for demonstration of compliance.

The communication regarding major changes to ATM/ANS equipment will indicate:

- (a) the description of the change;
- (b) the impact on the equipment and its associated life cycle data for demonstration of compliance;
- (c) the impact on the demonstration of compliance with the EASA applicable detailed specifications and certification basis, identifying in particular:
  - (1) the compliance demonstration with any new detailed specifications, not subject to the initial certificate or declaration;
  - (2) any new limitations;
  - (3) any new deviations;
  - (4) changes in the means of compliance with the applicable detailed specifications; and
- (d) the proposed EASA level of involvement, in the case of ATM/ANS equipment subject to certification.

## GM2 DPO.OR.B.005(b) Change management

*ED Decision 2024/002/R*

### REACTION BY THE DPO TO AN UNPLANNED (MAJOR) CHANGE

The procedure may also include the process for the reaction by the DPO to an unplanned (major) change that may arise with the need for urgent action that would normally require prior approval by the Agency.

## GM3 DPO.OR.B.005(b) Change Management

*ED Decision 2024/002/R*

### CASES IN WHICH THE DPO REACTS TO AN UNPLANNED (MAJOR) CHANGE

The cases in which the DPO reacts to an unplanned (major) change usually are when the DPO responds immediately to a safety, security or interoperability problem or when an emergency situation arises in which the DPO has to take immediate action (e.g. security patches) to ensure the safety, security or interoperability of its equipment in operation.

## DPO.OR.B.010 Facility requirements

*Regulation (EU) 2023/1769*

An organisation involved in the design or production of ATM/ANS equipment shall ensure that its facilities and equipment, including testing facilities and equipment, are adequate and suitable to perform and manage all its tasks and activities in accordance with the applicable requirements.



## **DPO.OR.B.015 Contracted activities**

*Regulation (EU) 2023/1769*

- (a) Contracted activities include all those activities that are within the scope of the organisation's activities, in accordance with the terms of the certificate, which are performed by other organisations either themselves certified to carry out such activities or, if not certified, working under such an organisation's supervision. An organisation involved in the design or production of ATM/ANS equipment shall ensure that when it contracts any part of its activities to, or when it purchases any part of its activities from, external organisations, the contracted or purchased activity, as applicable, conforms with the applicable requirements.
- (b) When an organisation involved in the design or production of ATM/ANS equipment contracts any part of its activities to an organisation that is not itself certified in accordance with this Regulation to carry out such activities, it shall ensure that the contracted organisation works under its supervision. An organisation involved in the design or production of ATM/ANS equipment shall ensure that the Agency is given access to the contracted organisation to determine its continued compliance with the applicable requirements of this Regulation.

## **AMC1 DPO.OR.B.015 Contracted activities**

*ED Decision 2024/002/R*

### **DPO RESPONSIBILITY WHEN CONTRACTING ACTIVITIES**

- (a) A DPO, responsible for ensuring that the design of the ATM/ANS equipment complies with the applicable certification basis requirements or detailed specifications used for the declaration of design compliance, as applicable, should ensure that components designed, or tasks performed, by external parties are acceptable. To discharge this responsibility, the DPO should implement documented methods that ensure the compliance of the finished (ready to be delivered) ATM/ANS equipment, and that make use of these components or task results, prior to issuing the final EASA release form.
- (b) As the responsibility for verification of compliance remains with the DPO, no specific qualification measures are required other than to pragmatically verify the capabilities of the external party, and to ensure that the required level of detail is met to enable the task results to be adequately verified.
- (c) If a DPO subcontracts the compliance monitoring function to an external party that conducts the task, but does not hold its own DPO approval, then the same requirements for the qualification, nomination and documentation apply to the person who is nominated and indicated in the DPO handbook of the contracting DPO.
- (d) Alternatively, if an organisation with a DPO approval obtains design substantiation data from a subcontractor that also holds a DPO approval, and the work that is conducted is within the approved scope of this subcontractor DPO, the subcontractor's design data becomes acceptable when the contracting DPO has verified that the results adequately meet the needs of the ATM/ANS equipment under development. Additional formal compliance verification by the contracting DPO is not required if the person responsible for compliance verification of the contracted DPO signs and approves the document under its DPO approval.

## AMC2 DPO.OR.B.015 Contracted activities

*ED Decision 2024/002/R*

### RESPONSIBILITY WHEN CONTRACTING ACTIVITIES

- (a) A contract should exist between the DPO and the contracted organisation clearly defining the contracted activities and the applicable requirements.
- (b) The contracted activities, performed by an organisation that is not itself approved in accordance with this Regulation to carry out such activity, should be included in the DPO's oversight process.
- (c) A DPO should ensure that the contracted organisation has the necessary authorisation, declaration or approval when required, and commands the resources and competence to undertake the task.

## GM1 DPO.OR.B.015 Contracted activities

*ED Decision 2024/002/R*

### RESPONSIBILITY WHEN CONTRACTING ACTIVITIES

Regardless of the approval status of the contracted organisation, the DPO is responsible for ensuring that all contracted activities are subject to compliance monitoring.

## DPO.OR.B.020 Personnel requirements

*Regulation (EU) 2023/1769*

- (a) An organisation involved in the design or production of ATM/ANS equipment shall appoint an accountable manager who has the authority to ensure that all activities may be financed and carried out in accordance with the applicable requirements of this Regulation. The accountable manager shall be responsible for establishing and maintaining an effective management system.
- (b) The authority, duties, and responsibilities of the nominated post-holders, in particular management personnel in charge of safety, quality, security, finance and human-resources, shall also be defined.

## DPO.OR.B.025 Record-keeping

*Regulation (EU) 2023/1769*

- (a) An organisation involved in the design or production of ATM/ANS equipment shall establish a record-keeping system that allows for the adequate storage of records and the reliable traceability of all its activities, covering in particular all the elements indicated in point [DPO.OR.B.001](#).
- (b) The format and the retention period of the records referred to in point (a) shall be specified in the organisation's management system procedures.
- (c) Records shall be stored in a manner that ensures their protection against damage, alteration, and theft.
- (d) An organisation involved in the design or production of ATM/ANS equipment shall maintain a register of the ATM/ANS equipment deployed.

## SUBPART C - TECHNICAL REQUIREMENTS (DPO.OR.C)

### DPO.OR.C.001 Organisations involved in the design or production of ATM/ANS equipment

*Regulation (EU) 2023/1769*

- (a) An applicant for, and a holder of, a design or production organisation approval for ATM/ANS equipment shall be entitled, as applicable, to any of the following:
- (1) hold or apply to be issued a certificate for the design of ATM/ANS equipment;
  - (2) issue a declaration of design compliance for ATM/ANS equipment;
  - (3) issue a statement of compliance for ATM/ANS equipment, upon request of an ATM/ANS provider.
- (b) As regards design activities, an organisation involved in the design or production of ATM/ANS equipment shall:
- (1) issue a declaration of design compliance for the ATM/ANS equipment, as applicable;
  - (2) issue data and information, including instructions, under its responsibility within the scope of its terms of approval as established by the Agency;
  - (3) prepare and maintain, for each model of each piece for which an ATM/ANS equipment declaration has been issued, an up-to-date file of complete technical data and records.
- (c) As regards production activities, an organisation involved in the design or production of ATM/ANS equipment shall:
- (1) manufacture each article ensuring that the completed ATM/ANS equipment conforms to its design data and is safe for installation;
  - (2) prepare and maintain, for each model of each piece for which an ATM/ANS equipment declaration has been issued, an up-to-date file of complete technical data and records;
  - (3) prepare, maintain and update the master copies of all manuals required by the applicable declaration specifications for the particular equipment;
  - (4) make available to the users of the ATM/ANS equipment, and to the Agency on request, those instructions for continued suitability necessary for the use and maintenance of the ATM/ANS equipment, and changes to those instructions;
  - (5) mark each article;
  - (6) continue to comply with the applicable requirements laid down in this Regulation.
- (d) In addition to point (c), an organisation involved in the production of ATM/ANS equipment shall be entitled, within the scope of its terms of approval, to determine that each completed ATM/ANS equipment conforms with the applicable design data and is in a condition for safe operation before issuing an EASA release form stating that the ATM/ANS equipment has been produced in accordance with the applicable requirements of this Regulation and with the applicable design data.

- (e) The EASA release form referred to in point (d) for each ATM/ANS equipment manufactured shall contain at least the following information:
- (1) a description of the ATM/ANS equipment;
  - (2) the part number of the ATM/ANS equipment;
  - (3) the serial number of the ATM/ANS equipment;
  - (4) a statement that the ATM/ANS equipment has been manufactured in conformity with the applicable design data and is in a condition for safe operation;
  - (5) a reference to the certificate or declaration of design compliance.

### **AMC1 DPO.OR.C.001(b) Organisations involved in the design or production of ATM/ANS equipment**

*ED Decision 2024/002/R*

#### **DESIGN ACTIVITIES**

- (a) Specifying, developing, and testing the ATM/ANS equipment before production should be considered design activities.
- (b) When components designed by contracted organisations are integrated into the ATM/ANS equipment, design activities by the DPO should also include the requirements specification (functional, performance, interfaces, adaptation) of these components at the level of their integration and corresponding verifications to ensure the overall compliance.

### **AMC1 DPO.OR.C.001(c) Organisations involved in the design or production of ATM/ANS equipment**

*ED Decision 2024/002/R*

#### **PRODUCTION ACTIVITIES**

The following should be considered production activities:

- (a) manufacturing/acquisition;
- (b) conformance to design data;
- (c) release process; and
- (d) delivery to customers.

## GM1 DPO.OR.C.001(c) Organisations involved in the design or production of ATM/ANS equipment

ED Decision 2024/002/R

### PRODUCTION ACTIVITIES

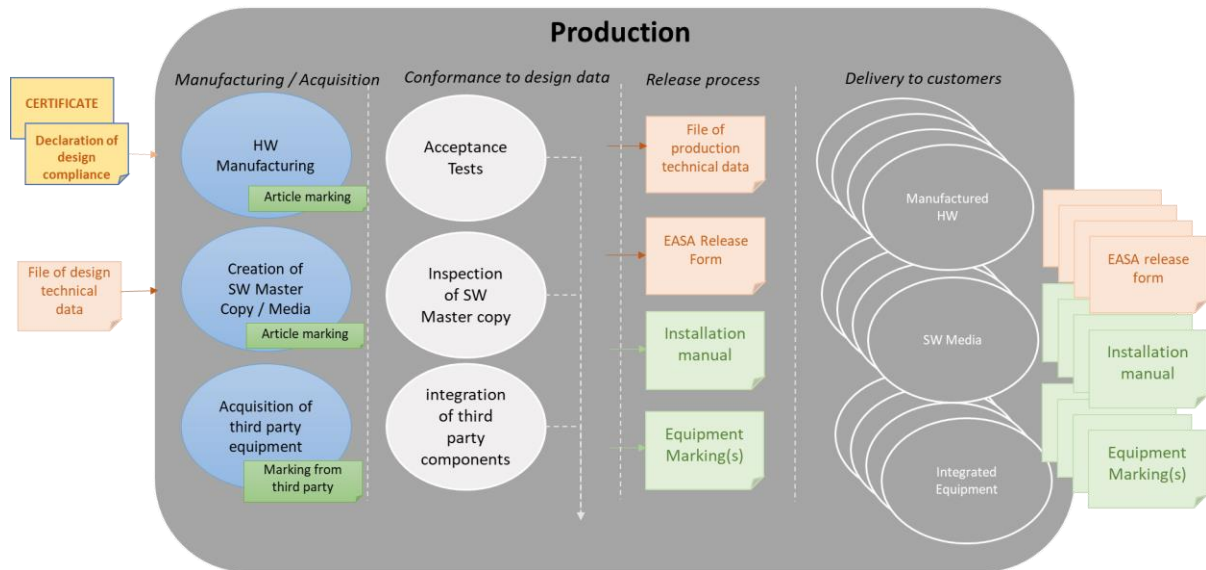


Figure 1 — Production activities

## AMC1 DPO.OR.C.001(d) Organisations involved in the design or production of ATM/ANS equipment

ED Decision 2024/002/R

### EASA RELEASE FORM

- (a) An EASA release form should be issued for ATM/ANS equipment produced by the DPO as per the organisation's scope of work relevant to the terms of approval.
- (b) Each organisation involved in the production of ATM/ANS equipment subject to conformity assessment under this Regulation should issue a statement of conformity regarding its production, using an EASA release form (see [AMC1 DPO.OR.C.001\(e\)](#)). This statement should be signed by an authorised person involved in the production of the ATM/ANS equipment.
- (c) An EASA release form should contain a statement that:
  - (1) the finished (ready to be delivered) ATM/ANS equipment conforms to the approved design data of the ATM/ANS equipment subject to certification or declaration in accordance with [Article 4](#) or [Article 5](#) of Delegated Regulation (EU) 2023/1768 respectively;
  - (2) the ATM/ANS equipment has been manufactured in compliance with Implementing Regulation (EU) 2023/1769.

## GM1 DPO.OR.C.001(d) Organisations involved in the design or production of ATM/ANS equipment

ED Decision 2024/002/R

### EASA RELEASE FORM

The term 'produced' should be considered as 'released' for ATM/ANS equipment that has a software component.

## AMC1 DPO.OR.C.001(e) Organisations involved in the design or production of ATM/ANS equipment

ED Decision 2024/002/R

### EASA RELEASE FORM | STANDARD FORM

ATM/ANS EQUIPMENT RELEASE FORM		
1. DPO reference	2. Statement ref No:	
3. ATM/ANS equipment serial number		
4. ATM/ANS equipment model name		
5. Part number	6. Certificate ref No: / Declaration ref No:	
7. Description of the ATM/ANS equipment		
8. Concessions		
9. Exemptions, waivers or derogations		
10. Remarks		
11. Statement of Conformity It is hereby certified that this ATM/ANS equipment conforms fully to the certificated design/the declaration of design compliance and to the items above in boxes 7, 8, 9 and 10. The ATM/ANS equipment is manufactured in compliance with Implementing Regulation (EU) 2023/1769.		
12. Signed	13. Name	14. Date (d/m/y)
15. DPO Approval Reference		

Block 1: The full name and the address of the location of the DPO that issues the statement. This block may be preprinted. Logos, etc. are permitted if the logo, etc. can be contained within the block.

Block 2: A unique form tracking number established by the numbering system/procedure of the DPO must be indicated.

Block 3: The serial number identification linked to a specific item assigned by the organisation involved in the production for control and traceability and product support purposes.

Block 4: The ATM/ANS equipment model name in full as specified in the certificate or declaration of design compliance.

Block 5: The part number identification of the ATM/ANS equipment, as it appears on the equipment marking, and on the certificate/declaration of design compliance.

Block 6: Reference to the certificate or declaration of design compliance reference numbers for the subject ATM/ANS equipment.

Block 7: Brief description of the ATM/ANS equipment, including its main functionalities.

Block 8: Unintentional differences from the approved design, referred to as 'concessions'.

Block 9: Only agreed<sup>1</sup> exemptions, waivers or derogations may be included here.

Block 10: Any statement, information, particular data or limitation which may affect the compliance of the ATM/ANS equipment. If there is no such information or data, state 'NONE'. List the design changes to the ATM/ANS equipment, under approved design data, and reference all the applicable ATM/ANS equipment directives (or equivalent) that have been applied on the equipment.

Block 11: The validity of the EASA release form is subject to the full completion of all the blocks on the form.

Block 12: The EASA release form is signed by an authorised person.

Block 13: The name of the person that signs the statement.

Block 14: The date on which the EASA release form is signed should be given.

Block 15: The EASA DPO approval reference should be quoted.

## **DPO.OR.C.005 Coordination**

*Regulation (EU) 2023/1769*

An organisation involved in the design or production of ATM/ANS equipment shall ensure:

- (a) the satisfactory coordination, with the appropriate arrangements, between design and production activities, as appropriate;
- (b) the satisfactory coordination with and proper support to the relevant ATM/ANS providers and aviation undertaking(s) as regards the continued suitability of the ATM/ANS equipment, as applicable.

## **DPO.OR.C.010 ATM/ANS equipment directives**

*Regulation (EU) 2023/1769*

When the Agency issues an ATM/ANS equipment directive, pursuant to point [ATM/ANS.EQMT.CERT.065](#) of [Annex II](#) to Delegated Regulation (EU) 2023/1768, the organisation involved in the design or production of ATM/ANS equipment shall:

- (a) propose an appropriate corrective action and submit it together with details to the Agency for approval;

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<sup>1</sup> 'agreed' refers to agreement between the approved DPO and EASA.

- (b) following the approval by the Agency of the proposal referred to in point (a), make available to all known users or owners of ATM/ANS equipment appropriate descriptive data and accomplishment instructions and, on request, to any person required to comply with the ATM/ANS equipment directive.



## DELEGATED REGULATION (EU) 2023/1768

### COVER REGULATION TO DELEGATED REGULATION (EU) 2023/1768

Commission Delegated Regulation (EU) (EU) 2023/1768 laying down detailed rules for the certification and declaration of air traffic management/air navigation services systems and air traffic management/air navigation services constituents

#### *Powers and recitals*

*Regulation (EU) 2023/1768*

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91<sup>1</sup>, and in particular Articles 47(1) and 62(13),

Whereas:

- (1) Regulation (EU) 2018/1139 establishes common essential requirements to provide for a high uniform level of civil aviation safety in the Union and to ensure that the integrity and safety-related performance of systems and constituents are fit for their intended purpose. The interoperability of the air traffic management/air navigation service (ATM/ANS) systems and ATM/ANS constituents should ensure the seamless operation of the European air traffic management network (EATMN).
- (2) Detailed specifications should be established to ensure compliance with the essential requirements; those detailed specifications should whenever possible rely on recognised industry standards from Standards Developing Organisations (SDOs) that reflect the state of the art and best design practices. The design and production of ATM/ANS systems and ATM/ANS constituents should be carried out with consideration given to requirements to issue certification and declarations of design compliance and in line with detailed specifications issued by the European Union Aviation Safety Agency ('the Agency').
- (3) It is appropriate to establish different attestation methods for assessing conformity with the requirements set out in an Annex to this Regulation and detailed specifications of ATM/ANS systems and ATM/ANS constituents. More stringent attestation methods should be used as regards the safe operation of aircraft, and as regards equipment that is critical in terms of the interoperability and security of the EATMN.
- (4) Within the ATM/ANS, the air traffic control (ATC) services are the most important as regards the safety risks related to navigation of aircraft, in particular due to issuing instructions to ensure aircraft separation and collision avoidance. Providers of ATC have the most complete view regarding the safety of the airspace. Therefore, the most critical ATM/ANS equipment,

<sup>1</sup> OJ L 212, 22.8.2018, p. 1.

namely the equipment supporting ATC should be subject to more stringent attestation methods, namely certification.

- (5) ATM/ANS equipment that supports air-to-ground communications delivers direct instructions to aircraft and should be subject to certification too.
- (6) The Communication, Surveillance, and Navigation services are used directly by the ATS to ensure safe navigation of aircraft, but the three services referred to do not have a complete view of traffic and do not play an active control over aircraft separation. Consequently, they play a less critical role. The ATM/ANS systems and ATM/ANS constituents that support them should be subject to a less stringent attestation method, namely declaration of design compliance.
- (7) Lastly, other less critical ATM/ANS systems and equipment that support meteorological services, aeronautical information services, airspace management services and air traffic flow management services should be subject to the least stringent attestation method, namely statement of compliance.
- (8) Additional criteria are possible to decide on criticality of ATM/ANS systems and ATM/ANS constituents in addition to the managerial control over safety risks of the services and functions that they support.
- (9) Therefore, three different levels of requirements and detailed specifications should be established, namely: (i) certification by the Agency, the most stringent level; (ii) declaration by an approved organisation involved in the design or production of ATM/ANS equipment, the medium level; and (iii) statement of compliance by the ATM/ANS provider that integrates the ATM/ANS equipment into its functional system, as defined in Commission Implementing Regulation (EU) 2017/373<sup>(1)</sup>, or, upon ATM/ANS provider's request, by an approved organisation involved in the design or production of ATM/ANS equipment.
- (10) In accordance with Article 29(2), point (a), of Regulation (EU) 2021/696 of the European Parliament and of the Council<sup>(2)</sup>, the European Union Agency for the Space Programme (EUSPA) has been entrusted with managing the European Geostationary Navigation Overlay Service (EGNOS), including the exploitation of EGNOS that covers, amongst other actions, support to certification and standardisation efforts.
- (11) Under Regulation (EU) 2021/696 both EUSPA and the European Space Agency (ESA) are responsible for the design of the EGNOS system and its equipment. The Agency should oversee the declarations of design compliance of the equipment of EGNOS in accordance with specific arrangements to be concluded with EUSPA. Those arrangements are to address technical, administrative, and financial aspects such as a requirement to consult EUSPA as regards the development of detailed specifications; the oversight by EASA of the declarations of design compliance of the EGNOS system; and the exchange of data between both agencies regarding the relevant International Civil Aviation Organization (ICAO) Standards and Recommended Practices (SARPS) compliance. Those arrangements are to ensure a level of safety and interoperability equivalent to the requirements of this Regulation.

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<sup>1</sup> Commission Implementing Regulation (EU) 2017/373 of 1 March 2017 laying down common requirements for providers of air traffic management/air navigation services and other air traffic management network functions and their oversight, repealing Regulation (EC) No 482/2008, Implementing Regulations (EU) No 1034/2011, (EU) No 1035/2011 and (EU) 2016/1377 and amending Regulation (EU) No 677/2011 (OJ L 62, 8.3.2017, p. 1).

<sup>2</sup> Regulation (EU) 2021/696 of the European Parliament and of the Council of 28 April 2021 establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013 and (EU) No 377/2014 and Decision No 541/2014/EU (OJ L 170, 12.5.2021, p. 69).

- (12) In certain remote territories, outside the ICAO European (EUR) region as defined in the European (EUR) Air Navigation Plan Volume I (Doc 7754) of ICAO, with low traffic volume and where that airspace borders only with airspace under the responsibility of third-country ATM/ANS providers, the application of the attestation methods of certification and declaration of design compliance of ATM/ANS equipment may be challenging or even unfeasible, due to their specific safety and interoperability needs. In such cases, for ATM/ANS equipment that is used by ATM/ANS providers in remote areas outside of the ICAO EUR region, it is deemed appropriate to provide derogations from the certification or declaration requirements applicable to such ATM/ANS equipment. Instead, in order to provide for safe and interoperable provision of ATM/ANS, the ATM/ANS provider in that region needs to ensure that applicable specifications are being met by issuing a statement of compliance.
- (13) It is necessary to ensure a smooth transition to the new regulatory framework established by this Regulation and to ensure that a high and uniform level of civil aviation safety in the Union is maintained. It is therefore necessary to provide sufficient time for the design and manufacturing industry of the ATM/ANS systems and ATM/ANS constituents, and for the Agency and Member States' administrations to adapt to this new framework. It is appropriate that the ATM/ANS equipment that is in operation and that was attested under the previous framework is considered as if it had been issued with certificates or declarations issued under the new framework during a transition period, unless the Agency states that such equipment does not ensure the level of safety and interoperability required by Regulation (EU) 2018/1139.
- (14) During the transition period, as regards any new ATM/ANS system and ATM/ANS constituent put into operation, a statement of compliance, issued by the ATM/ANS provider that integrates it in its functional system, or, upon request, by the design and production organisation that designs and manufactures it, should be submitted to the competent authority of the referred ATM/ANS provider defined in Article 4(1) of Implementing Regulation (EU) 2017/373.
- (15) After the transition period the Agency should be solely responsible for certification and for receiving declarations concerning certain ATM/ANS equipment; it is therefore appropriate for the Agency to evaluate the compliance information submitted to national authorities under the previous framework, before such ATM/ANS equipment comes under the remit of the Agency. Therefore, national authorities should make this information available to the Agency. After the evaluation by the Agency, the ATM/ANS equipment should be deemed to have been issued with a certificate or declaration of compliance. The evaluation needs to be made public by decision of the Agency's executive director.
- (16) The measures provided for in this Regulation are based on Opinion No 01/2023, issued by the European Union Aviation Safety Agency in accordance with Article 75(2), points (b) and (c), and Article 76(1) of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

## **Article 1 — Subject matter and scope**

*Regulation (EU) 2023/1768*

This Regulation lays down common technical requirements and administrative procedures for the certification and declaration of design compliance of ATM/ANS systems and ATM/ANS constituents. This Regulation lays down the rules on:

- (a) identifying ATM/ANS systems and ATM/ANS constituents which are either subject to certification, declaration, or a statement of compliance;
- (b) issuing certificates for ATM/ANS systems and ATM/ANS constituents;

- (c) issuing declarations of design compliance of ATM/ANS systems and ATM/ANS constituents by organisations involved in the design or production of ATM/ANS systems and ATM/ANS constituents and which were approved in accordance with Commission Implementing Regulation (EU) 2023/1769 <sup>(1)</sup> to have the privileges to issue such declarations of compliance;
- (d) issuing statements of compliance of ATM/ANS systems and ATM/ANS constituents by ATM/ANS providers certified in accordance with Implementing Regulation (EU) 2017/373 or by organisations involved in the design or production thereof approved in accordance with Implementing Regulation (EU) 2023/1769;
- (e) issuing ATM/ANS equipment directives by the Agency.

## **Article 2 – Definitions**

*Regulation (EU) 2023/1768*

For the purpose of this Regulation, the following definitions apply:

- (1) ‘ATM/ANS equipment’ means ATM/ANS constituents as defined by Article 3(6) of Regulation (EU) 2018/1139 and ATM/ANS systems as defined by Article 3(7) of that Regulation, excluding airborne constituents, which are subject to Commission Regulation (EU) No 748/2012 <sup>(2)</sup>;
- (2) ‘ATM/ANS equipment directive’ means a document issued by the Agency which mandates actions to be performed by ATM/ANS providers on ATM/ANS equipment to address an unsafe and/or insecure condition that has been identified and restore the performance and interoperability of that ATM/ANS equipment when evidence shows that the safety, security, performance or interoperability of that particular equipment may otherwise be compromised;
- (3) ‘European air traffic management network’ (EATMN) means the collection of systems, listed in point 3.1 of Annex VIII to Regulation (EU) 2018/1139, enabling air navigation services in the Union to be provided, including the interfaces at boundaries with third countries;
- (4) ‘functional system’ means a combination of procedures, human resources and equipment, including hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions.

## **Article 3 – Competent authority**

*Regulation (EU) 2023/1768*

- 1. The competent authority responsible for issuing certificates for ATM/ANS equipment in accordance with [Article 4](#), for accepting declarations of design compliance of ATM/ANS equipment issued in accordance with [Article 5](#), and for the oversight of certificate and declarations, shall be the Agency. For that purpose, the Agency shall comply with the requirements laid down in Annex I.
- 2. The competent authority responsible for the oversight of the statement of compliance issued by an ATM/ANS provider in accordance with [Article 6](#) shall be the same competent authority as the authority responsible for the certification and oversight of that ATM/ANS provider.

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<sup>1</sup> Commission Implementing Regulation (EU) 2023/1769 of 12 September 2023 laying down technical requirements and administrative procedures for the approval of organisations involved in the design or production of air traffic management/air navigation services systems and constituents and amending Implementing Regulation (EU) 2023/203 (see page 19 of this Official Journal).

<sup>2</sup> Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1).

## AMC1 Article 3(2) Competent authority; Article 6(1) Statement of compliance

*ED Decision 2023/016/R*

### **GENERAL**

The competent authority for the oversight of a statement of compliance (SoC) issued by an organisation involved in the design or production of ATM/ANS equipment (DPO) approved in accordance with Commission Implementing Regulation (EU) 2023/1769 should be the competent authority responsible for the certification and oversight of the ATM/ANS provider requesting the DPO to issue the SoC on its behalf.

## GM1 Article 3(2) Competent authority; Article 6(1) Statement of compliance

*ED Decision 2023/016/R*

### **GENERAL**

As part of the support during the oversight activities, the ATM/ANS provider may request the presence of a representative of the approved DPO.

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## **Article 4 — Certification of ATM/ANS equipment**

*Regulation (EU) 2023/1768*

1. The following ATM/ANS equipment shall be issued with a certificate as set out in Annex II:
  - (a) equipment supporting controller–pilot communications;
  - (b) equipment supporting air traffic control (ATC) services when enabling the separation of aircraft or the prevention of collisions.
2. The certificate referred to in paragraph 1 shall be issued by the Agency.
3. The certificate referred to in paragraph 1 shall be issued for an unlimited duration. It shall remain valid indefinitely except where:
  - (a) the certificate holder no longer complies with the requirements of this Regulation; or
  - (b) as regards ATM/ANS equipment, there is no valid organisation approval issued by the Agency in accordance with Implementing Regulation (EU) 2023/1769; or
  - (c) the ATM/ANS equipment no longer complies with its certification basis in accordance with point [ATM/ANS.EQMT.CERT.025](#) of Annex II; or
  - (d) the certificate has been surrendered by its holder or revoked by the Agency.

Upon surrender or revocation of the certificate, if issued in a paper format, it shall be returned to the Agency without delay.
4. By way of derogation from paragraph 1, ATM/ANS equipment that is solely being used in a limited part of airspace outside of the ICAO EUR region with low traffic volume, and where that part of the airspace borders only with airspace under the responsibility of a third country, shall not be required to be issued with a certificate. In such a case, the ATM/ANS equipment shall be issued with a statement of compliance in accordance with [Article 6](#).

## GM1 Article 4 Certification of ATM/ANS equipment; Article 5 Declaration of design compliance of the ATM/ANS equipment; Article 6 Statement of compliance

ED Decision 2023/016/R

### SCOPE OF ATM/ANS EQUIPMENT SUBJECT TO CERTIFICATION, DECLARATION AND STATEMENT OF COMPLIANCE

The table below provides a pictorial representation of which means of conformity assessment applies for the various types of ATM/ANS equipment.

#	Point 3 of Annex VIII 'Essential requirements for ATM/ANS and air traffic controllers' to Regulation (EU) 2018/1139	Article 4 Certification of ATM/ANS equipment	Article 5 Declaration of design compliance of the ATM/ANS equipment	Article 6 Statement of compliance
	The <i>equipment should</i> include in particular <i>equipment</i> required to support the following functions and services:			
1.	airspace management ( <i>ASM</i> )			X
2.	air traffic flow management ( <i>ATFM</i> )			X
3.	air traffic services ( <i>ATS</i> ), in particular flight data processing systems, surveillance data processing systems and human-machine interface systems;			
	<i>3a. controller-pilot communications</i>	X		
	<i>3b. air traffic control (ATC) services when enabling the separation of aircraft or the prevention of collisions</i>	X		
	<i>3c. other ATS equipment not covered in points 3a and 3b</i>			X
4.	communications ( <i>COM</i> ) including ground-to-ground/space, air-to-ground and air-to-air/space communications			
	<i>4a. ground-to-ground communications</i>		X	
	<i>4b. air-to-ground communications (i.e. controller-pilot communication)</i>	X		
5.	navigation ( <i>NAV</i> )		X	
6.	surveillance ( <i>SUR</i> )		X	
7.	aeronautical Information services ( <i>AIS</i> )			X
8.	meteorological services ( <i>MET</i> )			X

## GM1 Article 4 Certification of ATM/ANS equipment

*ED Decision 2024/001/R*

### GENERAL INTERACTIONS AMONG INVOLVED PARTIES

For ATM/ANS equipment subject to certification in accordance with [Article 4](#) of this Regulation, the approved DPO, following the acceptance of the certification programme by EASA, demonstrates compliance with the ATM/ANS equipment certification basis before a certificate against the design is issued. The DPO produces ATM/ANS equipment against the design data and issues an EASA release form to be provided to the ATM/ANS provider. Figure 1 shows the interactions between the regulated parties when the ATM/ANS equipment is subject to certification.



Article 4

**Certification of ATM/ANS equipment**

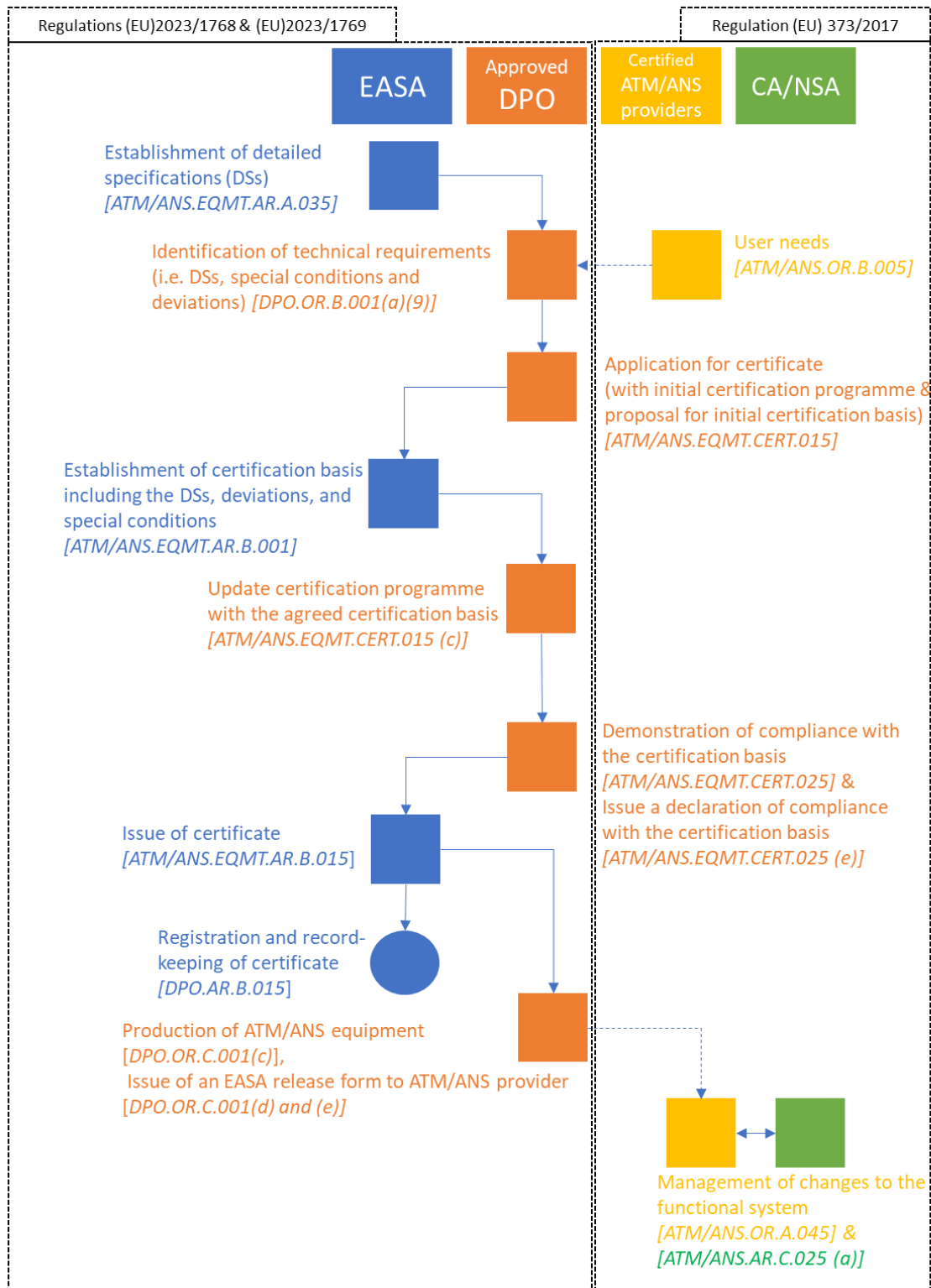


Figure 1

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## **Article 5 — Declaration of design compliance of the ATM/ANS equipment**

*Regulation (EU) 2023/1768*

1. The following ATM/ANS equipment when it generates, receives, and transmits data and/or signals in space for the purpose of ensuring safe and interoperable air navigation shall be issued with a declaration of design compliance as set out in Annex III:
  - (a) equipment supporting ground-to-ground communications;
  - (b) equipment supporting navigation or surveillance.
2. Declarations of design compliance shall be issued by organisations involved in the design or production of ATM/ANS equipment and which are approved in accordance with Implementing Regulation (EU) 2023/1769.
3. Declarations of design compliance of the ATM/ANS equipment shall be issued for an unlimited duration. Declarations shall remain valid unless they have been deregistered in accordance with point DPO.AR.C.015(g)(6) of Annex I to Implementing Regulation (EU) 2023/1769 as a result of one of the following:
  - (a) the ATM/ANS equipment no longer complies with the detailed specifications which enabled the declaration to be issued;
  - (b) the issuer of the declaration no longer complies with the applicable requirements of Implementing Regulation (EU) 2023/1769 or its approval has been surrendered, suspended or revoked;
  - (c) the ATM/ANS equipment has proved to give rise to unacceptable risk or unacceptable performance in service;
  - (d) the organisation has withdrawn the declaration of design compliance.
4. By way of derogation from paragraph 1, ATM/ANS equipment that is solely being used in a limited part of airspace outside of the ICAO EUR region with low traffic volume, and where that part of the airspace borders only with airspace under the responsibility of a third country, shall not be required to be issued with a declaration of design compliance. In such a case, the ATM/ANS equipment shall be issued with a statement of compliance in accordance with [Article 6](#).
5. As regards the ATM/ANS equipment of the European Geostationary Navigation Overlay Service (EGNOS) system, the declaration of design compliance as set out in Annex III to this Regulation shall be issued by the European Union Agency for the Space Programme (EUSPA) established by Regulation (EU) 2021/696, which shall be considered as an organisation involved in the design or production of EGNOS equipment.
6. Points [ATM/ANS.EQMT.DEC.005](#) and [ATM/ANS.EQMT.DEC.045](#) of Annex III shall not be applicable to EUSPA. EUSPA shall ensure that the Agency is given access to evidence from the different entities involved in the design and production of the ATM/ANS equipment of the EGNOS system, in order to determine continued compliance with the applicable technical specifications against which the ATM/ANS equipment declaration was made in accordance with Annex III.

## **GM1 Article 5 Declaration of design compliance of the ATM/ANS equipment**

*ED Decision 2024/001/R*

### **GENERAL INTERACTIONS AMONG INVOLVED PARTIES**

For ATM/ANS equipment subject to declaration of design compliance in accordance with Article 5 of this Regulation, the DPO is privileged to design and produce ATM/ANS equipment in accordance with the terms of the EASA approval. The test and verification activities leading to the issue of declaration of design compliance will be subject to continuous oversight by EASA. Figure 2 shows the interactions between the regulated parties when the ATM/ANS equipment is subject to declaration of design compliance.

Article 5

Declaration of design compliance of ATM/ANS equipment

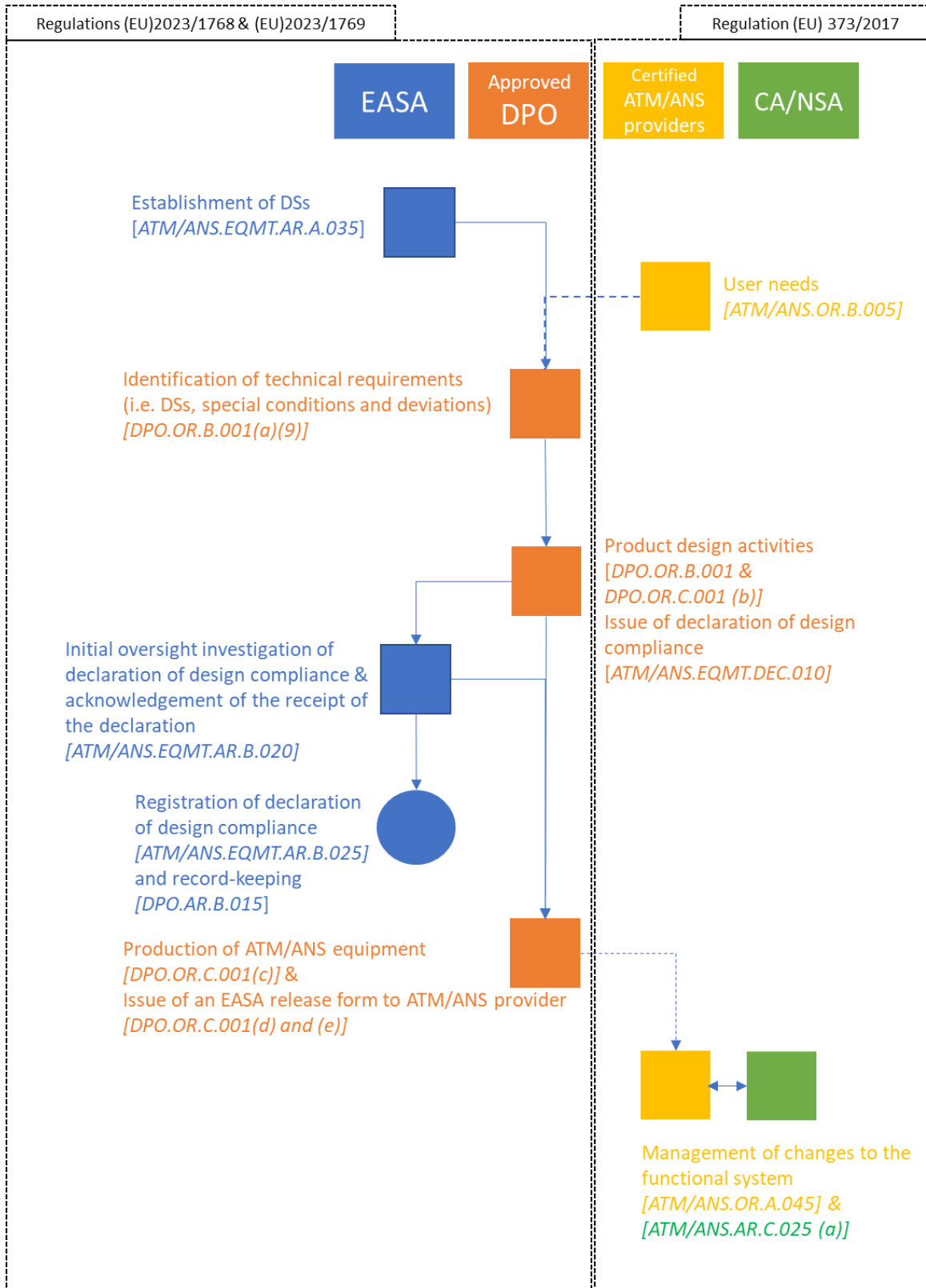


Figure 2

## **Article 6 – Statement of compliance**

*Regulation (EU) 2023/1768*

1. The following ATM/ANS equipment shall be issued with a statement of compliance:
  - (a) equipment that is neither subject to certification in accordance with Article 4 nor to a declaration of compliance in accordance with [Article 5](#); and
  - (b) it supports air traffic services, communication, navigation or surveillance services, airspace management, air traffic flow management, aeronautical information services or meteorological services.

The statement of compliance shall confirm that the ATM/ANS equipment complies with the detailed specifications issued by the Agency in accordance with Article 76(3) of Regulation (EU) 2018/1139.
2. A statement of compliance for ATM/ANS equipment shall be issued by the ATM/ANS provider that integrates such ATM/ANS equipment in its functional system or, upon request of the ATM/ANS provider, by an organisation involved in the design or production of such ATM/ANS equipment approved in accordance with Implementing Regulation (EU) 2023/1769.
3. A statement of compliance for ATM/ANS equipment shall be issued for an unlimited duration. It shall remain valid unless any of the following applies:
  - (a) the ATM/ANS equipment no longer complies with the essential requirements set out in Annex VIII and, if applicable, in Annex VII to Regulation (EU) 2018/1139;
  - (b) the ATM/ANS provider no longer complies with the applicable requirements of Implementing Regulation (EU) 2017/373 or it has surrendered the certificate issued in accordance with Article 6 of Implementing Regulation (EU) 2017/373, or the certificate has been suspended or revoked;
  - (c) the ATM/ANS provider has withdrawn the statement of compliance or enforcement measures have been taken in accordance with point ATM/ANS.AR.C.050(e) of Annex II to Implementing Regulation (EU) 2017/373.

### **AMC1 Article 6 Statement of compliance**

*ED Decision 2023/016/R*

#### **REISSUE**

- (a) Having identified the need for a change (modification) to ATM/ANS equipment, the ATM/ANS provider or an approved DPO acting on its behalf should classify the change as minor unless one or more of the following apply, in which case the change is classified as major and a reissue of the SoC is required:
  - (1) The change (modification) includes one of the following technological evolutions:
    - (i) new concept of operation;
    - (ii) new technologies in the ATM/ANS equipment;
    - (iii) new or modified functionalities to the ATM/ANS equipment software;
    - (iv) changes in the ATM/ANS equipment hardware; or
    - (v) modified ATM/ANS equipment architecture.

- (2) The change (modification) introduces a new or modified means of compliance with the detailed specifications.
  - (3) The change (modification) introduces a modification in the limitation(s) to or a deviation from the detailed specifications.
- (b) Minor changes should be processed according to the approved ATM/ANS equipment change management procedure ensuring that the change (modification) does not adversely affect the compliance with the detailed specifications. For minor changes, the ATM/ANS provider should:
- (1) record the change description and the justification for the change classification;
  - (2) update all related technical documents including the user manual;
  - (3) record continued compliance with the ATM/ANS equipment SoC.
- (c) For major changes, the ATM/ANS provider should apply [Article 6](#) of this Regulation and reissue a SoC.
- (d) The procedure, which could be part of an integrated ATM/ANS provider's change management procedure, addressing the changes (modifications) to ATM/ANS equipment should also include the process for the reaction by the ATM/ANS provider to an unplanned (major) change (modification) that may arise with the need for urgent action. This is the case in which the ATM/ANS provider responds immediately to a safety, security or interoperability problem or when an emergency situation arises in which the ATM/ANS provider has to take immediate action (e.g. security patches) to ensure the safety, security or interoperability of its equipment in operation.

## GM1 Article 6 Statement of compliance

*ED Decision 2024/001/R*

### GENERAL INTERACTIONS AMONG INVOLVED PARTIES

- (a) To issue a SoC for ATM/ANS equipment, the ATM/ANS provider must perform the necessary verification and test activities, as required. The competent authority oversees the SoC as part of the management of changes to the functional system or during the continuous oversight of the ATM/ANS provider and, as necessary, applies enforcement measures to the ATM/ANS provider. Figure 3 shows the interactions between the regulated parties when the ATM/ANS equipment is subject to a SoC and such SoC is issued by the ATM/ANS provider.

Article 6

**Statement of Compliance of ATM/ANS GE | Scenario 1**

(issued by the ATM/ANS provider)

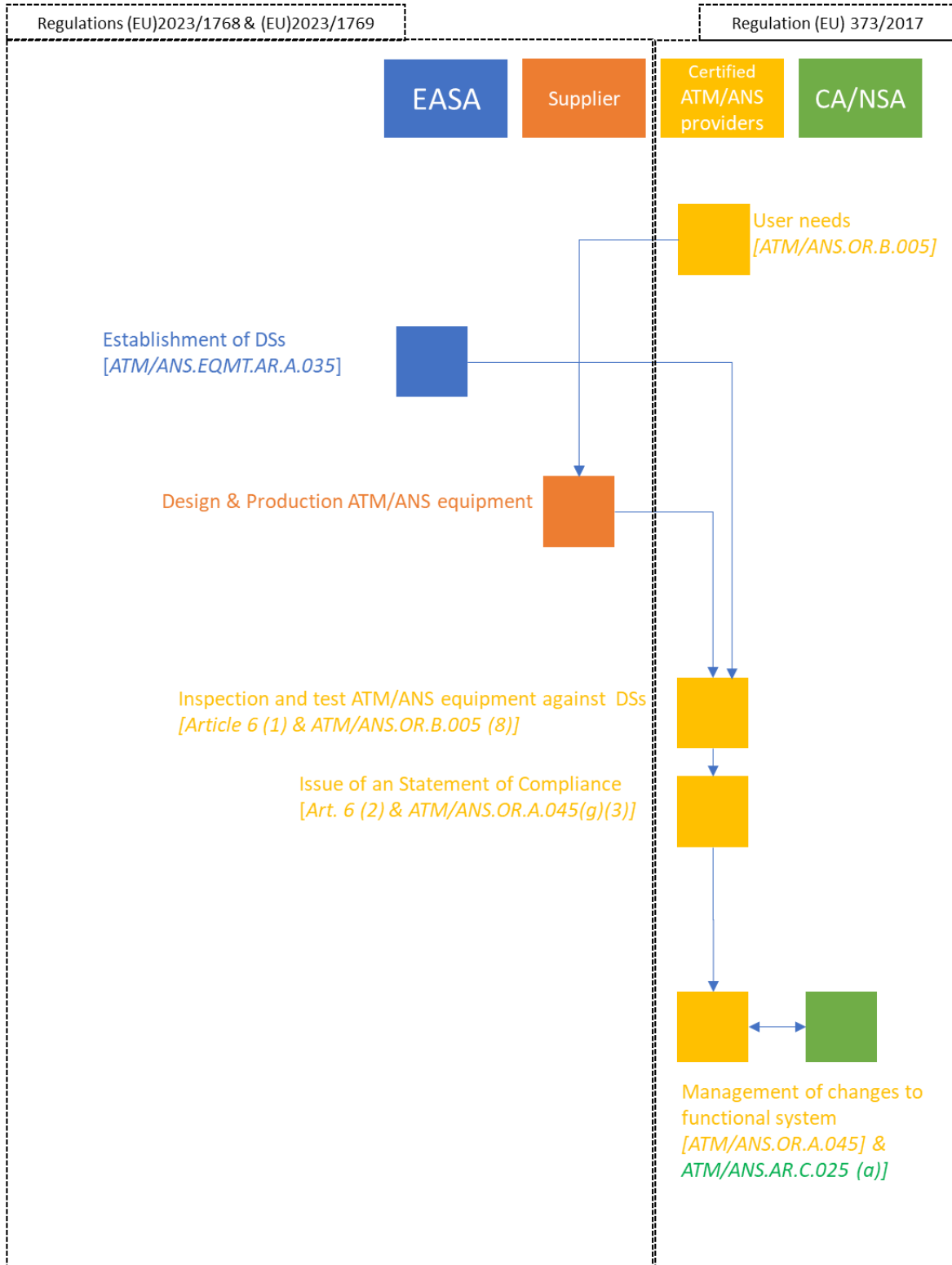


Figure 3

- (b) A DPO can obtain privileges in accordance with the terms of the EASA approval to issue a SoC on behalf of an ATM/ANS provider, upon its request. There is an expectation that DPOs apply all processes and procedures under its EASA's approval terms for such ATM/ANS equipment in accordance with Implementing Regulation (EU) 2023/1769, although this is not explicitly required, and thus, an EASA release form may be issued. Such EASA release form will provide additional assurance to competent authorities that finished ATM/ANS equipment ready to be delivered has been manufactured in conformity with the design data. The competent authority oversees the SoC as part of the management of changes to the functional system or during the continuous oversight of the ATM/ANS provider. If, during the continuous oversight of the ATM/ANS provider, the competent authority identifies any non-compliance of the SoC, that competent authority will inform EASA about any enforcement measures required. Figure 4 shows the interactions between the regulated parties when the ATM/ANS equipment is subject to a SoC and such SoC is issued by the DPO.



Article 6

Statement of Compliance of ATM/ANS GE | Scenario 2  
(by approved DPO)

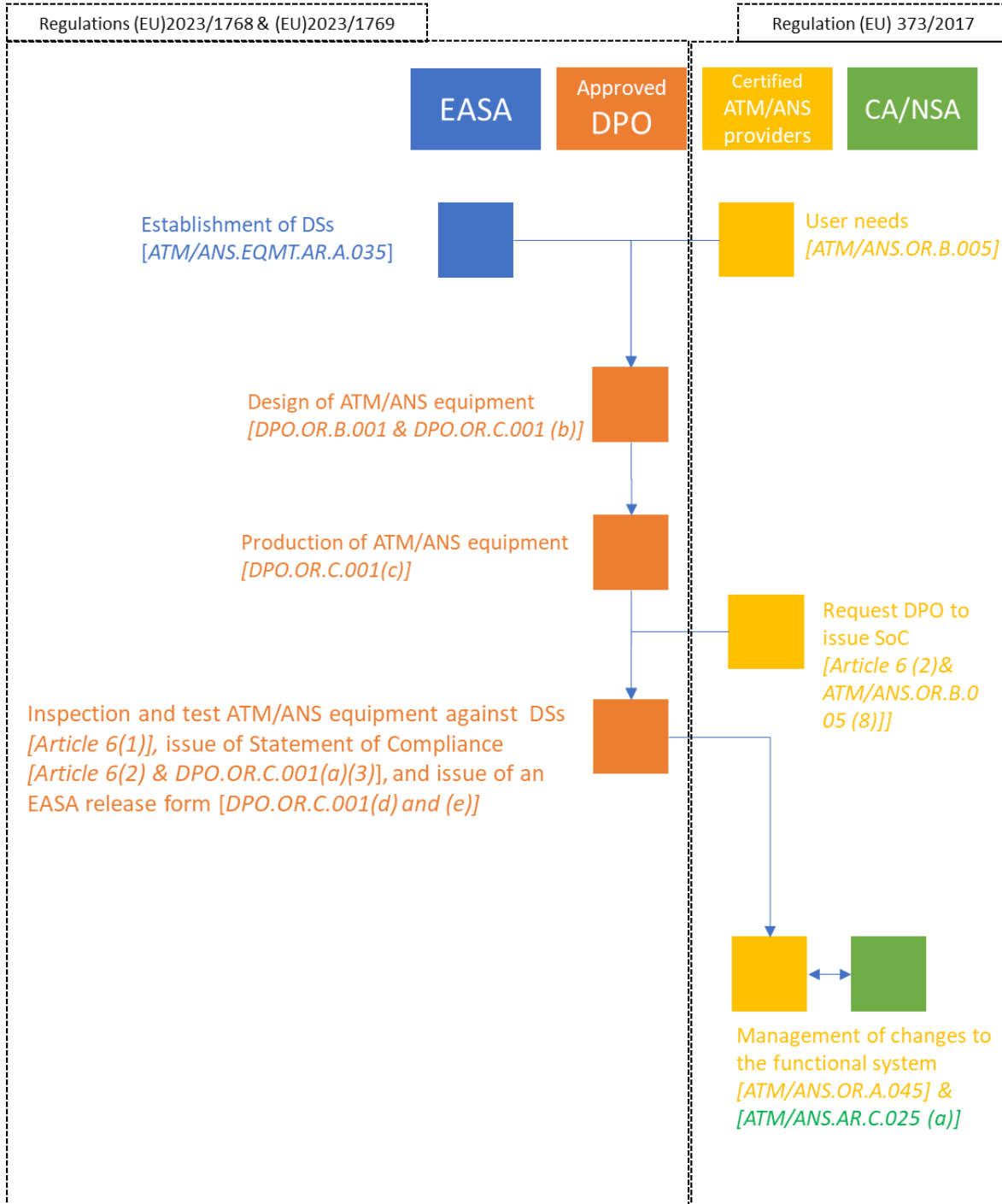


Figure 4

## AMC2 Article 6(1) Statement of compliance

ED Decision 2023/016/R

### ISSUE

- (a) The SoC should contain the following information:
- a brief description, identification and scope of the ATM/ANS equipment;
  - the Regulation reference requiring the issue of the SoC<sup>1</sup>;
  - the name and address of the certified, in accordance with Regulation (EU) 2017/373, ATM/ANS provider, where the ATM/ANS equipment will be deployed or on its behalf, the trade name and full address of the DPO approved in accordance with Regulation (EU) 2023/1769 issuing the SoC;
  - the reference to the detailed specifications adopted by EASA in accordance with Article 76(3) of Regulation (EU) 2018/1139, as far as applicable, for the intended use, and any deviations therefrom;
  - the reference to the procedure followed in order to declare compliance with the applicable ATM/ANS equipment detailed specifications;
  - deviations;
  - remarks;
  - limitations;
  - conditions;
  - date and version;
  - identification of the signatory.
- (b) The SoC should be accompanied by all documents that form the basis for the issuance of it and, when issued by an approved DPO, an EASA release form issued in accordance with [DPO.OR.C.001](#)(d) of Commission Implementing Regulation (EU) 2023/1769 by the same DPO.

## AMC3 Article 6(1) Statement of compliance

ED Decision 2023/016/R

### ACTIVITIES

The ATM/ANS provider should verify the functionalities of the ATM/ANS equipment subject to conformity assessment in accordance with Commission Delegated Regulation (EU) 2023/1768 to ensure that it complies with the applicable detailed specifications in the context in which it is intended to operate within the functional system.

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<sup>1</sup> Note:

For ATM/ANS equipment subject to statement of compliance, Article 6 of Commission Delegated Regulation (EU) 2023/1768 should be indicated.

During the transition period (until 13 September 2028), for ATM/ANS equipment subject to certification and declaration in accordance with Articles 4 and 5 respectively, a reference to Article 7(3) of Commission Delegated Regulation (EU) 2023/1768 should be indicated.

## AMC4 Article 6(1) Statement of compliance

*ED Decision 2023/016/R*

### RECORD-KEEPING

- (a) In the context of ATM/ANS.OR.B.030 of Regulation (EU) 2017/373, a copy of the SoC should be kept by the ATM/ANS provider throughout the service life of the ATM/ANS equipment and should be provided to the competent authority concerned upon request.
- (b) The ATM/ANS provider should keep the records for a period of at least 3 years after the end of the service life of the ATM/ANS equipment unless otherwise specified by other applicable requirements.

## GM1 Article 6(1) Statement of compliance

*ED Decision 2023/016/R*

### STANDARD FORM

SoC No [internal numbering]

Issue No [version of this SoC<sup>1</sup>]

1. Name and address of ATM/ANS provider
2. Description, identification and scope of the ATM/ANS equipment  
Note: It should include e.g. type, SW/HW version number and master drawing record, as applicable.
3. Regulation reference requiring the issue of the SoC
4. Specification reference, i.e. EASA detailed specification No.
5. Reference to the qualification test report to show compliance with the applicable detailed specifications and the procedure followed in order to be compliant
6. Service and instruction manual reference number
7. SoC with the applicable EASA detailed specification, as far as applicable for the intended use, and any deviations, remarks, limitations, conditions.
8. The declaration in this document is made under the authority of .....  
(Name of ATM/ANS provider or approved DPO)

(approved DPO's name) cannot accept responsibility for equipment used outside the limiting conditions stated above without their agreement.

Date: ..... Signed.....(ATM/ANS provider's or approved DPO's authorised representative)

<sup>1</sup> A 'new' version is introduced in the case of major changes.

## GM2 Article 6(1) Statement of compliance

*ED Decision 2023/016/R*

### **RESPONSIBILITY WHEN PURCHASING ATM/ANS EQUIPMENT SUBJECT TO SoC**

- (a) The procurement contract between the ATM/ANS provider and the manufacturer(s) should clearly define the ATM/ANS equipment to be purchased and the applicable detailed specifications.
- (b) The contract should address that the ATM/ANS equipment purchased from the manufacturer(s) is manufactured and verified and the ATM/ANS functions thereof have been tested for the intended use.

## GM3 Article 6(1) Statement of compliance

*ED Decision 2023/016/R*

### **DOCUMENTS**

The documents that form the basis for the issuance of the SoC encompass, but are not limited to:

- (a) test results; and
- (b) descriptions of the test environment.

## AMC1 Article 6(2) Statement of compliance

*ED Decision 2023/016/R*

### **SoC ISSUED BY DPO**

During the oversight activities on a SoC issued by an approved DPO, that DPO should support the ATM/ANS provider to the extent required.

## **Article 7 – Transitional provisions**

*Regulation (EU) 2023/1768*

1. The following transitional provisions shall apply to ATM/ANS equipment holding EC declarations issued in accordance with Articles 5 or 6 of Regulation (EC) No 552/2004 of the European Parliament and of the Council <sup>(1)</sup> and that has been put into operation before the date of entry into force of this Regulation:
  - (a) ATM/ANS equipment which falls within the category of ATM/ANS equipment that requires certification in accordance with [Article 4](#) shall be deemed to have been issued with a certificate in accordance with [Article 4](#) unless the Agency determines, following the evaluation referred to in paragraph 2, that such ATM/ANS equipment does not ensure a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation;
  - (b) ATM/ANS equipment which falls within the category of ATM/ANS equipment that is required to be declared in accordance with [Article 5](#) shall be deemed to have been issued with a declaration of design compliance in accordance with [Article 5](#) unless the Agency determines, following the evaluation referred to in paragraph 2, that such ATM/ANS equipment does not ensure a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation;
  - (c) as regards ATM/ANS equipment which is subject to a statement of compliance in accordance with [Article 6](#), the EC declarations of verification of systems that have been issued or recognised in accordance with Article 6 of Regulation (EC) No 552/2004 shall continue to be valid for an unlimited duration and shall be deemed to have a statement of compliance pursuant to [Article 6](#).
2. The Agency shall evaluate the ATM/ANS equipment referred to in paragraph 1, points (a) and (b), within 5 years from the date of entry into force of this Regulation and shall publish the results of that evaluation. For that purpose, the competent authorities responsible for the certification and oversight of the ATM/ANS providers referred to in Article 4(1) of Implementing Regulation (EU) 2017/373 shall provide the Agency with the relevant information to facilitate this evaluation. The objective of that evaluation shall be to determine whether the relevant ATM/ANS equipment ensures a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation. The result of the evaluation shall be published and any measure to change the ATM/ANS equipment identified by the evaluation shall be applied after 5 years from the date of entry into force of this Regulation, regardless of the actual date when the evaluation takes place, unless the evaluation reveals a deficiency that may have a detrimental effect on safety. In the case a deficiency that may have a detrimental effect is detected, any measure to change the ATM/ANS equipment revealed by the evaluation shall be applied immediately. After 5 years from the date of entry into force of this Regulation, the ATM/ANS equipment referred to in paragraph 1, points (a) to (b), shall be deemed to comply with the requirements of this Regulation.
3. ATM/ANS equipment that is subject to certification in accordance with [Article 4](#) or a declaration in accordance with [Article 5](#) may be put into operation from the date of entry into force of this Regulation until 12 September 2028 on the basis of a statement of compliance made in accordance with [Article 6](#). As from 13 September 2028, the following provisions shall apply to such ATM/ANS equipment:

<sup>1</sup> Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (OJ L 96, 31.3.2004, p. 26).

- (a) ATM/ANS equipment which falls within the category of ATM/ANS equipment that requires certification in accordance with [Article 4](#) and for which a statement of compliance was issued by the ATM/ANS provider shall be deemed to have been issued with a certificate in accordance with [Article 4](#) unless the Agency determines, following the evaluation referred to in paragraph 4, that such ATM/ANS equipment does not ensure a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation;
  - (b) ATM/ANS equipment which falls within the category of ATM/ANS equipment that requires a declaration of design compliance in accordance with [Article 5](#) and for which a statement of compliance was issued by the ATM/ANS provider shall be deemed to have been issued with a declaration of design compliance in accordance with Article 5 unless the Agency determines, following the evaluation referred to in paragraph 4 that such ATM/ANS equipment does not ensure a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation.
4. The Agency shall evaluate the ATM/ANS equipment referred to in paragraph 3 not later than 12 September 2030. For that purpose, the competent authorities responsible for the certification and oversight of the ATM/ANS providers referred to in Article 4(1) of Implementing Regulation (EU) 2017/373 shall provide the Agency with the relevant information to facilitate this evaluation. The objective of that evaluation shall be to determine whether the particular ATM/ANS equipment meets a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation.

## AMC1 Article 7(2) Transitional provisions

ED Decision 2023/016/R

### RELEVANT INFORMATION

For the purpose of the evaluation referred to in [Article 7\(2\)](#), the competent authorities responsible for the certification and oversight of the ATM/ANS providers referred to in Article 4(1) of Implementing Regulation (EU) 2017/373 should provide the following information to EASA upon request:

**ATM/ANS provider's name:** the name of the ATM/ANS provider(s) that has deployed the ATM/ANS equipment subject to [Articles 4](#) or [5](#) of this Regulation and has issued the declaration of verification (DoV) in accordance with Article 6 of Regulation (EC) No 552/2004.

**Company Name:** the name of the responsible DPO(s)<sup>1</sup> that has (have) issued the Declaration(s) of Compliance (DoC) or the Declaration(s) for Suitability for Use (DSU).

**Date:** the date on which the information was released.

**Description:** a brief description of the ATM/ANS equipment.

**Reference:** reference to the Community specifications, when available, and the references to the documents contained in the technical file.

**Additional information:** additional information, if any, that has been required and requested by the competent authority to oversee the DoV(s) confirming compliance.

<sup>1</sup> DPO should be understood as the manufacturer or its authorised representative established within the Community.

**Limitations/Remarks:**

- all the relevant temporary or definitive provisions to be complied with by the ATM/ANS equipment and in particular, where appropriate, any operating restrictions or conditions;
- if temporary: duration of validity of DoV.

**Authorised signature:** identification of the signatory empowered to enter into commitments on behalf of the manufacturer or of the manufacturer's authorised representative, where available.

## GM1 Article 7(2) Transitional provisions

ED Decision 2023/016/R

**SUBMISSION OF INFORMATION**

The relevant information may be provided in a form of the DoV for the ATM/ANS system(s), including its (their) technical file(s), issued by the ATM/ANS provider under the oversight of the competent authority.

## GM2 Article 7(2) Transitional provisions

ED Decision 2023/016/R

**RELEVANT INFORMATION**

For the purpose of the evaluation referred to in [Article 7\(2\)](#), the competent authorities responsible for the certification and oversight of the ATM/ANS providers referred to in Article 4(1) of Implementing Regulation (EU) 2017/373 may provide EASA with any certificate, approval, licence, authorisation, attestation, technical file or other document issued as a result of a process attesting compliance of the ATM/ANS equipment with the applicable essential requirements laid down in Regulation (EC) No 552/2004.

## AMC1 Article 7(3) Transitional provisions

ED Decision 2023/016/R

**STATEMENT OF COMPLIANCE**

- (a) In order to issue a SoC for ATM/ANS equipment that is subject to certification in accordance with [Article 4](#) or a declaration in accordance with [Article 5](#) of Regulation (EU) 2023/1768, the ATM/ANS providers or the organisations involved in the design or production of ATM/ANS equipment (DPOs) acting on their behalf, should demonstrate compliance of ATM/ANS equipment with:
- (1) the detailed specifications (DSs) set out in *Part 1 — General* of the Detailed Specifications and Acceptable Means of Compliance & Guidance Material for certification or declaration of design compliance of ATM/ANS ground equipment (DS-GE.CER/DEC); and
  - (2) the additional specific DS set out in *Part 2 — ATM/ANS equipment subject to certification* or *Part 3 — ATM/ANS equipment subject to declaration of design compliance* of (DS-GE.CER/DEC), if available.
- (b) The basis for the issue of a SoC should be the DSs that are applicable to the ATM/ANS equipment on the date of the issue of the SoC.

## **Article 8 — Entry into force**

*Regulation (EU) 2023/1768*

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

## **Signature**

*Regulation (EU) 2023/1768*

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

Done at Brussels, 14 July 2023.

*For the Commission*

*The President*

Ursula VON DER LEYEN



## **ANNEX I — REQUIREMENTS FOR THE AGENCY (PART- ATM/ANS.EQMT.AR)**

### **SUBPART A — GENERAL REQUIREMENTS (ATM/ANS.EQMT.AR.A)**

#### **ATM/ANS.EQMT.AR.A.001 Scope**

*Regulation (EU) 2023/1768*

This Annex establishes the requirements for the Agency concerning the conditions for conducting certification and other necessary activities to ensure effective oversight of ATM/ANS equipment and the conditions and procedures for the accreditation of qualified entities by the Agency.

#### **ATM/ANS.EQMT.AR.A.020 Allocation of tasks to qualified entities**

*Regulation (EU) 2023/1768*

- (a) When the Agency decides to allocate tasks related to the certification of ATM/ANS equipment subject to this Regulation, the approval or the continuing oversight of organisations subject to Implementing Regulation (EU) 2023/ 1769 to qualified entities, it shall ensure that it has established and documented an agreement with the qualified entity(ies), approved by both parties to that agreement at the appropriate management level, which clearly defines:
- (1) the tasks to be performed;
  - (2) the declarations, reports and records to be provided;
  - (3) the technical conditions to be met when performing the tasks;
  - (4) the related liability coverage;
  - (5) the protection given to information acquired when carrying out the tasks.
- (b) The Agency shall ensure that the internal audit process and the safety risk management process required by point [DPO.AR.B.001](#) (a)(5) of Implementing Regulation (EU) 2023/1769 cover all the tasks performed on its behalf by the qualified entity(ies).
- (c) With regard to the approval and oversight of the organisation's compliance with point [DPO.OR.B.001](#) (d) of Implementing Regulation (EU) 2023/1769, the Agency may allocate tasks to qualified entities in accordance with point (a), or to any relevant authority responsible for information security or cybersecurity within the Union. When allocating tasks, the Agency shall ensure that:
- (1) all aspects related to aviation safety are coordinated and taken into account by the qualified entity or relevant authority;
  - (2) the results of the approval and oversight activities performed by the qualified entity or relevant authority are integrated in the overall certification and oversight files of the organisation;
  - (3) its own information security management system established in accordance with point [DPO.AR.B.001](#) (d) of Implementing Regulation (EU) 2023/1769 covers all the certification and continuing oversight tasks performed on its behalf.

## ATM/ANS.EQMT.AR.A.030 ATM/ANS equipment directives

Regulation (EU) 2023/1768

- (a) The Agency shall issue an ATM/ANS equipment directive when:
- (1) an unsafe, insecure, underperformance or non-interoperability condition has been determined by the Agency to exist in the equipment as a result of a deficiency in the equipment; and
  - (2) that condition is likely to exist or develop in other ATM/ANS equipment.
- (b) An ATM/ANS equipment directive shall contain at least the following information:
- (1) identification of the unsafe, insecure, underperformance or non-interoperability condition;
  - (2) the affected ATM/ANS equipment;
  - (3) the required action(s) and the rationale;
  - (4) the accomplishment time for the required action(s);
  - (5) the date of entry into force.

## GM1 ATM/ANS.EQMT.AR.A.030 ATM/ANS equipment directives

ED Decision 2024/001/R

### ATM/ANS EQUIPMENT DIRECTIVE IN CASE OF DISCONTINUATION OF DPO APPROVAL

Certificates of ATM/ANS equipment issued in accordance with [Article 4](#) and declarations of design compliance of ATM/ANS equipment issued in accordance with [Article 5](#) lose their validity in case the holder of the certificate/issuer of the declaration of design compliance is no longer compliant with Implementing Regulation (EU) 2023/1769.

In the above situations, EASA would typically:

- (a) revoke the certificate or deregister the declaration of design compliance, as appropriate;
- (b) inform ATM/ANS providers that are users of the ATM/ANS equipment concerned and their competent authorities, as in the absence of an approved DPO with appropriate privileges from that moment on:
- the affected ATM/ANS equipment cannot be integrated into any functional system as the requirements in ATM/ANS.OR.A.045 (g) of Implementing Regulation (EU) 2017/373 will be no longer met;
  - the affected ATM/ANS equipment already integrated into a functional system cannot be modified until a valid certificate or declaration is in place, in accordance with points ATM/ANS.OR.A.045 (g)(1) and (g)(2) of Implementing Regulation (EU) 2017/373. This requires another DPO with appropriate privileges to take responsibility for the compliance of the equipment with the applicable technical specifications;
  - the continuous operation of the ATM/ANS equipment already integrated into the functional system of ATM/ANS providers may not necessarily be immediately impacted. However, ATM/ANS providers will have to consider how the absence of the DPO impacts the suitability for use of the equipment, the defined conditions of use, and any prescribed limitations; and

- (c) issue an ATM/ANS equipment directive to replace the ATM/ANS equipment concerned in case an unsafe, insecure, under-performing or non-interoperability condition has been identified or is likely to develop, as in the absence of a DPO with appropriate privileges and responsibility for ensuring that the equipment continues complying with the applicable technical specifications, design changes to the ATM/ANS equipment to restore performance are not possible. This ATM/ANS equipment directive will be addressed to all known users of the ATM/ANS equipment and their competent authorities.

*Note: In case the DPO approval is still valid, e.g. during a suspension/revocation process, EASA will require the DPO to make appropriate descriptive data and accomplishment instructions available to all known users of the ATM/ANS equipment and their competent authorities.*

Urgent operational needs might require certain exceptions to the principles described above, allowing integration or modification of equipment without a valid certificate or declaration. In those cases, the exemptions are to be managed under the flexibility provisions in Article 71 of Regulation (EU) 2018/1139, subject to all relevant conditions laid down in such article. In particular, the Member State must provide adequate justification for the following aspects:

- (1) it is not possible for another DPO to obtain a valid certificate or issue a declaration for the equipment;
  - (2) safety, environmental protection and compliance with the applicable essential requirements are ensured, where necessary through the application of mitigation measures;
  - (3) any possible distortion of market conditions as a consequence of the granting of the exemption will be mitigated as far as possible; and
  - (4) the exemption is limited in scope and duration to the extent strictly necessary and it is applied in a non-discriminatory manner; and
- (d) take any other necessary further enforcement measures which are necessary to mitigate the consequences of the discontinuation of a DPO approval.

## ATM/ANS.EQMT.AR.A.035 Detailed specifications for the equipment design compliance

Regulation (EU) 2023/1768

- (a) The Agency shall establish and make available detailed specifications which organisations may use to demonstrate compliance with the relevant essential requirements set out in Annex VIII and, if applicable, Annex VII to Regulation (EU) 2018/1139 when they:
- (1) apply for the certification of ATM/ANS equipment in accordance with [Article 4](#);
  - (2) declare design compliance of ATM/ANS equipment in accordance with [Article 5](#);
  - (3) make a statement of compliance in accordance with [Article 6](#).
- (b) The detailed specifications referred to in point (a) shall indicate design standards which reflect the state of the art and best design practices, and which build on valuable experience gained and scientific and technical progress, and on the best available evidence and analyses as regards ATM/ANS equipment.

## SUBPART B — CERTIFICATION, OVERSIGHT, AND ENFORCEMENT (ATM/ANS.EQMT.AR.B)

### ATM/ANS.EQMT.AR.B.001 ATM/ANS equipment certification basis

*Regulation (EU) 2023/1768*

- (a) The Agency shall establish the ATM/ANS equipment certification basis and notify it to the applicant for an ATM/ANS equipment certificate. The certification basis shall consist of the following:
- (1) detailed certification specifications issued by the Agency in accordance with point [ATM/ANS.EQMT.AR.A.035](#) that are applicable to the ATM/ANS equipment on the date of submission of the application for that certificate, unless:
    - (i) the applicant chooses to comply, or is required to comply in accordance with point [ATM/ANS.EQMT.CERT.015](#)(e), with detailed certification specifications that became applicable after the date of the submission of the application, in which case the Agency shall include in the ATM/ANS equipment certification basis any other certification specifications that are directly related; or
    - (ii) the Agency accepts any alternative to a determined detailed certification specification that cannot be complied with, for which compensating factors have been found that provide an equivalent level of safety or to ensure equivalence with the applicable certification specifications; and
  - (2) any special conditions prescribed by the Agency in accordance with point [ATM/ANS.EQMT.AR.B.005](#).
- (b) The possible inclusion of additional features, characteristics or functions not initially included in the certification basis shall be agreed by the Agency.

### GM1 ATM/ANS.EQMT.AR.B.001(a)(1) ATM/ANS equipment certification basis

*ED Decision 2024/001/R*

#### DETAILED SPECIFICATIONS

The ATM/ANS equipment certification basis is established on the basis of the detailed specifications that were effective on the date of application and applicable for that certificate.

The validity period of an application for the issue of an ATM/ANS equipment certificate may be extended, as per point [ATM/ANS.EQMT.CERT.015](#)(e)(2). In such a case, the certification basis is then revised accordingly.

It is also possible for an applicant to elect to comply with a detailed specification that became applicable after the date of the submission of the application.

EASA will assess whether the proposed certification basis is appropriate.

During the transitional period, detailed specifications may not be fully developed, and only the general part of the detailed specifications might be available and applicable for the ATM/ANS equipment. Additional technical specifications will then be proposed by the DPO to be part of the certification basis.

## AMC1 ATM/ANS.EQMT.AR.B.001(b) ATM/ANS equipment certification basis

*ED Decision 2024/001/R*

Additional features, characteristics or functions not specified into the applicable detailed specifications should be addressed through demonstration to provide assurance that their inclusion in the certification basis does not detrimentally interfere with those specified in the applicable detailed specifications, as per point [ATM/ANS.EQMT.CERT.025\(f\)](#), when demonstrating the suitability of the ATM/ANS equipment for its intended use.

## ATM/ANS.EQMT.AR.B.005 Special conditions

*Regulation (EU) 2023/1768*

- (a) The Agency shall establish additional requirements, named ‘special conditions’, for ATM/ANS equipment if the related applicable detailed specifications are not deemed adequate because of one of the following:
- (1) the ATM/ANS equipment has novel or unusual design features relative to the design practices on which the applicable detailed specifications are based;
  - (2) the intended use of the ATM/ANS equipment is unconventional;
  - (3) experience with other similar ATM/ANS equipment in service having similar design features or newly identified risks has shown that unwanted conditions may develop;
  - (4) the environment at the location of installation physically prevents the fulfilment of certain requirements of the applicable detailed specifications.
- (b) Special conditions contain safety, performance, security, and interoperability standards that the Agency finds necessary to ensure that the appropriate level of performance of the ATM/ANS equipment is equivalent to that required by the applicable detailed specifications.

## ATM/ANS.EQMT.AR.B.010 Level of involvement

*Regulation (EU) 2023/1768*

- (a) The Agency shall determine its level of involvement in the verification of compliance-demonstration activities and data related to an application for the issue of a certificate or for changes to it. It shall determine this based on the assessment of subjective groups of compliance-demonstration activities and data from the certification programme.

The assessment shall address all of the following:

- (1) the likelihood of an unidentified non-compliance with the certification basis;
- (2) the potential impact of that non-compliance on safety, security, service specifications and functioning of the ATM/ANS equipment.

It shall consider at least the following elements:

- (i) novel or unusual features of the certification project, including operational, organisational and knowledge- management aspects;
- (ii) complexity of the design and/or the demonstration of compliance;
- (iii) criticality of the design or the technology, the related safety, security or service-compliance risks and the functioning of the ATM/ANS equipment, including those identified on similar designs;

- (iv) performance and experience of the applicant in the domain concerned.
- (b) The Agency shall notify its level of involvement to the applicant and shall update its level of involvement when this is warranted by information which has an appreciable impact on the risk previously assessed in accordance with point (a). The Agency shall notify the applicant about any change to the level of involvement.

## **ATM/ANS.EQMT.AR.B.015 Issue of an ATM/ANS equipment certificate**

*Regulation (EU) 2023/1768*

- (a) The Agency shall issue a certificate for ATM/ANS equipment, provided the following:
  - (1) the applicant has demonstrated compliance with point [ATM/ANS.EQMT.CERT.015](#);
  - (2) the Agency has not identified any non-compliance with the ATM/ANS equipment certification basis through the verification of the compliance-demonstration activities determined in accordance with point [ATM/ANS.EQMT.AR.B.010](#);
  - (3) no feature or characteristic has been identified that may render the equipment unsafe for the intended use.
- (b) The ATM/ANS equipment certificate shall include the operating limitations, the data sheet for continued suitability, the applicable ATM/ANS equipment certification basis with which the Agency records compliance, and any other conditions or limitations prescribed in the applicable detailed specifications and special conditions.

## **ATM/ANS.EQMT.AR.B.020 Initial oversight investigation of declaration of design compliance of ATM/ANS equipment**

*Regulation (EU) 2023/1768*

- (a) Upon receiving a declaration of design compliance of the ATM/ANS equipment from an organisation involved in the design or production of ATM/ANS equipment and approved by the Agency in accordance with Implementing Regulation (EU) 2023/1769, the Agency shall verify that the following is complied with:
  - (1) the declarant has the privilege to declare design compliance in accordance with point [ATM/ANS.EQMT.DEC.005](#);
  - (2) the declaration contains all the information listed in point [ATM/ANS.EQMT.DEC.010](#);
  - (3) the declaration does not contain information that indicates a non-compliance with the applicable requirements of Annex III and no feature or characteristic has been identified that may render the ATM/ANS equipment unsafe for the intended use.
- (b) The declaration of design compliance of the ATM/ANS equipment shall include the operating limitations, the data sheet for continued suitability, the applicable detailed specifications with which the organisation has demonstrated compliance, and any other conditions or limitations set out in the applicable detailed specifications and special conditions.
- (c) If the declaration is not consistent with the organisation's privileges or contains information that indicates non-compliance with the applicable detailed specifications and special conditions, the Agency shall notify the organisation concerned about the non-compliance and request further information, corrective actions, and evidence thereof.

- (d) If the requirements in points (a) and (b) are met, the Agency shall acknowledge the receipt of the declaration.

## **ATM/ANS.EQMT.AR.B.025 Registration of a declaration of design compliance of ATM/ANS equipment**

*Regulation (EU) 2023/1768*

The Agency shall register a declaration of design compliance of ATM/ANS equipment in a suitable database, provided that:

- (a) the declarant has declared compliance of the ATM/ANS equipment design in accordance with point [ATM/ANS.EQMT.DEC.010](#);
- (b) the declarant has committed to undertake the obligations laid down in Annex III;
- (c) there are no unresolved issues in accordance with point [ATM/ANS.EQMT.AR.B.020](#).

## **ATM/ANS.EQMT.AR.B.030 Changes to declarations**

*Regulation (EU) 2023/1768*

- (a) Upon receiving a notification of changes in accordance with point [ATM/ANS.EQMT.DEC.020](#), the Agency shall verify the completeness of the notification in accordance with point [ATM/ANS.EQMT.AR.B.020](#).
- (b) When the change(s) affects (affect) any aspect of the declaration that is registered in accordance with point [ATM/ANS.EQMT.AR.B.025](#), the Agency shall update the register.
- (c) Upon completion of the activities required by points (a) and (b), the Agency shall acknowledge receipt of the notification to the organisation involved in the design or production of ATM/ANS equipment.

## **ANNEX II — ATM/ANS EQUIPMENT CERTIFICATES (PART- ATM/ANS.EQMT.CERT)**

### **ATM/ANS.EQMT.CERT.001 Scope**

*Regulation (EU) 2023/1768*

This Annex establishes the procedures for the issue of certificates for ATM/ANS equipment in accordance with [Article 4](#), and the rights and obligations of the applicant for, and holder of, those certificates.

### **ATM/ANS.EQMT.CERT.005 Eligibility**

*Regulation (EU) 2023/1768*

Any natural or legal person who has demonstrated, or is in the process of demonstrating, their design capability in accordance with point [ATM/ANS.EQMT.CERT.010](#), may apply for the issue of an ATM/ANS equipment certificate under the conditions laid down in this Annex.

### **ATM/ANS.EQMT.CERT.010 Demonstration of capability**

*Regulation (EU) 2023/1768*

An applicant for an ATM/ANS equipment certificate shall hold a design organisation approval issued by the Agency in accordance with Implementing Regulation (EU) 2023/1769 that covers the respective ATM/ANS equipment.

### **ATM/ANS.EQMT.CERT.015 Application for an ATM/ANS equipment certificate**

*Regulation (EU) 2023/1768*

- (a) An application for an ATM/ANS equipment certificate, or for changes to it, shall be made in a form and manner established by the Agency.
- (b) An application for an ATM/ANS equipment certificate shall include, as a minimum:
  - (1) preliminary descriptive data of the ATM/ANS equipment and its intended use;
  - (2) a certification programme for the demonstration of compliance in accordance with point [ATM/ANS.EQMT.CERT.025](#), consisting of the following:
    - (i) a detailed description of the design, including all the configurations to be certified;
    - (ii) the proposed equipment characteristics and limitations;
    - (iii) the intended use of the ATM/ANS equipment;
    - (iv) a proposal for the initial certification basis, including applicable detailed certification specifications, proposed special conditions, proposed equivalent safety findings, as well as a proposed means of compliance and proposed deviations, as applicable, prepared in accordance with the requirements and options set out in point [ATM/ANS.EQMT.AR.B.001](#);



- (v) a proposal for a breakdown of the certification programme into subjective groups of compliance- demonstration activities and data, including a proposal for the means of compliance and related compliance- demonstration documents;
  - (vi) a proposal for the assessment of the subjective groups of compliance- demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the certification-basis requirements and the potential impact of that non-compliance on the ATM/ANS equipment; the proposed assessment shall take into account at least the elements set out in points (a)(2)(i) to (iv) of point [ATM/ANS.EQMT.AR.B.010](#); based on this assessment, the application shall include a proposal for the Agency's level of involvement in the verification of the compliance-demonstration activities and data;
  - (vii) a project schedule including the major milestones.
- (c) Following the initial submission of the application to the Agency, the applicant shall update the certification programme when there are changes to the certification project that affect any of points (b)(2)(i) to (vii).
- (d) An application for the issue of an ATM/ANS equipment certificate shall be valid for 5 years unless the applicant demonstrates at the time of the application that it requires a longer period of time to demonstrate compliance and the Agency agrees to extend that period of time.
- (e) In the case where an ATM/ANS equipment certificate has not been issued, or it is evident that it will not be issued, within the time limit provided for in point (d), the applicant may:
- (1) submit a new application and comply with the requirements for certification basis, as established and notified by the Agency in accordance with point [ATM/ANS.EQMT.AR.B.001](#) for the date of submission of the new application; or
  - (2) apply for an extension of the time limit provided for in point (d) and propose a new date for the issue of the certificate; in that case, the applicant shall comply with the requirements for certification basis, as established and notified by the Agency in accordance with point [ATM/ANS.EQMT.AR.B.001](#) for a date to be selected by the applicant; however, that date shall not precede the new date proposed by the applicant for the issue of the certificate by more than 5 years for an application for the issue of an ATM/ANS equipment certificate.

## GM1 ATM/ANS.EQMT.CERT.015(b)(2) Application for an ATM/ANS equipment certificate

*ED Decision 2024/001/R*

### DEFINITION OF CERTIFICATION PROGRAMME

The certification programme is a document used to establish a protocol of communication between the applicant and EASA in the context of certification of ATM/ANS equipment under Article 4 of Delegated Regulation (EU) 2023/1768, which allows to manage and control the evolving design, as well as the process of compliance demonstration and its verification.

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

## GM2 ATM/ANS.EQMT.CERT.015(b)(2) Application for an ATM/ANS equipment certificate

ED Decision 2024/001/R

### CONTENT OF THE CERTIFICATION PROGRAMME

The following information is typically included in a certification programme:

#### Description of the ATM/ANS equipment

An overview of the equipment will be provided, covering, as a minimum, the description of the following:

- type of system, architecture and functions;
- performance;
- dimensions, if applicable;
- materials, if applicable, and technologies;
- operational limitations;
- electronic hardware, and software;
- additional features, characteristics or functionalities not covered by applicable detailed specifications, as per point ATM/ANS.EQMT.AR.B.001(b);
- considerations of intended use of the equipment and operating characteristics; and
- other items, if considered to be more appropriate, that are relevant to the specific ATM/ANS equipment.

A special emphasis on novelties being part of the design (e.g. new technologies, new materials, etc.) and peculiarities of the configuration will be included. The certification programme must be detailed enough, in particular on aspects related to novelty and complexity, to allow EASA to properly estimate its level of involvement as required by point ATM/ANS.EQMT.AR.B.010.

#### Certification aspects

The following information related to certification will be provided:

- a proposal for the initial certification basis, in accordance with point ATM/ANS.EQMT.CERT.015(b)(2)(iv), including applicable detailed specifications, reference to special conditions, and reference to equivalent safety findings;
- a proposal for deviations that are requested at the time of establishing the certification programme, which provide an equivalent level of safety;
- a proposal for limitations that are expected at the time of establishing the certification programme; and
- the identification of applicable industry standards, certification memoranda, and guidance material. Where AMC to detailed specifications specifies a certain industry standard(s), and the applicant does not elect to comply with it (them) (partly or completely), the certification programme must identify the request to deviate from the AMC, propose alternative industry standard(s), and demonstrate its (their) equivalence.

For equipment embedding software, the description will identify the main failure conditions that will drive the architecture of the equipment, the classification of the software assurance level (SWAL) to use, and any associated assumption made to define the SWAL.

### **Equipment configuration**

The certification programme must define the equipment model name, part number, and provide the means to configure anticipated minor changes when previously agreed with EASA as part of the DPO change management procedure as required in point DPO.OR.B.005(b) of Implementing Regulation (EU) 2023/1769.

### **Demonstration of compliance**

The certification programme will include the following, as far as this information is available at the time of submission to EASA:

- the proposed means of compliance, and the related compliance document(s) as specified in Appendix 1;
- identification of technical procedures, technical documents and specifications that were followed in the demonstration of compliance;
- when the compliance demonstration involves testing, a description of the test article(s), test method(s), test location(s), test schedule, test house(s), test conditions, as well as of the intent/objective(s) of the testing; and
- when the compliance demonstration involves analyses/calculations, a description/identification of the tools (e.g. name and version/release of the software programmes) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose; furthermore, the validation and verification of such tools and methods will be addressed.

For every aspect mentioned above, the applicant will clearly identify whether the demonstration of compliance involves any method (analysis or test) which is novel to or unusual for the applicant.

The applicant will detail the list of documents generated during the development and that will be used to demonstrate compliance with the applicable certification basis.

The applicant will break down the certification programme into one or more meaningful groups of compliance-demonstration activities and data, in accordance with point ATM/ANS.EQMT.CERT.015(b)(2)(v), hereafter referred to as compliance-demonstration items (CDIs), and provide their proposal for EASA's Lol.

A CDI will be used as a meaningful group of compliance-demonstration activities and data identified in the certification programme which can be considered in isolation for the purpose of performing the certification risk assessment that allows EASA to determine its Lol using a risk-based approach.

The applicant must provide sufficient detailed information about the novelty, complexity, and criticality aspects of the proposed CDI.

### **Desing organisation and schedule aspects**

- Identification of the relevant personnel who make decisions affecting safety, security and interoperability, and who will interface with EASA, unless otherwise communicated to EASA (e.g. within the DPO procedures);
- A project schedule including the major milestones;
- Subcontracting arrangements for design and/or production.

## Appendix 1 to GM2 ATM/ANS.EQMT.CERT.015(b)(2) Application for an ATM/ANS equipment certificate

*ED Decision 2024/001/R*

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analysis
Tests	MC4: laboratory tests	
	MC5: tests on related ATM/ANS equipment	(g) Test programmes (h) Test reports (i) Test interpretations
	MC6: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC8: ATM/ANS equipment qualification	Note: Equipment qualification is a process that may include all previous means of compliance at equipment level.

## ATM/ANS.EQMT.CERT.020 Changes that require the issue of a new ATM/ANS equipment certificate

*Regulation (EU) 2023/1768*

An approved design organisation that proposes changes to ATM/ANS equipment shall apply for the issue of a new certificate where the changes in the design or the functionality of that ATM/ANS equipment are so extensive that a complete investigation of compliance with the applicable certification basis is required.

## ATM/ANS.EQMT.CERT.025 Demonstration of compliance with the ATM/ANS equipment certification basis

*Regulation (EU) 2023/1768*

- (a) An applicant shall, following the acceptance of the certification programme by the Agency, demonstrate compliance with the ATM/ANS equipment certification basis as established and notified to the applicant by the Agency in accordance with point [ATM/ANS.EQMT.AR.B.001](#), and shall provide the Agency with the means by which such compliance has been demonstrated.
- (b) An applicant for an ATM/ANS equipment certificate shall update the certification programme with the updated certification basis in case the Agency identifies the need for the applicant to do so following the initial submission established in accordance with point [ATM/ANS.EQMT.CERT.015](#).
- (c) An applicant shall report to the Agency any difficulty or event encountered during the process of demonstration of compliance that may have an appreciable effect on the assessment under point [ATM/ANS.EQMT.CERT.015](#)(b)(2)(vi) or on the certification programme or may otherwise require a change to the level of involvement of the Agency previously notified to the applicant in accordance with point [ATM/ANS.EQMT.AR.B.010](#)(b).
- (d) An applicant shall record demonstrations of compliance within the compliance documents as referred to in the certification programme.
- (e) Upon completion of all compliance-demonstration activities in accordance with the certification programme, including any inspections and tests carried out in accordance with point [ATM/ANS.EQMT.CERT.040](#), an applicant shall declare and submit in a form and manner established by the Agency that:
  - (1) it has demonstrated compliance with the certification basis, as established and notified by the Agency, following the certification programme as accepted by the Agency in accordance with point (a);
  - (2) no feature or characteristic has been identified that may render the ATM/ANS equipment unsuitable for its intended use.
- (f) The applicant shall demonstrate that the features, characteristics or functions that do not form part of the certification basis have no interference or detrimental effect on the suitability of the ATM/ANS equipment for its intended use.

## GM1 ATM/ANS.EQMT.CERT.025(e) Demonstration of compliance with the ATM/ANS equipment certification basis

*ED Decision 2024/001/R*

### DECLARATION AT THE END OF COMPLIANCE DEMONSTRATION

Upon completion of all compliance-demonstration activities, the DPO will provide a final declaration indicating that all compliance-demonstration activities have been performed in accordance with the certification programme. This declaration will be provided in the form of a document signed by the DPO accountable manager. The document will typically contain the following:

- a description of the final equipment configuration;
- a statement confirming the completion of all compliance-demonstration activities that are performed in accordance with the certification programme as accepted by the Agency;

- a list of all the applicable life cycle data that supports the demonstration of compliance;
- a list of the applicable deviations;
- a list of the applicable limitations;
- a declaration that:
  - it has demonstrated compliance with the certification basis, as established and notified by the Agency;
  - no feature or characteristic has been identified that may render the ATM/ANS equipment unsuitable for its intended use; and
  - the features, characteristics or functions that do not form part of the certification basis have no interference or detrimental effect on the suitability of the ATM/ANS equipment for its intended use.

### **ATM/ANS.EQMT.CERT.030 Means of compliance**

*Regulation (EU) 2023/1768*

- (a) The Agency shall develop acceptable means of compliance ('AMC') that may be used to establish compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (b) Alternative means of compliance may be used to establish compliance with this Regulation.

### **ATM/ANS.EQMT.CERT.035 ATM/ANS equipment design**

*Regulation (EU) 2023/1768*

- (a) The ATM/ANS equipment design shall consist of:
  - (1) the drawings and specifications, and a listing of those drawings and specifications, necessary to define the configuration and the design features shown to comply with the certification basis;
  - (2) information on the processes and methods of manufacture and assembly of the equipment necessary to ensure the conformity of the ATM/ANS equipment;
  - (3) an approved limitations section of the instructions for continued suitability as defined by the applicable detailed certification specifications;
  - (4) any other data that allows by comparison the determination of the suitability of the design.
- (b) Each design shall be adequately identified.

### **ATM/ANS.EQMT.CERT.040 Inspection and testing**

*Regulation (EU) 2023/1768*

- (a) Before each test is undertaken during the demonstration of compliance required by point [ATM/ANS.EQMT.CERT.025](#), the applicant shall have verified:
  - (1) for the test specimen, that:
    - (i) the standard parts, elements, configuration, coding and processes conform to the specifications for the proposed design;

- (ii) the developed ATM/ANS equipment conforms to the proposed design;
  - (iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed equipment design; and
- (2) for the test and the measuring equipment to be used for the test, that those are adequate for the test and appropriately calibrated.
- (b) On the basis of the verifications carried out in accordance with point (a), the applicant shall issue a statement of verification listing any potential non-conformity, together with a justification that this will not affect the test results and shall allow the Agency to perform any inspection it considers necessary to check the validity of that statement.
- (c) The applicant shall allow the Agency to:
  - (1) review any data and information related to the demonstration of compliance;
  - (2) witness or carry out any test or inspection conducted for the purpose of demonstration of compliance.
- (d) For all the tests and inspections witnessed by the Agency:
  - (1) the applicant shall submit to the Agency a statement of verification in accordance with point (b);
  - (2) no change that affects the validity of the statement of verification shall be made to the test specimen, or the test and measuring equipment, between the time the statement of verification provided for in point (b) was issued and the time the test specimen is presented to or witnessed by the Agency for testing.

## **ATM/ANS.EQMT.CERT.045 Record-keeping**

*Regulation (EU) 2023/1768*

In addition to the record-keeping requirements appropriate to or associated with the management system, all relevant design information, drawings and test reports, including inspection records and tests recorded, shall be made available by the certificate holder to the Agency and shall be retained in order to provide the information necessary to ensure the continued compliance.

## **ATM/ANS.EQMT.CERT.050 Manuals**

*Regulation (EU) 2023/1768*

The holder of an ATM/ANS equipment certificate shall produce, maintain and update master copies of all manuals required by the applicable certification basis, and provide copies, on request, to the Agency.

## **ATM/ANS.EQMT.CERT.055 Maintenance instructions**

*Regulation (EU) 2023/1768*

- (a) The holder of an ATM/ANS equipment certificate shall furnish at least one set of complete maintenance instructions, comprising descriptive data and accomplishment instructions prepared in accordance with the applicable certification basis, to all known users and shall make them available on request to any other person that is required to comply with any of these maintenance instructions.

- (b) Changes to the maintenance instructions shall be made available to all known users and shall be made available on request to any person that is required to comply with any of these maintenance instructions. A programme that shows how changes to the maintenance instructions are made available to all known users shall be submitted to the Agency.

## ATM/ANS.EQMT.CERT.060 Changes to the ATM/ANS equipment certification basis

*Regulation (EU) 2023/1768*

- (a) All changes shall be approved by the Agency once the certificate holder demonstrates that the changes, and the areas affected by the changes, comply with the certification basis as established by the Agency in accordance with point [ATM/ANS.EQMT.AR.B.001](#).
- (b) By way of derogation from point (a), the changes within the scope of the organisation's privileges following an approved change management procedure shall be managed by the approved design organisation and shall be limited to specific configuration(s) of the ATM/ANS equipment to which the changes relate.
- (c) For that purpose, the holder of an ATM/ANS equipment certificate shall have a system in place to identify the scope of the changes to ATM/ANS equipment as 'minor' and 'major'.
- (d) The changes shall be issued with a statement in accordance with point (b)(2) of point [DPO.OR.C.001](#) of the Annex II (Part-DPO.OR) to Implementing Regulation (EU) 2023/1769.

## ATM/ANS.EQMT.CERT.065 ATM/ANS equipment directives

*Regulation (EU) 2023/1768*

When an ATM/ANS equipment directive is issued to correct the condition referred to in point (b) of [ATM/ANS.EQMT.AR.A.030](#), the holder of the ATM/ANS equipment certificate, unless otherwise determined by the Agency in case urgent action is needed, shall:

- (a) propose appropriate corrective action and submit details of that proposal to the Agency for approval;
- (b) following the approval by the Agency, make available to all known users of the ATM/ANS equipment and to the competent authorities concerned, and if applicable and on request, to any person required to comply with the ATM/ANS equipment directive, appropriate descriptive data and accomplishment instructions.

## ATM/ANS.EQMT.CERT.070 Inspections performed by the Agency

*Regulation (EU) 2023/1768*

Upon the Agency's request, each organisation that holds a certificate issued by the Agency under this Annex shall:

- (a) grant the Agency access to any facility, equipment, document, record, data, process, procedure or any other material, and allow the Agency to review any report, make any inspection and perform or witness any test that is necessary to verify the compliance of the organisation with the applicable requirements of this Annex;
- (b) if the natural or legal person employs partners, suppliers or subcontractors, make arrangements with them to ensure that the Agency has access to them and may investigate as described in point (a).



## **ANNEX III — DECLARATION OF DESIGN COMPLIANCE OF THE ATM/ANS EQUIPMENT (PART-ATM/ANS.EQMT.DEC)**

### **ATM/ANS.EQMT.DEC.001 Scope**

*Regulation (EU) 2023/1768*

This Annex establishes the procedures for declaring compliance of the ATM/ANS equipment design, and establishes the rights and obligations of organisations involved in the design of ATM/ANS equipment that are authorised to issue declarations.

### **ATM/ANS.EQMT.DEC.005 Eligibility and demonstration of compliance**

*Regulation (EU) 2023/1768*

An organisation involved in the design of ATM/ANS equipment shall demonstrate its capability to declare the compliance of the design of certain ATM/ANS equipment by holding an organisation approval issued by the Agency in accordance with Implementing Regulation (EU) 2023/1769, as specified in the terms of the organisation approval.

### **ATM/ANS.EQMT.DEC.010 Declaration of design compliance of the ATM/ANS equipment**

*Regulation (EU) 2023/1768*

An approved organisation shall submit to the Agency a dated and signed declaration of compliance of the design of certain ATM/ANS equipment. The declaration shall contain at least the following information:

- (a) description of the design, including all the configurations;
- (b) the rated performance of the equipment, where appropriate, either directly or by reference to other supplementary documents;
- (c) a statement of compliance certifying that the equipment meets the applicable specifications, and a list of the declaration specifications and special conditions, as applicable;
- (d) reference to relevant supporting evidence, including test reports;
- (e) reference to the appropriate operation, set-up and maintenance manuals;
- (f) the levels of compliance, where various levels of compliance are allowed by the declaration specifications;
- (g) list of deviations, as applicable.

## ATM/ANS.EQMT.DEC.015 Means of compliance

*Regulation (EU) 2023/1768*

- (a) The Agency shall develop acceptable means of compliance ('AMC') that may be used to establish compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (b) Alternative means of compliance may be used to establish compliance with this Regulation.

## ATM/ANS.EQMT.DEC.020 Changes to the declaration of ATM/ANS equipment design

*Regulation (EU) 2023/1768*

- (a) An approved organisation involved in the design of ATM/ANS equipment may make changes to the design that are within the scope of the approved organisation's privileges. In this case, the changed equipment shall keep its original part number.
- (b) Any change to the design that is within the scope of the approved organisation's privileges and that is extensive enough to require a complete investigation in accordance with point [ATM/ANS.EQMT.AR.B.020](#) to determine its compliance shall require the assignment of a new model designation to the equipment.

## ATM/ANS.EQMT.DEC.025 Record-keeping

*Regulation (EU) 2023/1768*

In addition to the record-keeping requirements appropriate to or associated with the management system, all relevant design information, drawings and test reports, including inspection records for the equipment tested, shall be made available to the Agency and shall be retained in order to provide the information necessary to ensure the continued suitability of the ATM/ANS equipment.

## ATM/ANS.EQMT.DEC.030 Manuals

*Regulation (EU) 2023/1768*

The organisation involved in the design of ATM/ANS equipment, which has made the declaration shall produce, maintain and update master copies of all manuals identified in the declaration, and provide copies, on request, to the Agency.

## ATM/ANS.EQMT.DEC.035 Maintenance instructions

*Regulation (EU) 2023/1768*

- (a) The design organisation which has made the declaration shall furnish at least one set of complete maintenance instructions, comprising descriptive data and accomplishment instructions prepared in accordance with the specifications applicable to the ATM/ANS equipment covered by the declaration, to all known users and shall make them available on request to any other person that is required to comply with any of the terms of these maintenance instructions.
- (b) Changes to the maintenance instructions shall be made available to all known users and shall be made available on request to any person that is required to comply with any of these maintenance instructions. A programme that shows how changes to the maintenance

instructions are made available to all known users shall be submitted to the Agency upon request.

## **ATM/ANS.EQMT.DEC.040 ATM/ANS equipment directives**

*Regulation (EU) 2023/1768*

When an ATM/ANS equipment directive is issued to correct the condition referred to in point (b) of [ATM/ANS.EQMT.AR.A.030](#), the declarant of the design compliance of the ATM/ANS equipment shall, unless otherwise determined by the Agency in case urgent action is needed, shall:

- (a) propose appropriate corrective action and submit details of that proposal to the Agency for approval;
- (b) following the approval by the Agency, make available to all known users of the equipment and to the competent authorities concerned, if applicable, and, on request, to any person required to comply with the ATM/ANS equipment directive, appropriate descriptive data and accomplishment instructions.

## **ATM/ANS.EQMT.DEC.045 Inspections performed by the Agency**

*Regulation (EU) 2023/1768*

Upon the Agency's request, each organisation that is authorised to issue a declaration in accordance with this Regulation shall:

- (a) grant the Agency access to any facility, equipment, document, record, data, process, procedure or any other material, and allow the Agency to review any report, make any inspection and perform or witness any test that is necessary to verify the compliance and the continued compliance of the organisation with the applicable requirements of this Annex;
- (b) if the natural or legal person uses partners, suppliers or subcontractors, make arrangements with them to ensure that the Agency has access to them and may investigate as provided for in point (a).