



Brussels, **XXX**
[...](2023) **XXX** draft

Annex to EASA Opinion No 01/2023

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

**laying down common technical requirements and administrative procedures for the
conformity assessment of ATM/ANS systems and ATM/ANS constituents**

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

The Single European Sky (SES) initiative was launched in 2004 with the aim of improving the performance of the European ATM system in terms of safety, capacity, cost-efficiency, and environmental compatibility. These elements remain as valid today as they were back then. Stressing the importance of that aim, it is acknowledged that the effective introduction of new technologies plays a crucial role in ensuring that the future ATM system will continue to efficiently support air traffic, including new categories of airspace users such as drones. Besides, ATM/ANS will increasingly rely on digital technologies and automation, and the conformity assessment of the related ATM/ANS equipment will require very specialised capabilities both for industry actors and national competent authorities and the Agency.

The EASA Basic Regulation (Regulation (EU) 2018/1139)⁽¹⁾ lays down interoperability requirements for the European Air Traffic Management network (EATMN) and mandates the development of the related delegated act as regards the conformity assessment (i.e. certification or declaration) of ATM/ANS systems and ATM/ANS constituents.

At the same time, Regulation (EC) No 552/2004⁽²⁾ (the interoperability Regulation) was repealed by the Basic Regulation, but Article 139 of the Basic Regulation establishes the transitional provisions whereby certain articles of the interoperability Regulation and its annexes remain applicable until the date of application of the related delegated acts and insofar as those acts cover the subject matter of the relevant provisions of the interoperability Regulation, and in any case not later than 12 September 2023.

In this context, it is necessary to introduce a new regulatory framework in relation to ATM/ANS systems and ATM/ANS constituents (referred to as ‘ATM/ANS equipment’) that ensures the safe, interoperable, and efficient provision of ATM/ANS services.

The requirements proposed would establish the criteria and conditions to determine the need for certification or for declaration of certain ATM/ANS equipment based on its safety criticality and benefits for the relevant stakeholders.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 128(4) of the Basic Regulation, before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. The present draft delegated act was presented to the Air Safety experts group, which includes representatives from the Member States, at its meeting on [...]. The present draft delegated act is based on EASA Opinion No XX/2023 whose contents had been publicly consulted through Notice of Proposed Amendment (NPA) 2022-09 ‘Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and ATM/ANS

¹ [OJ L 212, 22.8.2018, p. 1](#)

² [OJ L 96, 31.3.2004, p. 26](#)

constituents (ATM/ANS equipment)' (RMT.0161 Subtask 1), published by EASA on 16 August 2022.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 47(1) of the Basic Regulation empowers the Commission to adopt delegated acts, in accordance with Article 128 of that Regulation, laying down detailed rules with regard to:

- the conditions for establishing and notifying to an applicant the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents for the purposes of certification in accordance with Article 45(2) of that Regulation;
- the conditions for issuing, maintaining, amending, limiting, suspending or revoking the certificates referred to in Article 45(2) of the same Regulation, and for the situations in which, with a view to achieving the objectives set out in Article 1 of that Regulation and while taking account of the nature and risk of the particular activity concerned, such certificates are to be required or declarations are to be permitted, as applicable;
- the privileges and responsibilities of the holders of certificates referred to in Article 45(2) of that Regulation;
- the privileges and responsibilities of the organisations issuing declarations in accordance with Article 45(1) and (2) of that Regulation;
- the conditions and procedures for the declaration by ATM/ANS providers, in accordance with Article 45(1), and for the situations in which, with a view to achieving the objectives set out in Article 1 of that Regulation and while taking account of the nature and risk of the particular activity concerned, such declarations are to be required;
- the conditions for establishing the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents which are subject to a declaration in accordance with Article 45(1) and (2) of that Regulation.

In addition, under Article 62(13), with regard to the tasks of the Agency related to certification, oversight and enforcement under the Basic Regulation, the Commission is empowered to adopt delegated acts, in accordance with Article 128 of that Regulation, laying down detailed rules concerning the conditions for conducting certification and for conducting the investigations, inspections, audits and other monitoring activities necessary to ensure effective oversight by the Agency of the natural and legal persons, ATM/ANS systems and ATM/ANS constituents, subject to the referenced Regulation.

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

laying down common technical requirements and administrative procedures for the conformity assessment of ATM/ANS systems and ATM/ANS constituents

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 ⁽³⁾, and in particular Articles 47(1), 62(13) and 68(3) thereof,

Whereas:

- (1) Regulation (EU) 2018/1139 establishes common essential requirements to provide for a high uniform level of civil aviation safety in the Union; it requires the necessary detailed rules to be adopted, taking into account the objectives of Regulation (EU) 2018/1139 and the nature and risk of the particular activity concerned; it establishes the European Union Aviation Safety Agency (hereinafter referred to as the ‘Agency’).
- (2) For the ATM/ANS systems and ATM/ANS constituents, the Commission is empowered under Article 47(1) of Regulation (EU) 2018/1139 to adopt delegated acts, in accordance with Article 128 of the same Regulation, laying down detailed rules with regard to the conditions for establishing and notifying to an applicant the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents for the purposes of certification in accordance with Article 45(2) of the same Regulation; the conditions for issuing, maintaining, amending, limiting, suspending or revoking the certificates referred to in Article 45(2) of Regulation (EU) 2018/1139, and for the situations in which, with a view to achieving the objectives set out in Article 1 and while taking account of the nature and risk of the particular activity concerned, such certificates are to be required or declarations are to be permitted, as applicable; the privileges and responsibilities of the holders of certificates referred to in Article 45(2) of Regulation (EU) 2018/1139; the privileges and responsibilities of the organisations issuing declarations in accordance with Article 45(1) and (2) of Regulation (EU) 2018/1139; the conditions and procedures for the declaration by ATM/ANS providers, in accordance with Article 45(1) of Regulation (EU) 2018/1139, and for the situations in which, with a view to achieving the objectives set out in Article 1 and while taking account of the nature and risk of the particular activity concerned such declarations are to be required; the conditions for establishing the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents which are subject to a declaration in accordance with Article 45(1) and (2) of Regulation (EU) 2018/1139.
- (3) With regard to the tasks of the Agency related to certification, oversight and enforcement under Regulation (EU) 2018/1139, the Commission is empowered under

Article 62 (13) of the same Regulation to adopt delegated acts, in accordance with Article 128 of the same Regulation, laying down detailed rules concerning the conditions for conducting certification and for conducting the investigations, inspections, audits and other monitoring activities necessary to ensure effective oversight by the Agency of the natural and legal persons, ATM/ANS systems and ATM/ANS constituents subject to Regulation (EU) 2018/1139; the conditions and procedures for the accreditation by the Agency of a qualified entity for the purpose of Article 69 to Regulation (EU) 2018/1139.

- (4) With regard to acceptance of third-country certificates, the Commission is empowered under Article 68(3) of Regulation (EU) 2018/1139 to adopt delegated acts in accordance with Article 128 of the same Regulation laying down detailed rules with regard to the acceptance of certificates and other documentation attesting compliance with civil aviation rules issued in accordance with the laws of a third country and ensuring an equivalent level of safety to that provided for in Regulation (EU) 2018/1139, including the conditions and procedures for achieving and maintaining the necessary confidence in regulatory systems of third countries.
- (5) The need to ensure uniformity in the application of common requirements for ATM/ANS systems and ATM/ANS constituents requires that common procedures be followed by the Agency, as applicable, and the competent authorities of the Member States, where applicable, to assess compliance with these requirements; the Agency should develop detailed specifications and guidance material to facilitate the necessary regulatory uniformity.
- (6) The Agency may either issue the certificates provided for in Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, or on the basis of certificates issued in accordance with the laws of a third country or accept certificates and other relevant documentation attesting compliance with civil aviation rules which were issued in accordance with the laws of a third country, if such possibility is provided in a delegated act adopted by the Commission in accordance with Article 68(3) of Regulation (EU) 2018/1139.
- (7) It is necessary to permit a smooth transition to the new regulatory framework of the Agency ensuring that a high and uniform level of civil aviation safety in the Union is maintained; it is necessary to provide sufficient time for the ATM/ANS systems and ATM/ANS constituents industry, the Agency and Member State administrations to adapt to this new framework.
- (8) The measures provided for in this Regulation are based on Opinion No xx/2023, issued by the European Union Aviation Safety Agency in accordance with Article 75(2)(b) and (c) and Article 76(1) of Regulation (EU) 2018/1139.
- (9) In accordance with Article 128(4) of Regulation (EU) 2018/1139, the Commission consulted experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down common technical requirements and administrative procedures for the certification and declaration of compliance of the design of ATM/ANS systems and ATM/ANS constituents, i.e. ‘ATM/ANS equipment’, specifying:

1. the identification of ATM/ANS equipment subject to certification, declaration, or a statement of compliance;
2. the issue of certificates for ATM/ANS equipment;
3. the making of a declaration of compliance of the design of ATM/ANS equipment by an organisation involved in the design and/or production of ATM/ANS equipment approved in accordance with Implementing Regulation (EU) .../... [implementing act on DPO approval] to have the privileges to issue such declarations of compliance;
4. the issue of a statement of compliance of ATM/ANS equipment by an ATM/ANS provider certified in accordance with Implementing Regulation (EU) 2017/373;
5. the issue of ATM/ANS equipment directives by the Agency.

Article 2

Definitions

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;
2. ‘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.

Article 3

Competent authority

1. The competent authority responsible for the issue of certificates for ATM/ANS equipment in accordance with Article 4 of this Regulation, and for the acceptance of declarations of compliance of the design of ATM/ANS equipment in accordance with Article 5 of this Regulation and for the oversight thereof shall be the Agency pursuant to Article 80(2)(c) of Regulation (EU) 2018/1139. For that purpose, the Agency shall comply with the requirements laid down in Annex II to this Regulation.
2. The competent authority responsible for the oversight of the statements of compliance issued by an ATM/ANS provider in accordance with Article 6 of this Regulation shall be the competent authority responsible for the certification and oversight of that ATM/ANS provider in accordance with Article 4(1) of Implementing Regulation (EU) 2017/373.

Article 4

Certification of ATM/ANS equipment

1. ATM/ANS equipment supporting the functions and services as listed in Annex I, when comprising functionalities for controller–pilot communications and for the separation of

aircraft and the prevention of collisions, shall be issued with a certificate by the Agency as specified in Annex III to this Regulation.

2. A certificate for ATM/ANS equipment shall be issued for an unlimited duration. It shall remain valid subject to the following conditions:
 - (a) the certificate holder remains in compliance with the requirements of this Regulation and, for ATM/ANS equipment, continuously demonstrates its capability by holding an organisation approval issued by the Agency in accordance with **Implementing Regulation (EU) .../... [implementing act on DPO approval]**;
 - (b) the certificate holder ensures the continuous demonstration of compliance of the ATM/ANS equipment with its certification basis in accordance with point ATM/ANS.EQMT.CERT.025; and
 - (c) the certificate has not been surrendered by its holder or revoked by the Agency.
3. Upon surrender or revocation of the certificate, if issued in a paper format, it shall be returned to the Agency without delay.

Article 5

Declaration of design compliance of the ATM/ANS equipment

1. ATM/ANS equipment supporting the functions and services as listed in Annex I, 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 specified in Annex IV to this Regulation by an organisation involved in the design and/or production of ATM/ANS equipment approved in accordance with **Implementing Regulation (EU) .../... [implementing act on DPO approval]** to have the privilege to issue such declarations.
2. A declaration of compliance of the design of the ATM/ANS equipment shall be issued for an unlimited duration. It shall remain valid unless it has been deregistered in accordance with point (g)(6) of point ATM/ANS.EQMT.AR.C.050 of Annex II as a result of the following:
 - (a) the ATM/ANS equipment no longer conforms with the applicable technical specifications against which the declaration has been made; or
 - (b) the issuer of the declaration no longer remains in compliance with the applicable requirements of **Implementing Regulation (EU) .../... [implementing act on DPO approval]** or its approval has been surrendered, suspended or revoked; or
 - (c) the ATM/ANS equipment has proved to give rise to unacceptable risk or unacceptable performance in service; or
 - (d) the organisation has withdrawn the declaration of compliance.

Article 6

Statement of compliance

1. ATM/ANS equipment which is neither subject to certification in accordance with Article 4 of this Regulation nor to a declaration of compliance in accordance with Article 5 of this Regulation and supporting the functions and services as listed in Annex

I shall be issued with a statement of compliance by the ATM/ANS provider or by an organisation involved in the design and/or production of ATM/ANS equipment approved in accordance with Implementing Regulation (EU) .../... [implementing act on DPO approval] confirming that the ATM/ANS equipment complies with the technical standards established by recognised standardisation bodies and listed in detailed specifications adopted 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 for an unlimited duration. It shall remain valid unless:
 - (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; or
 - (b) the ATM/ANS provider no longer remains in compliance with the applicable requirements of Implementing Regulation (EU) 2017/373 or it has surrendered the certificate, or the certificate has been suspended or revoked; or
 - (c) the ATM/ANS equipment has proved to give rise to unacceptable risk or unacceptable performance in service; or
 - (d) 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 Regulation (EU) 2017/373.

Article 7

Third-country organisations involved in the design and/or production of ATM/ANS equipment

An organisation whose principal place of business is in a third country, may demonstrate its capability by holding a certificate issued by that third country that covers the ATM/ANS equipment for the certification of which that organisation applies to the Agency in accordance with Article 4, provided that the Agency has determined that the system of that third country includes the same independent level of checking of compliance as provided for by **Implementing Regulation (EU) .../... [implementing act on DPO approval]**, either through an equivalent system of approvals of organisations or through the direct involvement of the competent authority(ies) of that third country. In such case that organisation shall be considered as a design organisation approval holder for the purpose of this Regulation.

Article 8

Transitional provisions

1. The following transitional provisions shall apply to ATM/ANS equipment with EC declarations issued in accordance with Article 5 or Article 6 of Regulation (EC) No

552/2004³ and that has been manufactured or put in operation by an ATM/ANS provider 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 of this Regulation shall, on a provisional basis, be deemed to have been issued with a certificate in accordance with Article 4 of this Regulation unless the Agency determines, following the evaluation referred to in point 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 requires declaration in accordance with Article 5 of this Regulation shall, on a provisional basis, be deemed to have been issued with a declaration of compliance in accordance with Article 5 of this Regulation unless the Agency determines, following the evaluation referred to in point 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 falls within the category of ATM/ANS equipment subject to a statement of compliance in accordance with Article 6 of this Regulation, 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 and shall be deemed to be a statement of compliance pursuant to Article 6 of this Regulation.
2. The Agency shall evaluate the ATM/ANS equipment referred to in points 1(a) and 1(b) within [5 years] from the date of entry into force of this Regulation.
- 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 that the particular ATM/ANS equipment ensures a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation.
3. ATM/ANS equipment that is subject to certification in accordance with Article 4 or a declaration in accordance with Article 5 of this Regulation may also be put into operation from [the date of entry into force of this Regulation] until [12 September 2028] subject to a statement of compliance issued in accordance with Article 6 of this Regulation. With effect from [13 September 2028], the following provisions shall apply to such ATM/ANS equipment:
- (a) ATM/ANS equipment which falls within the category of ATM/ANS equipment that requires certification in accordance with Article 4 of this Regulation and for which

³ 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 (the interoperability Regulation) (OJ L 96, 31.3.2004, p. 26)

a statement of compliance was issued by the ATM/ANS provider shall, on a provisional basis, be deemed to have been issued with a certificate in accordance with Article 4 of this Regulation unless the Agency determines, following the evaluation referred to in point (c), 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 of this Regulation and for which a statement of compliance was issued by the ATM/ANS provider shall, on a provisional basis, be deemed to have been issued with a declaration of design compliance in accordance with Article 5 of this Regulation unless the Agency determines, following the evaluation referred to in point (c) 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) The Agency shall evaluate the ATM/ANS equipment referred to in points 3(a) and 3(b) 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 that 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.

Article 9

Entry into force

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

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

Done at Brussels,

For the Commission
The President
[...]

ANNEX I

ATM/ANS EQUIPMENT SUBJECT TO CONFORMITY ASSESSMENT

		<i>Article 4</i> <u>Certifiable</u> ATM/ANS equipment	<i>Article 5</i> <u>Declarable</u> ATM/ANS equipment	<i>Article 6</i> <u>SoC</u> ATM/ANS equipment
The ATM/ANS equipment shall include in particular those required to support the following functions and services:				
1.	Airspace management			X
2.	Air traffic flow management			X
3.	Air traffic services, in particular flight data processing systems, surveillance data processing systems and human-machine interface systems;	X		
4.	Communications including ground-to-ground/space, air-to-ground and air-to-air/space communications			
4a	<i>Ground-to-ground communications</i>		X	
4b	<i>Air-to-ground communications</i>	X		
5.	Navigation		X	
6.	Surveillance		X	
7.	Aeronautical information services			X
8.	Meteorological services			X

ANNEX II

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

This Annex establishes the requirements for the administration and management systems of the Agency for the certification, registration of declarations, oversight and enforcement of ATM/ANS equipment when it exercises its tasks and responsibilities set out in Annexes III and IV to this Regulation with regard to:

- (a) the issue, maintenance, amendment, limitation, suspension or revocation of certificates for ATM/ANS equipment;
- (b) the verification of declarations for ATM/ANS equipment and their registrations;
- (c) the approval, oversight and enforcement in respect of the fulfilment of the requirements set out in the Annex (Part-DPO.OR) to Implementing **Regulation (EU) .../...** *[implementing act on DPO approval]* by organisations involved in the design and/or production of ATM/ANS equipment.

ATM/ANS.EQMT.AR.A.005 Certification, oversight and enforcement documentation

The Agency shall make available to its staff all applicable legislative acts, standards, rules, technical publications and related documentation to allow them to perform their tasks and discharge their responsibilities.

ATM/ANS.EQMT.AR.A.010 Exchange of information between the competent authorities and the Agency

- (a) The competent authorities referred to in Article 4 of Implementing Regulation (EU) 2017/373 and the Agency shall exchange the information which is available to them through their investigations conducted and oversight performed, and which is relevant for the other party when performing certification, oversight or enforcement tasks under this Regulation.
- (b) The competent authority of the Member State referred to in Article 4(1) of Implementing Regulation (EU) 2017/373 and the Agency shall coordinate a product-focused investigation and oversight of the ATM/ANS equipment designed and produced in accordance with this Regulation, including, where necessary, the performance of joint oversight visits.

ATM/ANS.EQMT.AR.A.015 Means of compliance

- (a) The Agency shall develop acceptable means of compliance (AMC) that may be used to demonstrate compliance with Regulation (EU) 2018/1139 and this Regulation.

- (b) Alternative means of compliance (AltMoC) may be used to demonstrate compliance with Regulation (EU) 2018/1139 and this Regulation.
- (c) The Agency shall establish a system to consistently evaluate that all alternative means of compliance used by organisations under its oversight allow for the establishment of compliance with Regulation (EU) 2018/1139 and this Regulation.
- (d) The Agency shall evaluate all AltMoC proposed by an organisation involved in the design and/or production of ATM/ANS equipment in accordance with point **DPO.OR.A.015 of the Annex to Implementing Regulation (EU) .../... [implementing act on DPO approval]** by analysing the documentation provided and, if considered necessary, conducting an inspection of the organisation.
- (e) When the Agency finds that the AltMoC are in compliance with Regulation (EU) 2018/1139 and this Regulation, it shall without undue delay notify the organisation that the proposed AltMoC may be used and, if applicable, amend the approval or certificate of the organisation accordingly.

ATM/ANS.EQMT.AR.A.020 Immediate reaction to a safety, security and interoperability problem

- (a) Without prejudice to Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on its basis, the Agency shall implement a system to appropriately collect, analyse, and disseminate safety, security and/or interoperability information.
- (b) Upon receiving the information referred to in point (a), the Agency shall take appropriate measures to address the safety security, and/or interoperability problem, including the issue of ATM/ANS equipment directives in accordance with point **ATM/ANS.EQMT.AR.A.030**.
- (c) The measures taken under point (b) shall immediately be notified to the organisation concerned to comply with them, in accordance with point **DPO.OR.A.035 of the Annex to Implementing Regulation (EU) .../... [implementing act on DPO approval]**. The competent authorities of the ATM/ANS providers concerned shall also be notified.

ATM/ANS.EQMT.AR.A.025 Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

- (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.

- (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 its delegated and implementing acts. The Agency shall also notify those measures, when combined action is required, to the competent authorities of the Member States concerned.

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

- (a) ‘ATM/ANS equipment directive’ means a document issued by the Agency that is responsible for the oversight of ATM/ANS equipment subject to certification issued in accordance with Article 4 or subject to declaration declared in accordance with Article 5, 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.
- (b) The Agency shall issue an ATM/ANS equipment directive when:
 - (a) an unsafe, insecure, underperformance or non-interoperability condition has been determined to exist in the equipment as a result of a deficiency in the equipment; and
 - (b) that condition is likely to exist or develop in other ATM/ANS equipment.
- (c) An ATM/ANS equipment directive shall contain at least the following information:
 - (1) identification of the unsafe, 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.

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

- (a) The Agency, in accordance with Article 76(3) of Regulation (EU) 2018/1139, shall establish and make available detailed technical specifications which organisations may use to demonstrate compliance with the relevant essential requirements set out in Annex VIII and, if applicable, Annex VII to that Regulation when they:
 - (1) apply for the certification of ATM/ANS equipment in accordance with Annex III to this Regulation;
 - (2) declare compliance of ATM/ANS equipment in accordance with Annex IV to this Regulation;
 - (3) make a statement of compliance in accordance with Article 6 of this Regulation and with point ATM/ANS.OR.A.045(g)(3) of Regulation (EU) 2017/373.

- (b) The detailed technical specifications referred to in point (a) shall provide design standards which reflect the state of the art and best design practices, and which build on valuable experience gained and scientific and technical progress, and on the best available evidence and analyses as regards ATM/ANS equipment.

SUBPART B — MANAGEMENT (ATM/ANS.EQMT.AR.B)

ATM/ANS.EQMT.AR.B.001 Management system

- (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 Regulation (EU) No 376/2014 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 Implementing Regulation (EU) 2017/373 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.040 of the Annex to Implementing Regulation (EU) .../... [implementing act on DPO approval]**.

- (d) In addition to the requirements contained in point (a), the management system established and maintained by the Agency shall comply with Annex I (Part-IS.AR) of Implementing Regulation (EU) 202X/XXXX [*on the basis of Opinion No 03/2021*] in order to ensure the proper management of information security risks which may have an impact on aviation safety.

ATM/ANS.EQMT.AR.B.005 Allocation of tasks to qualified entities

- (a) The Agency may allocate its tasks related to the certification or the continuing oversight of organisations subject to Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis to qualified entities. When allocating its tasks, the Agency shall ensure that it has:
- (1) put a system in place to initially and continuously assess that the qualified entity(ies) complies (comply) with Annex VI to Regulation (EU) 2018/1139; this system and the results of the assessments shall be documented;
 - (2) established and documented an agreement with the qualified entity(ies), approved by both parties at the appropriate management level, which clearly defines:
 - (i) the tasks to be performed;
 - (ii) the declarations, reports and records to be provided;
 - (iii) the technical conditions to be met when performing the tasks;
 - (iv) the related liability coverage; and
 - (v) 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 ATM/ANS.EQMT.AR.B.001(a)(5) 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) to Regulation (EU) 2023/XXX [*laying down technical requirements and administrative procedures for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents*], 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 European 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 ATM/ANS.EQMT.AR.B.001(d) covers all the certification and continuing oversight tasks performed on its behalf.

ATM/ANS.EQMT.AR.B.010 Changes in the management system

- (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 defined in Regulation (EU)

2018/1139 and Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on their bases. 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 Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on their bases, in a timely manner, so as to ensure the effective implementation of its management system.

ATM/ANS.EQMT.AR.B.015 Record-keeping

- (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 **ATM/ANS.EQMT.AR.B.001(a)(3)**;
 - (3) the allocation of tasks, covering the elements required by point ATM/ANS.EQMT.AR.B.005, as well as the details of the allocated tasks;
 - (4) the approval process as regards organisations involved in the design and/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 and/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 compliance of ATM/ANS equipment design 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 AltMoC proposed by organisations involved in the design and/or production of ATM/ANS equipment and the assessment of these AltMoC;
 - (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 5 years after the approval(s) and certificate(s) cease to be valid or the declaration(s) is(are) withdrawn, subject to the applicable data protection law.
 - (d) All the records referred to in points (a) and (b) shall be made available upon request to the competent authorities referred to in Article 4 of Implementing Regulation (EU) 2017/373.

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

ATM/ANS.EQMT.AR.C.001 ATM/ANS equipment certification basis

- (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 Article 76(3) of Regulation (EU) 2018/1139 and point ATM/ANS.EQMT.AR.A.035 of this Annex, which 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 as per point ATM/ANS.EQMT.CERT.015(e) with a detailed certification specification, as per point ATM/ANS.EQMT.AR.C.005, which became applicable after the date of the submission of the application; if the applicant chooses to comply with a certification specification which became applicable after the date of the submission of the application, the Agency shall include it in the ATM/ANS equipment certification basis; or
 - (ii) the Agency accepts any alternative to a determined certification specification that cannot be complied with, for which compensating factors have been found to ensure equivalence with the applicable certification or declaration specification(s); and
 - (2) any special conditions prescribed by the Agency in accordance with point ATM/ANS.EQMT.AR.C.005.
- (b) The possible inclusion of additional features, characteristics or functions not initially included in the certification basis shall be agreed by the Agency.

ATM/ANS.EQMT.AR.C.005 Special conditions

- (a) The Agency shall prescribe additional requirements, named ‘special conditions’, for ATM/ANS equipment if the related applicable certification specifications are not deemed adequate because:
- (1) the ATM/ANS equipment has novel or unusual design features relative to the design practices on which the applicable certification specifications are based;
 - (2) the intended use of the 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; or

- (4) the environment at the location of installation physically prevents the fulfilment of certain requirements of the applicable certification 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 certification specifications.

ATM/ANS.EQMT.AR.C.010 Level of involvement

- (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 the following:
 - (1) the likelihood of an unidentified non-compliance with the certification basis; and
 - (2) the potential impact of that non-compliance on safety, service specifications and functioning of the ATM/ANS equipment,
and 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; and
 - (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.A.015 Issue of an ATM/ANS equipment certificate

- (a) The Agency shall issue a certificate for ATM/ANS equipment, provided that:
 - (1) the applicant has demonstrated compliance with point ATM/ANS.EQMT.CERT.015;
 - (2) the Agency, through the verification of the demonstration of compliance in accordance with its level of involvement determined in accordance with point ATM/ANS.EQMT.AR.C.010, has not identified any non-compliance with the certification basis; and

- (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 for the product in the applicable certification specifications and special conditions.

ATM/ANS.EQMT.AR.C.020 Initial oversight investigation of declaration of design compliance of the ATM/ANS equipment

- (a) Upon receiving a declaration of compliance of the ATM/ANS equipment design from an organisation involved in the design of ATM/ANS equipment and approved by the Agency in accordance with Implementing Regulation (EU) .../... [implementing act on DPO approval], the Agency shall verify that:
 - (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 specified in point ATM/ANS.EQMT.DEC.010; and
 - (3) the declaration does not contain information that indicates a non-compliance with the applicable requirements of Annex IV to this Regulation and no feature or characteristic has been identified that may render the ATM/ANS equipment unsafe for the intended use.
- (b) The ATM/ANS equipment design compliance declaration shall include the operating limitations, the data sheet for continued suitability, the applicable specifications with which the organisation has demonstrated compliance, and any other conditions or limitations prescribed for the product in the applicable certification 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 declaration specification, 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.C.025 Registration of a declaration of design compliance of ATM/ANS equipment

The Agency shall register a declaration of design compliance 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 IV to this Regulation;

- (c) there are no unresolved issues in accordance with point ATM/ANS.EQMT.AR.C.020.

ATM/ANS.EQMT.AR.C.030 Issue of approvals to organisations involved in the design and/or production of ATM/ANS equipment

- (a) Upon receiving an application for the issue of an approval to an organisation involved in the design and/or production of ATM/ANS equipment, the Agency shall verify the organisation's compliance with the applicable requirements laid down in Implementing Regulation (EU) .../... [implementing act on DPO approval] and in Annexes III and IV 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 certificate holder is entitled to exercise the privileges.
- (d) The certificate shall not be issued where a level 1 finding 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 certificate.
- (e) Each change to the approval and to its conditions shall be approved by the Agency.

ATM/ANS.EQMT.AR.C.035 Oversight programme

- (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 and/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; and

- (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 of the Annex to Implementing Regulation (EU) .../... [implementing act on DPO approval]**;
- (ii) no level 1 findings have been issued;
- (iii) all corrective actions have been implemented within the time period accepted or extended by the Agency as defined in point ATM/ANS.EQMT.AR.C.050.

If, in addition to the above, 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;
 - (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 any.
- (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 ATM/ANS.EQMT.AR.C.050 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.

ATM/ANS.EQMT.AR.C.040 Changes to declarations

- (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.C.020.
- (b) When the change(s) affects (affect) any aspect of the declaration that is registered in accordance with point ATM/ANS.EQMT.AR.C.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 and/or production of ATM/ANS equipment.

ATM/ANS.EQMT.AR.C.045 Changes to the information security management system

- (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) 202X/XXXX *[on the basis of Opinion No 03/2021]*, the Agency shall include the review of such changes in its continuing oversight programme in accordance with the principles laid down in point ATM/ANS.EQMT.AR.C.035. If any non-compliance is found, the Agency shall notify the organisation thereof, request further changes and act in accordance with point ATM/ANS.EQMT.AR.C.050.
- (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) 202X/XXXX *[on the basis of Opinion No 03/2021]*:
 - (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.

ATM/ANS.EQMT.AR.C.050 Findings, corrective actions, and enforcement measures

- (a) When the Agency, during investigation or oversight or by any other means, identifies a non-compliance with the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis of a procedure or manual required by that Regulation, or of a certificate or declaration issued in accordance with that Regulation, it shall, without prejudice to any additional action required by that Regulation, raise a finding.
- (b) The Agency shall have a system in place to analyse findings for their safety and interoperability significance and identify appropriate enforcement measures, including the suspension or revocation of approvals and certificates, and 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 any significant non-compliance is identified which may lead to an uncontrolled non-compliance and to a potential unwanted condition as per point ATM/ANS.EQMT.AR.C.001.

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 when any other non-compliance is identified with the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis, with the procedures and manuals required by that Regulation, or with the approval issued in accordance with that Regulation, which is not classified as level 1 finding.
- (e) When a finding is raised, during oversight or by any other means, 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 to the organisation concerned in writing 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 included in 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, 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;
 - (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) not register a declaration of design compliance as long as there are unresolved findings from the initial oversight investigation;

- (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 a 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 it to the addressee, state the reasons for it, and inform the addressee of its right to appeal.

Appendix 1

**SPECIFICATIONS OF THE APPROVAL OF AN ORGANISATION INVOLVED IN THE
DESIGN AND/OR PRODUCTION OF ATM/ANS EQUIPMENT**

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; and
- (h) the additional conditions and/or limitations attached to it.

ATM/ANS EQUIPMENT CERTIFICATES

(Part-ATM/ANS.EQMT.CERT)

ATM/ANS.EQMT.CERT.001 Scope

This Annex establishes the procedures for the issue of certificates for ATM/ANS equipment in accordance with Article 4 of this Regulation, and the rights and obligations of the applicant for, and holder of, those certificates.

ATM/ANS.EQMT.CERT.005 Eligibility

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 Subpart.

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

Except as provided in Article 7, an applicant for an ATM/ANS equipment certificate shall hold a design organisation approval issued by the Agency in accordance with **Implementing Regulation (EU) .../... [implementing act on DPO approval]** that covers the respective ATM/ANS equipment.

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

- (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:
 - (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 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 specified in point ATM/ANS.EQMT.AR.C.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.C.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; and
 - (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 of its product 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 certification-basis requirements, as established and notified by the Agency in accordance with point ATM/ANS.EQMT.AR.C.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 certification-basis requirements, as established and notified by the Agency in accordance with point ATM/ANS.EQMT.AR.C.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.

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

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 substantially 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

- (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.C.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 risk 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.C.010(b).
- (d) An applicant shall record justifications 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); and
 - (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 usability of the ATM/ANS equipment.

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

- (a) Alternative means of compliance to the acceptable means of compliance (AMC) adopted by the Agency may be used by an organisation involved in the design and/or production of ATM/ANS equipment to establish and demonstrate compliance with Regulation (EU) 2018/1139 and this Regulation.
- (b) When an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the Agency with a full description of that alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and this Regulation.

An organisation involved in the design and/or production of ATM/ANS equipment may use any alternative means of compliance subject to prior approval by the Agency and upon receipt of the notification as provided for in point (d) of point ATM/ANS.EQMT.AR.A.015 of Annex II (Part-ATM/ANS.EQMT.AR) to this Regulation.

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

- (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 product 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 certification specifications; and
 - (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

- (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, coding and processes adequately conform to the specifications for the proposed design;
 - (ii) the developed ATM/ANS equipment adequately conforms to the proposed design; and
 - (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; and
 - (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 validation in accordance with point (b); and
 - (2) no change that affects the validity of the statement of validation shall be made to the test specimen, or the test and measuring equipment, between the time the statement of conformity 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

Further 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

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

- (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

- (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.C.001.
- (b) By way of derogation from point (a), the changes within the scope of the organisation's privileges following the approved 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.

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'.

The changes shall be issued with a statement as per point (b)(2) of point DPO.OR.C.001 of the Annex (Part-DPO.OR) to Implementing Regulation (EU) .../... *[implementing act on DPO approval]*.

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

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, 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

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, product, part, 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).

DECLARATION OF COMPLIANCE OF THE ATM/ANS EQUIPMENT DESIGN

(Part-ATM/ANS.EQMT.DEC)

ATM/ANS.EQMT.DEC.001 Scope

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 have the privilege to make such declarations.

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

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) ... [implementing act on DPO approval]**, as specified in the terms of the organisation approval.

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

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 product, where appropriate, either directly or by reference to other supplementary documents;
- (c) a statement of compliance certifying that the product meets the applicable specifications, and a list of the declaration specifications;
- (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 certification or declaration specifications;
- (g) list of deviations, as applicable.

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

- (a) Alternative means of compliance to the acceptable means of compliance (AMC) adopted by the Agency may be used by an organisation involved in the design and/or production of ATM/ANS equipment to establish and demonstrate compliance with Regulation (EU) 2018/1139 and this Regulation.
- (b) When an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the Agency with a full description of that alternative means of compliance. The description shall include any revisions to manuals or procedures that

may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and this Regulation.

An organisation involved in the design and/or production of ATM/ANS equipment may use any alternative means of compliance subject to prior approval by the Agency and upon receipt of the notification as provided for in point (d) of point ATM/ANS.EQMT.AR.A.015 of Annex II (Part-ATM/ANS.EQMT.AR) to Delegated Regulation (EU) .../... [*delegated act on the attestation of ATM/ANS equipment*].

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

- (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 substantially complete investigation in accordance with point ATM/ANS.EQMT.AR.C.020 to determine its compliance shall require the assignment of a new model designation to the equipment.

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

Further 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

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

- (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

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

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

- (a) grant the Agency access to any facility, product, part, 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 described in point (a).