



Notice of Proposed Amendment 2022-09

in accordance with Article 6(3) of MB Decision No 1-2022

Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment)

RMT.0161 — SUBTASK 1

EXECUTIVE SUMMARY

The objective of the proposals put forward in this Notice of Proposed Amendment (NPA), considering the technical, scientific and operational needs, is to maintain a high level of safety and to provide for cost-efficient requirements in the field of ATM/ANS systems and ATM/ANS constituents — i.e. ATM/ANS equipment. Furthermore, the objective is to meet the relevant security, performance, and interoperability objectives that would allow the proper functioning of the European Air Traffic Management network (EATMN).

This NPA proposes a regulatory framework for the certification of certain ATM/ANS equipment (i.e. ATM/ANS systems and ATM/ANS constituents) as well as of organisations involved in its design and/or production once it has been found to comply with the applicable essential requirements of Regulation (EU) 2018/1139. The proposed regulatory framework aims to reduce the fragmentation of the ATM/ANS (ground) equipment market and facilitate industry cooperation at European level. As a result, the application of the proposed provisions would facilitate the development and implementation of new technologies and speed up the introduction of new operational concepts that are required in order to increase the capacity of the ATM system and improve its performance.

ATM/ANS equipment manufacturers would need to apply for and be granted an organisation approval with the necessary privileges as well as hold ATM/ANS equipment certificates for certain ATM/ANS equipment they design and/or produce. This would provide for long-term benefits in terms of specifications harmonisation and a more efficient and flexible use of resources. ATM/ANS providers and similarly their competent authorities will also benefit from the attestation of certain ATM/ANS equipment by the organisations involved in its design and/or production, and their responsibilities will be focused on the operational integration of already attested ATM/ANS equipment.

The proposed new implementing and delegated acts and the amending implementing act are expected to maintain safety or even marginally increase it through the enhanced commonality and interoperability of the EATMN while reducing the regulatory burden, increasing cost-effectiveness, and improving harmonisation among the regulated entities.

Domain:	ATM/ANS		
Related rules:	Annex II (Part-ATM/ANS.AR) and Annex III (Part-ATM/ANS.OR) to Implementing Regulation (EU) 2017/373		
Affected stakeholders:	ATM/ANS providers; organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents; national competent authorities (NCAs), including EASA; and where applicable, aerodrome operators		
Driver:	Efficiency/proportionality	Rulemaking group:	Yes
Impact assessment:	Yes	Consultation:	Public

EASA rulemaking procedure milestones

Start Terms of Reference	Public consultation NPA 2022-09	Proposal to the Commission EASA Opinion	Adoption by the Commission Implementing/Delegated act	Decision Certification Specifications, Acceptable Means of Compliance, Guidance Material
14.2.2020	16.8.2022	2022/Q3	2023/Q3	2023/Q3



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1. About this NPA

1.1. How this NPA was developed

The European Union Aviation Safety Agency (EASA) developed this Notice of Proposed Amendment (NPA) in the context of Rulemaking Task (RMT).0161¹, which is included in Volume II of the European Plan for Aviation Safety (EPAS) for 2022-2026². RMT.0161 has been structured into three subtasks to clearly describe the work undertaken with this rulemaking activity as follows:

- **Subtask 1:** Establishment of an EU regulatory framework and amendment of the respective provisions on the conformity assessment of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment) to contribute to the safety and interoperability of the European ATM network (EATMN) operation.
- **Subtask 2:** Review of the Single European Sky (SES) interoperability Regulation (implementing Regulation (EC) No 552/2004 repealed by Regulation (EU) 2018/1139³ (the Basic Regulation)) to update and adapt it to the EASA regulatory framework.
- **Subtask 3:** Establishment of the related acceptable means of compliance (AMC) and guidance material (GM) that support Subtask 1 deliverables and the first set of the EASA detailed specifications (DSs) based on existing interoperability rules and related Community specifications⁴.

The proposal is in line with the Basic Regulation and the Rulemaking Procedure⁵.

EASA developed this NPA with the support of Rulemaking Group (RMG) RMT.0161 as well as by duly taking into account the strategic inputs provided by the Steering Group on ATM ground equipment. It is hereby submitted to all interested parties for consultation in accordance with Article 115 of the Basic Regulation and Article 6(3) of the Rulemaking Procedure.

The major milestones of this RMT are presented on the cover page.

¹ <https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-rmt0161>

² [European Plan for Aviation Safety 2022 - 2026 | EASA \(europa.eu\)](https://www.easa.europa.eu/easa/media/14421/epas-volume-ii-2022-2026)

³ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139>).

⁴ [Community specifications \(europa.eu\)](https://www.easa.europa.eu/easa/media/14421/epas-volume-ii-2022-2026)

⁵ EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 01-2022 of 2 May on the procedure to be applied by EASA for the issuing of opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure'), and repealing Management Board Decision No 18-2015 (<https://www.easa.europa.eu/downloads/136443/en>).

1.2. How to comment on this NPA

Please submit your comments using the automated **Comment-Response Tool (CRT)** available at <http://hub.easa.europa.eu/crt/>⁶.

The deadline for the submission of comments is **30 September 2022**.

1.3. The next steps

Following the public consultation period, EASA will review and analyse all the comments received, further revise the proposed regulatory proposal, as appropriate, and issue an opinion. In this context, EASA might perform focused consultation activities to discuss and address specific issues, as deemed appropriate, for which the stakeholders' views are considered essential or require further evaluation. Together with the opinion, EASA will also publish a comment-response document (CRD)⁷ that will contain all the comments received during the public consultation of the NPA.

The opinion shall be issued and addressed to the European Commission, which will use it as a technical basis to consider the adoption of the proposed implementing and delegated acts.

Upon adoption by the European Commission of the implementing and delegated acts proposed with the opinion, EASA will issue a decision with the first set of the related detailed (certification/declaration) specifications (CSs/DSs), acceptable means of compliance (AMC) and guidance material (GM) which can be used by organisations involved in the design and/or production of ATM/ANS equipment for the purpose of certification and demonstration of compliance in terms of safety, interoperability, and performance. Before the publication of such decision, the related proposed CSs/DSs/AMC/GM will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

⁶ In case of technical problems, please send an email to crt@easa.europa.eu with a short description.

⁷ <https://www.easa.europa.eu/document-library/comment-response-documents>

2. In summary — why and what

The Single European Sky (SES) initiative was launched in 2004 with the aim to improve 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 attestation of the related ATM/ANS equipment will require very specialised capabilities both for industry actors and competent authorities.

In this context, the following is considered ‘ATM/ANS equipment’:

- ATM/ANS systems (excluding airborne constituents), and
- ATM/ANS constituents.

The 2019 Report of the Wise Persons Group on the Future of the Single European Sky⁸ acknowledged the challenge in terms of seamless interoperability and network efficiency for the European ATM system that results from the variety of national ATM/ANS systems operated by national air navigation service providers (ANSPs).

The Basic Regulation lays down interoperability requirements for the European Air Traffic Management network (EATMN) and mandates the development of the related delegated and implementing acts as regards the certification or declaration of ATM/ANS systems and ATM/ANS constituents as well as of the organisations involved in their design, production, and maintenance. At the same time, Regulation (EC) No 552/2004⁹ (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 new regulatory framework proposed with this NPA would enable the certification/declaration of certain ATM/ANS equipment as well as of the organisations involved in their design, production, and maintenance once they have been found to comply with the applicable essential requirements of the Basic Regulation.

Accordingly, it will introduce the necessary detailed requirements for the issue of the certificates for certain safety-critical ATM/ANS equipment and for the declarations to be made for other ATM/ANS equipment. Such requirements are proposed considering the objectives of the Basic Regulation as well as the nature and risk of the particular activity where ATM/ANS equipment is involved.

⁸ <https://www.sesarju.eu/sites/default/files/documents/reports/report-wise-persons-group-future-ses.pdf>

⁹ 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) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R0552&qid=1657106139572>).

The requirements proposed with this NPA 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. They also address the oversight of organisations involved in the design, production, and maintenance of the ATM/ANS equipment in question.

2.1. Why we need to propose new implementing and delegated acts — issue/rationale

The SES Interoperability framework did not explicitly regulate organisations involved in the design and/or production of ATM/ANS equipment; they were indirectly affected by those requirements for ATM/ANS providers that make use of that equipment. Subsequently, the responsibilities of the various parties involved in the ATM/ANS equipment conformity assessment process, and particularly of the various parties involved and their oversight, were not clearly defined and thus their oversight was not performed in a standardised and consistent manner.

With the repeal of the interoperability Regulation, point 2 of Article 140 ‘Transitional provisions’ of the Basic Regulation requires that not later than 12 September 2023 the implementing rules adopted on the basis of Regulations (EC) No 216/2008 and (EC) No 552/2004 shall be adapted to the Basic Regulation. In this context, the establishment of a new conformity assessment framework has been considered by means of delegated and implementing acts by the referenced date. This initiative offers a unique opportunity to address all shortcomings of the previous framework, which are summarised in the following paragraphs.

The SES Interoperability framework allocated the responsibilities for the conformity assessment in a manner that has resulted in a lack of level playing field, with differing arrangements between the regulated entities (national competent authorities, ANSPs, and manufacturers) across Europe. Based on implementation feedback, this has caused also unnecessary complexity and economic burden for manufacturers as well as for ATM/ANS providers, and it does not facilitate the coordinated introduction of new, agreed, and validated concepts of operation and technologies.

The prevalence of national technical specifications used in procurement has led to the fragmentation of the ATM/ANS ground equipment market and does not facilitate industry cooperation at European Union level. As a result, the manufacturing industry is negatively affected since it needs to adapt its products to various national markets; these practices render the development and implementation of new technologies unnecessarily difficult and slow down the introduction of new operational concepts that are required to increase the capacity of the ATM system and improve its performance.

Article 45 of the Basic Regulation stipulates that, where the related delegated acts so provide, ATM/ANS systems and ATM/ANS constituents shall be subject to certification and shall be issued with a certificate, or be subject to declaration by the organisation involved in their design and/or production.

In order to address the above-mentioned lack of harmonisation, this NPA introduces the certification and declaration scheme for certain ATM/ANS equipment, considering the objectives of the Basic Regulation and the nature and risk of the particular activity.

In addition, the SES Interoperability Regulation has put the onus for the conformity assessment on ATM/ANS providers, only indirectly addressing the organisations involved in the manufacturing of ATM/ANS equipment. Although the mitigation of the safety risks is ultimately the responsibility of the ATM/ANS service providers that use ATM/ANS equipment, the contribution of the organisations that

are directly involved also in the design and manufacturing of such ATM/ANS equipment needs to be adequately addressed. This proposal systematises the processes to ensure that responsibilities linked to design and/or production are appropriately discharged when the criticality of the ATM/ANS equipment so requires. This would allow applying processes whose efficiency has been demonstrated for decades in the field of airworthiness, similar but not identical to those used for aircraft modifications and aircraft parts and appliances, thereby facilitating the work of the ATM/ANS providers and reducing costs related to ATM/ANS equipment that can be standardised in terms of performance and functions.

Moreover, the framework established by the SES Interoperability Regulation did not provide the necessary clarity as regards the requirements such ATM/ANS equipment must fulfil; in particular, it did not specify the criteria against which the declarations (verification of systems, and constituent conformity or suitability for use) had to be issued. On the contrary, the new regulatory framework on ATM/ANS equipment aims to provide the manufacturers concerned and ATM/ANS providers with the necessary legal certainty.

As regards verification of compliance with the essential requirements of the Basic Regulation, EASA aims to adequately allocate the responsibilities of the various affected stakeholders along the ATM/ANS equipment life cycle, thus providing for legal clarity and allowing swifter and more efficient compliance assessment processes. At the same time, this improved allocation of responsibilities would facilitate the planning of the necessary capabilities by the different stakeholders.

2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation and are complemented by Article 4, in which several principles are established. The proposals of this NPA will contribute to achieving the overall objectives by addressing the issues described in Section 2.1.

Additionally, the proposed regulatory framework will ensure that the relevant safety, security, performance, and interoperability objectives are met by supporting the efficient functioning of the EATMN, in compliance with the applicable requirements of the Basic Regulation and of the delegated and implementing acts adopted on its basis.

In this context, the specific objectives are to:

- minimise any undesirable implementation issues that may compromise operational functionalities, and promote technical interoperability by using detailed specifications;
- promote the development of the internal market by ensuring fair competition while facilitating the free movement of ATM/ANS equipment through the mutual recognition of certificates or declarations, without further requirements or evaluation, in all Member States;
- facilitate the development and implementation of new technologies in the ATM/ANS sector;
- enable increased efficiency and reduced costs as regards the procurement and maintenance of ATM systems, as well as improved operational coordination for the attestation process;
- optimise the use of resources during the demonstration of compliance and minimise the administrative burden; and
- maximise the synergies with existing processes to introduce changes to ATM/ANS functional systems resulting from the deployment of new or updated ATM/ANS equipment.

2.3. How we want to achieve it — overview of the proposed implementing and delegated acts

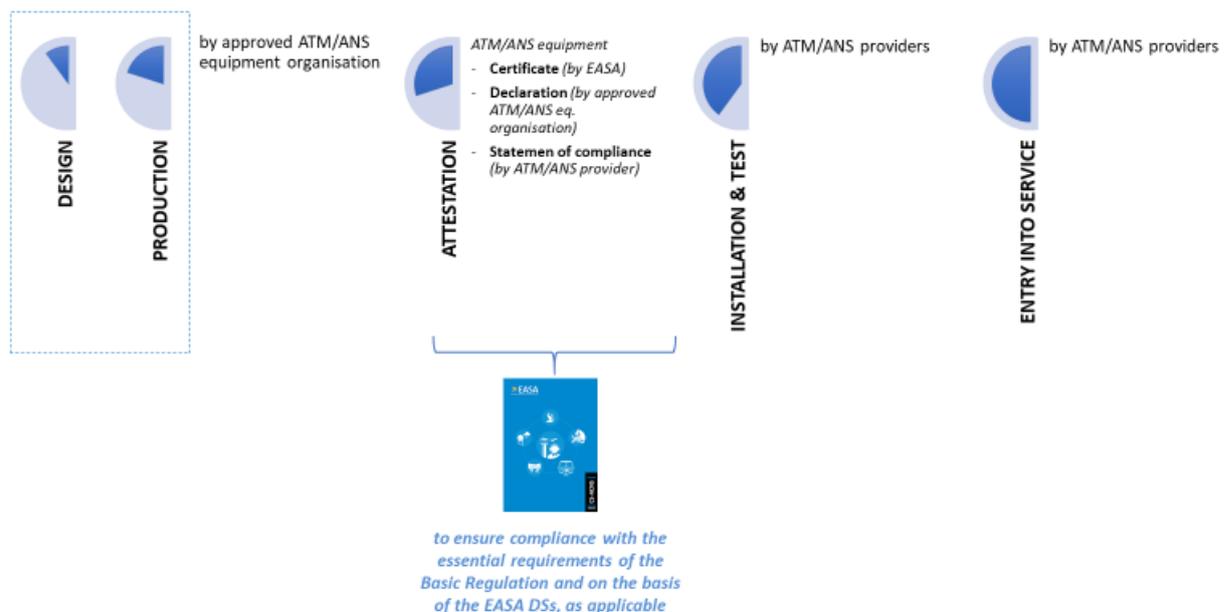
To achieve the objectives described in Section 2.2, it is proposed to develop a single, harmonised and mutually recognised mechanism to attest compliance of certain ATM/ANS equipment based on its intended use for the safe, interoperable, and efficient operation of the EATMN for all phases of flight.

The proposed new framework is expected to address identified weaknesses of the current approach, including the following:

- limited technical harmonisation and its voluntary application;
- limited, or even a lack of, oversight in the design and/or production of ATM/ANS equipment;
- a variety in the maturity of compliance demonstration across the Member States leading to different interpretation of the approach and evidence required to support such process;
- application of the ‘one-size-fits-all’ approach whereby ATM/ANS providers and ATM/ANS equipment manufacturers are required to follow the same attestation process (issue of EC declarations) for all ATM/ANS systems and constituents, without considering the risk and the safety criticality of that particular activity (i.e. the functions performed by the ATM/ANS equipment).

The proposal would enable a holistic, end-to-end and performance-based approach as regards the attestation of ATM/ANS equipment (as illustrated in Figure 1 below), facilitating the provision of ATM/ANS services in Europe as it will address the various phases of the life cycle of ATM/ANS equipment.

Figure 1



2.3.1. Proposals

This NPA proposes the introduction of a new EU regulatory framework for the conformity assessment of ATM/ANS equipment in order to contribute to the improvement of the safety and interoperability of the EATMN operation. The proposal is structured as follows:

- a new implementing act (IA) laying down requirements on the approval of organisations involved in the design and/or production of ATM/ANS equipment (hereinafter referred to as 'ATM/ANS equipment manufacturers');
- a new delegated act (DA) on an attestation scheme for ATM/ANS equipment; in this context, it should be noted that the new framework will provide three different instruments as a means of attestation, namely: certification, declaration, and statement of compliance; and
- the necessary amendments proposed to Implementing Regulation (EU) 2017/373¹⁰ with the objective to implement a total system approach and ATM/ANS equipment end-to-end performance.

2.3.1.1 Draft implementing act (IA) on the approval of organisations involved in the design and/or production of ATM/ANS equipment

In accordance with the provisions of the Basic Regulation, this proposal introduces a scheme according to which organisations that are involved in the design and/or production of ATM/ANS equipment are required to demonstrate the capability to carry out their activities. This scheme shall be based on the issuance of an organisation approval specifying the privileges granted to organisations involved in the design and/or production of ATM/ANS equipment.

This draft implementing act (IA) proposes the requirements for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents (i.e. ATM/ANS equipment).

The typical life cycle of ATM/ANS equipment consists of various phases, i.e. design, production, installation, operation, and maintenance. Some of these phases are usually performed by the ATM/ANS provider, while others are undertaken by the organisations involved in the design and/or production of ATM/ANS equipment.

In the context of this regulatory proposal, the technical requirements and the procedures for the approval are intended to reflect a single set of privileges in the area of design and production of ATM/ANS equipment.

The ATM/ANS equipment design and/or production responsibilities covered under the organisation approval would comprise the following:

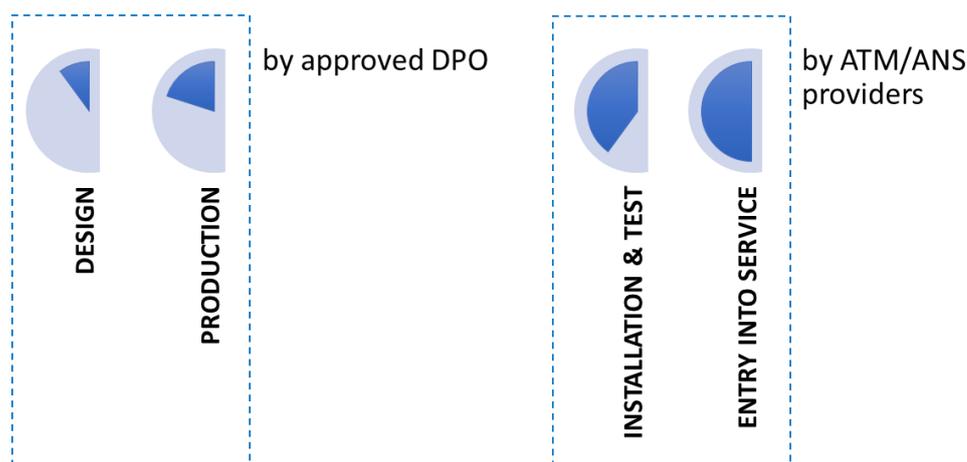
- identification of the functional requirements for ATM/ANS equipment;

¹⁰ 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) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0373&qid=1657185766802>).

- definition of the technical requirements;
- detailed architectural design;
- definition of the processes and methods for manufacture and assembly;
- manufacture in accordance with design documentation;
- preparation and update of complete technical documentation and records; and
- preparation and update of all required manuals to be provided with the equipment.

Installation and maintenance/operation are considered ATM/ANS provider responsibilities (as defined in Implementing Regulation (EU) 2017/373), and thus already covered under the ATM/ANS provider certificate. Regarding those activities that are closer to the interface between ATM/ANS equipment manufacturer and ATM/ANS provider, recurrent maintenance is considered part of the ATM/ANS provider activities, while evolutive maintenance is considered typically a design and production function under the responsibility of the ATM/ANS equipment manufacturer.

Figure 2



An organisation approval would be required for organisations involved in the design and/or production of ATM/ANS equipment when the ATM/ANS equipment is subject to certification or declaration. Only an approved organisation would be entitled to apply for the certification of ATM/ANS equipment, or declare compliance of the design with detailed declaration specifications (DSs).

ATM/ANS equipment manufacturers, i.e. organisations involved in the design and/or production of ATM/ANS equipment, are those primarily affected by the proposed new regulatory framework. The proposal structures the processes in such a way to ensure that the responsibilities linked to design and production are appropriately discharged.

ATM/ANS providers will remain responsible for the maintenance of the equipment¹¹ and for operational tasks, as it is the case today ('business as usual'), but for the most critical ATM/ANS equipment they will be relieved of the responsibility to consolidate the conformity assessment work and attest the equipment. Their focus will be on the operational integration of ATM/ANS equipment after receiving the ATM/ANS equipment attestation from the organisation involved in its design and/or production. Similarly, the responsible competent authorities of the ATM/ANS service providers could focus their respective efforts on overseeing the integration and entry into service of the ATM/ANS equipment¹².

Consequently, manufacturers would be required to demonstrate their capability associated with the design and/or production of certain ATM/ANS equipment, when so prescribed in the implementing acts. This does not imply that manufacturers (organisations) should be systematically regulated in order to relieve the responsibility of ATM/ANS providers with regard to ATM/ANS equipment manufacturers that produce equipment, but only in those cases where this would add value on the level of the overall system. Examples of cases where they would be required to be regulated is for ATM/ANS equipment considered essential for the deployment of certain Single European Sky ATM Research (SESAR) projects. In this context, organisations involved in the design and/or production of ATM/ANS equipment will be required to establish and maintain a management system in order to manage their activities and achieve their objectives. The management system establishes the policy and objectives, and defines the structure, processes and resources needed to achieve those objectives. It is anticipated that an ATM/ANS equipment manufacturer management system will contain items such as the following:

- the overall philosophies and principles of the design and production organisation (DPO);
- the lines of responsibility and accountability throughout the organisation, including the direct accountability of accountable managers;
- processes for:
 - compliance monitoring with the applicable requirements including a feedback system to the accountable manager to ensure effective implementation of corrective actions;
 - verification of the performance of the DPO in light of the performance indicators and performance targets of the management system;
 - identification of changes within the DPO which may affect established processes, procedures and products, and where necessary modify the management system to accommodate those changes;
 - communication to ensure that all DPO staff are fully aware of the management system;

¹¹ For further details, please refer to Section 2.3.2.

¹² For further details, please refer to Section 2.3.1.3.

- identification of the scope of changes to the design and production of ATM/ANS equipment and the associated risk;
- the design and production, and changes, including:
 - ensuring compliance with the applicable specifications,
 - an independent checking function, and
 - production control procedures;
- the verification of the acceptability of GE and of (any) tasks performed by contracted organisations;
- ensuring that sufficient numbers of experienced staff are involved in the design and production, and have been made aware of their responsibilities, and authorised to discharge their allocated responsibilities;
- coordination within departments and between departments.

The proposal considers **EASA to act as the competent authority** for the approval of organisations involved in the design and/or production of ATM/ANS equipment as well as for the certification of, and the receipt of declarations for, ATM/ANS equipment (as further explained in Section 2.3.1.2).

According to Article 80(1)(c) of the Basic Regulation, EASA is responsible for the certification of organisations involved in the design, production, or maintenance of ATM/ANS systems and ATM/ANS constituents, including where they contribute to the Single European Sky ATM Research (SESAR) implementation, used in the provision of the services referred to in Article 80(1)(b), meaning pan-European ATM/ANS (provided by ATM/ANS providers certified by EASA).

As the objective of the Basic Regulation is to promote cost-efficiency by, among others, avoiding duplication, and promoting effectiveness in the regulatory, certification and oversight processes, as well as making efficient use of the related resources at Union and national level, point (c) of Article 80(1) of the Basic Regulation is to be read together with the regulatory solution proposed for the certification and declaration of ATM/ANS systems and ATM/ANS constituents. In this respect, this proposal addresses the responsibilities of organisations involved in the design and/or production of ATM/ANS equipment, after carefully considering the following aspects:

- Before the ATM/ANS equipment is designed or produced, it is impossible to determine upfront how it will be used afterwards when it is to be put into service by an ATM/ANS provider, i.e. whether it will be used solely for the provision of ATM/ANS services within the national airspace of a Member State, or also for cross-border employment in the national airspace of most or all Member States. EASA considers that the future regulatory system should allow for any ATM/ANS equipment designed or produced in the EU to be potentially used also for the provision of pan-European ATM/ANS services; thus, it would require prior EASA approval.
- As regards the framework, the need should also be avoided for an organisation involved in the design and/or production of ATM/ANS equipment to hold several approvals — one issued by a national authority and one by EASA, for exactly the same type of activity only because certain equipment designed and/or produced by that organisation would be used for the provision of

ATM/ANS services within the national airspace of a Member State, while some other pieces of ATM/ANS equipment for the provision of pan-European ATM/ANS. Such situation would create unnecessary and costly duplication and administrative burden mainly for organisations involved in the design and/or production of ATM/ANS equipment and their authorities provided that the requirements for design/production are the same irrespective of the way the ATM/ANS equipment will be used afterwards.

- Furthermore, as described in Section 2.3.1.2 and in accordance with Article 80(2) of the Basic Regulation, EASA is responsible for all competent authority tasks related to certificates and declarations for ATM/ANS systems and ATM/ANS constituents (i.e. ATM/ANS equipment). To avoid significant complications, the responsibilities for the approval and oversight of organisations involved in the design and/or production of ATM/ANS equipment, which are the ones entitled to apply for the certification or the issue of declarations for the ATM/ANS equipment, should be allocated consistently with those responsibilities related to the certification of, and receipt of declarations for and oversight of, that ATM/ANS equipment.

Theoretically, there could still be organisations whose business plan would be to design and/or produce critical ATM/ANS equipment (subject to certification or declaration) and market it exclusively for the provision of ATM/ANS at national level. However, today, this case is not representative of the European ATM/ANS equipment market and the current digitalisation trends make it even less likely in the future. In this regard, this proposal builds on the exclusive competence of EASA to approve design and production organisations in order to avoid duplication, promote efficiency and effectiveness of the certification and oversight processes, thus resulting in an efficient use of resources at Union and national level.

This would allow to apply a similar approach whose efficiency has been demonstrated for decades in the field of airworthiness. Similarly, EASA would develop the relevant staff resources to ensure the initial approval and continuing oversight of organisations involved in the design and/or production of ATM/ANS equipment.

In addition to the considerations above, it has to be noted that a **definition** of ‘**pan-European ATM/ANS**’ is not provided in the Basic Regulation, but is stipulated on the level of an implementing act: Article 2(4) of Implementing Regulation (EU) 2017/373 defines ‘pan-European ATM/ANS’ as ‘an activity which is designed and established for users within most or all Member States and which may also extend beyond the airspace of the territory to which the Treaty applies’. Due to the fact that the term ‘pan-European ATM/ANS’ was developed and defined before the entry into force of the Basic Regulation, it does not adequately reflect the nature, the objectives, and the risks of the services whose provision is supported by the employment of ATM/ANS equipment and by its proposed certification according to the new scheme proposed by this NPA. Subsequently, EASA is of the opinion that the aforementioned definition needs to be further clarified to better scope the area in which such pan-European ATM/ANS services are provided in relation to the approval and oversight of organisations involved in the design and/or production of ATM/ANS equipment.

2.3.1.2 Draft delegated act (DA) on the certification and declaration scheme for ATM/ANS equipment

The draft delegated act establishes the new framework on the conformity assessment of certain ATM/ANS equipment that should be proportionate to the risks involved, making use of existing

methodologies and best practices. Thus, the new framework establishes three possible instruments based on the principles established by the Basic Regulation:

- certification by EASA of certain safety-critical ATM/ANS equipment based on detailed certification specifications adopted by EASA (**Article 4**).
- declaration by an approved organisation involved in the design and/or production of ATM/ANS equipment for other critical ATM/ANS equipment based on detailed declaration specifications adopted by EASA (**Article 5**); and
- statement of compliance by the ATM/ANS provider for all other ATM/ANS equipment (**Article 6**); this approach constitutes a similar approach to the current EC declarations scheme based on the interoperability Regulation.

The draft delegated act defines the criteria against which the certification of or declaration for the ATM/ANS equipment is respectively required, considering the nature and the risk of a particular operation or functionality. Where certification or declaration is required, this will be based on the demonstration of compliance with the relevant detailed certification/declaration specifications, which is the novelty to be introduced in accordance with Article 47(1)(a) of the Basic Regulation. The draft delegated act (in particular its point **ATM/ANS.EQMT.AR.A.040 Detailed specifications for the certification and declaration of design compliance**) lays down the requirements for the establishment of the criteria that shall be sufficiently detailed and specific so that they may be used by applicants and/or approved organisations to demonstrate compliance with the relevant essential requirements set out in Annex VIII and, if applicable, Annex VII to the Basic Regulation.

In this context, it should be highlighted that the interoperability Regulation had identified a list of systems, their constituents, and associated procedures, to which the interoperability framework applied. Therefore, to promote innovation and avoid constraints, it is considered essential to specify the scope and definition of the ATM/ANS equipment subject to certification at EU regulation level, and the particularities and the specific ATM/ANS equipment listed at detailed specification and AMC level. This approach takes into account the related recommendation of the CNS Advisory Group.

It is anticipated that, when developing the detailed specifications for ATM/ANS equipment, EASA may decide to refer to widely recognised international standards published by industry, through standards development organisations (SDOs), to be used as a means of compliance in accordance with Article 1(3)(d) of the Basic Regulation.

This attestation scheme would enable the full coverage and effective oversight of ATM/ANS equipment in a standardised manner while promoting and enabling the development and implementation of new technologies with clear responsibilities established for each of the actors involved (i.e. organisations involved in the design and/or production of ATM/ANS equipment, ATM/ANS providers as customers and users, as well as national competent authorities and EASA responsible for the oversight of ATM/ANS providers).

Article 3 defines EASA as the competent authority for certification, oversight, and enforcement in accordance with Article 62(2) of the Basic Regulation with respect to certificates, and declarations issued by approved organisations, for ATM/ANS equipment, and following the principles laid down in Article 80(2) of the Basic Regulation.

Following this principle, **Article 4** scopes the ATM/ANS equipment subject to certification. While recognising that to date no significant safety issues have been identified in relation to the operation of ATM ground equipment in the EATMN, it should be noted that the provision of ATM/ANS is highly influenced by a considerable degree of redundancy and number of mitigating measures (e.g. safety barriers) put in place.

The forecast evolution of the ATM/ANS landscape, necessary to fulfil the performance and user requirements, will increase the safety and security criticality of key EATMN elements. This is the case especially for ATM/ANS equipment employed for the processing and integration of data for onward transmission and direct use for the purpose of safe and interoperable EATMN operations, in particular encompassing certain air traffic services (ATS) functionalities (trajectory management, collision avoidance, separation management, aerodrome situational awareness, surface guidance and routing, air traffic flow management, voice communications). Therefore, such ATM/ANS equipment is proposed to be subject to certification by EASA once compliance with a detailed certification specification has been demonstrated by an approved organisation involved in the design and/or production of ATM/ANS equipment. The certificates shall be valid and recognised in all Member States without any further requirements or technical evaluation.

There are several reasons why this cluster has been considered the most critical equipment in terms of interoperability and safety impact:

- The processing and delivery of data to support real-time operational functions is key for the functioning of the ATM system. Strategic reflection has indicated that the effective free flow of data among interoperable ATM/ANS systems is the key enabler for the required resilience, flexibility, and scalability of the ATM/ANS system — since the digitalisation of Europe’s aviation infrastructure is a key element of Europe’s strategy on a single digital market.
- The full interoperability of the main functions in the data layer can only be optimally achieved through the application of common specifications. Furthermore, a centralised approach is highly recommended due to the fact that appropriate attestation and oversight require very specialised knowledge.
- The interoperability and safety criticality of the functions with regard to processing and delivering data for operations will become more reliable only through the further automation of the ATM system in the coming decades, in particular considering the forecast air traffic growth and the increasing operational complexity through the integration of new airspace users (e.g. unmanned aircraft systems (UASs), higher-airspace operations (HAOs)).

Examples of ATM/ANS equipment that would be subject to certification are the following:

- flight data processing systems;
- surveillance data processing systems;
- central ATFM systems; and
- certain integration of these systems (e.g. remote tower system).

While not providing for the same level of safety or interoperability criticality as the ATM/ANS equipment subject to certification, the impact of certain ATM/ANS equipment in terms of EATMN interoperability is important. Therefore, **Article 5** defines that ATM/ANS equipment shall be subjected to declaration by an approved organisation involved in the design and/or production of ATM/ANS

equipment based on detailed declaration specifications adopted by EASA. It is proposed that ATM/ANS equipment that generates, transmits and receives data and/or signals in space for the purpose of safe and interoperable air navigation be attested through a declaration by an organisation involved in the design and/or production of that ATM/ANS equipment. COM/NAV/SUR sensors, transceivers and aids are well specified (e.g. at ICAO level), and the declaration by an approved organisation would be the most proportionate means to ensure the necessary ATM/ANS equipment safety and interoperability. Examples of ATM/ANS equipment for which declaration is the proposed approach include the following:

- GBAS,
- conventional NAV AIDS: e.g. ILS, VOR, NDB, etc.,
- SUR sensors: ADS-B, MODE-S radar, etc.

Considering the importance of the subject, EASA wishes to seek stakeholders' views on the inclusion of the equipment used for surveillance within the scope of the equipment subject to declaration.

Stakeholders are invited to comment whether sensors (for example, PSR/SSR radars, ADS-B receivers or MLAT equipment) which are used for surveillance should be subjected to declaration by approved ATM/ANS equipment manufacturers, including a justification.

Furthermore, these ATM/ANS equipment manufacturers shall submit the referenced ATM/ANS equipment declarations to EASA as the competent authority for their registration and oversight. These declarations shall be valid and recognised in all Member States without any further technical requirements or evaluation.

It shall be noted that the implementation of Article 4 'Certification of ATM/ANS equipment' and Article 5 'Declaration of ATM/ANS equipment' could be performed only with the availability of accompanying EASA measures (i.e. detailed specifications (DSs) and associated acceptable means of compliance (AMC) and guidance material (GM)).

For this purpose, EASA will develop and consult by means of an NPA the first set of the detailed certification/declaration specifications and the associated draft AMC and GM in due time with the aim of publishing them via the issue of an EASA Decision concurrently with the adoption of the proposed implementing and delegated acts. For further details, please refer to Section 2.3.4.

Article 6 introduces the third instrument for the attestation of ATM/ANS equipment: the statement of compliance (SoC) issued by ATM/ANS providers. It is considered crucial that ATM/ANS providers continue to verify certain ATM/ANS equipment attesting that it complies with the technical standards established by recognised standardisation bodies and listed in detailed specifications (i.e. for that ATM/ANS equipment not required to be certified nor declared by organisations involved in its design and/or production), which is to be put into operation and used for the provision of their services. This approach is similar to the current method of declaration of verification (DoV).

The essential requirements as regards ATM/ANS equipment laid down in the Basic Regulation are similar in terms of nature and granularity to those of the repealed interoperability Regulation.

However, it is necessary to detail how compliance of the currently deployed ATM/ANS equipment that will be subjected to certification or declaration under the new scheme will be ensured.

Article 7 ‘Transitional provisions’ contains the necessary transitional measures for the introduction of the new framework which stipulates that ATM/ANS equipment already deployed would not negatively affect the intended objectives or would represent any regression from the current safety and interoperability levels. Considering the three instruments (i.e. certification, declaration, and statement of compliance) being introduced as a means of attestation, the transitional provisions would only be relevant for ATM/ANS equipment subject to certification and declaration under the new regulatory framework.

Two groups of transitional measures are proposed, addressing respectively:

- equipment that holds an EC Declaration of Verification (DoV), pursuant to Regulation (EC) No 552/2004, issued until 12 September 2023; and
- equipment manufactured or put into operation after 12 September 2023, but before all the building blocks of the new regulatory framework are in place.

For **equipment that holds an EC Declaration of Verification (DoV)**, the envisaged approach is to treat it from 13 September 2023 as provisionally meeting the requirements of the new regulatory framework, without any additional requirements for the ATM/ANS providers that operate that equipment.

With regard to ATM/ANS equipment subject to certification/declaration, EASA will be required to perform an evaluation of its compliance within a defined period (e.g. 5 years). For that purpose, the competent authorities responsible for the certification and oversight of ATM/ANS providers (i.e. those to which the EC Declaration of Verification (DoV) and the Technical Files have been submitted pursuant to Regulation (EC) No 552/2004) will be required to provide EASA with the relevant information to facilitate this evaluation. Following that evaluation, EASA should conclude whether the applicable essential requirements of the Basic Regulation and the corresponding delegated and implementing acts are met, and in case any non-compliance is identified, appropriate action is taken.

As regards ATM/ANS equipment that falls within the category of ATM/ANS equipment subject to a statement of compliance issued by the ATM/ANS provider, the EC DoV of the systems that has been issued or recognised will continue to be valid and shall be considered a statement of compliance under the new regulatory framework.

For **ATM/ANS equipment manufactured or put into operation during the transitional period**, there is a need to differentiate between the different attestation methods (i.e. certification, declaration, or statement of compliance). As from 13 September 2023, the new framework will require ATM/ANS providers to issue a statement of compliance for the ATM/ANS equipment being deployed and subject to the new framework during this transitional period. The introduction and the full implementation of the certification and declaration scheme would require time for the regulated parties, including EASA, to set up all the necessary enablers for the functioning of the new regulatory framework (e.g. granting approvals to organisations involved in the design and/or production of ATM/ANS equipment, adoption of certification/declaration/detailed specifications for ATM/ANS equipment); consequently, the transitional provisions take into account some of the building blocks of the new framework that require time to be implemented: e.g. between 1 to 3 years might be needed for the approval of the organisations involved in the design and/or production of ATM/ANS equipment following the adoption of the new regulatory framework. In addition, when defining the transitional period, the fact is acknowledged that applicants will need time to demonstrate that the deployed ATM/ANS

equipment complies with the certification/declaration specifications. In this regard, the approach being considered is based on the deferred application of the requirements related to certification or declaration. Those requirements will only become applicable after a certain number of years, which may be the same period of 5 years as in the case of equipment that holds an EC DoV, aiming for simplicity. This would allow for the adequate and necessary preparation of the industry concerned.

2.3.1.3 Draft implementing act amending Implementing Regulation (EU) 2017/373

For the most critical ATM/ANS equipment in terms of safety, performance and interoperability, certification will be the mandated attestation method. Declaration will be the method mandated for an intermediate layer in terms of criticality. Considering the SES IOP framework, in these two cases of certification and declaration of ATM/ANS equipment, the ATM/ANS provider is relieved of the responsibility to perform the conformity assessment and attest the equipment and the responsibility is delegated to the design and/or production organisation. Additionally, oversight responsibilities will be placed with EASA, while within the SES IOP framework the oversight responsibilities were not clearly defined but remained within the scope of the NSAs' activities when overseeing the provision of ATM/ANS services.

In the case of the third attestation method (i.e. Statement of Compliance), oversight responsibilities will lie with the competent authority responsible for the oversight of the provision of ATM/ANS services, i.e. NSAs, or EASA in the case of pan-European or third-country ATM/ANS providers. The new framework will ensure a better link between the oversight of the conformity assessment activities and the use of the generated evidence in the context of the review of changes to the functional systems of the ATM/ANS providers, ensuring a seamless information exchange and cooperation of the relevant competent authorities using the tools of the EASA system.

In order to ensure regulatory consistency of the new framework with the existing implementing acts, as well as to ensure a total system approach and to address end-to-end performance of the deployed ATM/ANS equipment, amendments to Implementing Regulation (EU) 2017/373 are also proposed with this NPA.

As explained in Section 2.3.1.1, ATM/ANS providers will remain responsible for the maintenance of the ATM/ANS equipment they deploy and for the related operational tasks as is currently the case ('business as usual') with the focus on the operational integration of the ATM/ANS equipment. Thus, ATM/ANS providers that will deploy certain ATM/ANS equipment will benefit from the certification/declaration of the ATM/ANS equipment. Similarly, the responsible competent authorities of the ATM/ANS providers could focus their respective efforts on overseeing the integration and entry into service of the ATM/ANS equipment.

Approval of a change to a functional system versus attestation of ATM/ANS equipment

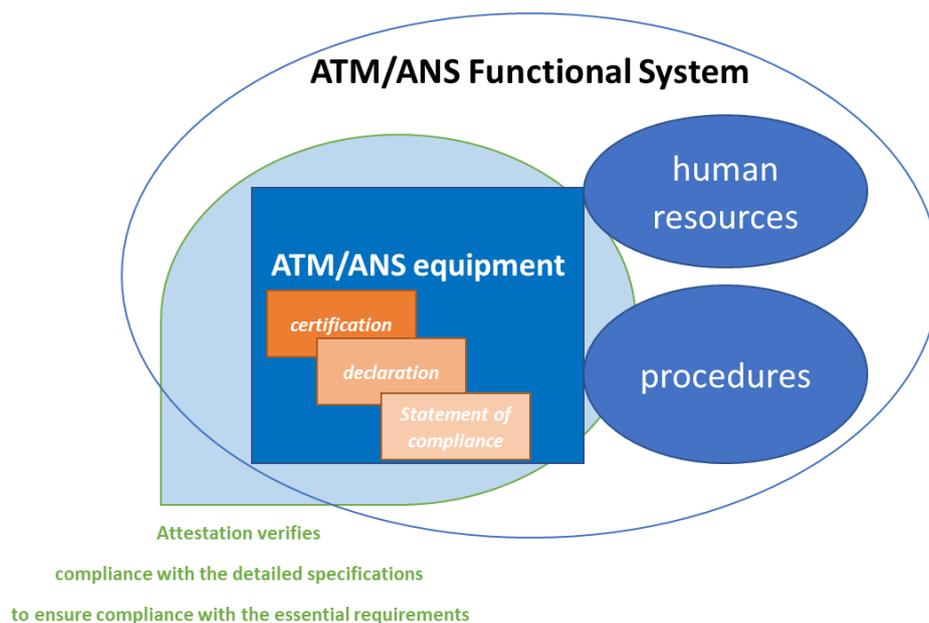
Point 56 of Annex I (Part-DEFINITIONS) to Regulation (EU) 2017/373 defines 'functional system' as 'a combination of procedures, human resources, and equipment, including hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions'.

In this context, it should be highlighted that the proposal on the attestation of ATM/ANS equipment aims to address the demonstration of compliance of the ATM/ANS equipment with the detailed specifications to ensure compliance with the essential requirements of the Basic Regulation. In other words, the draft delegated act addresses demonstration of compliance only on the level of

‘equipment, including hardware and software’, while the changes to the functional system address demonstration of compliance at system level, which is part of the amendments proposed to Implementing Regulation (EU) 2017/373.



Figure 3



2.3.2. Maintenance activities

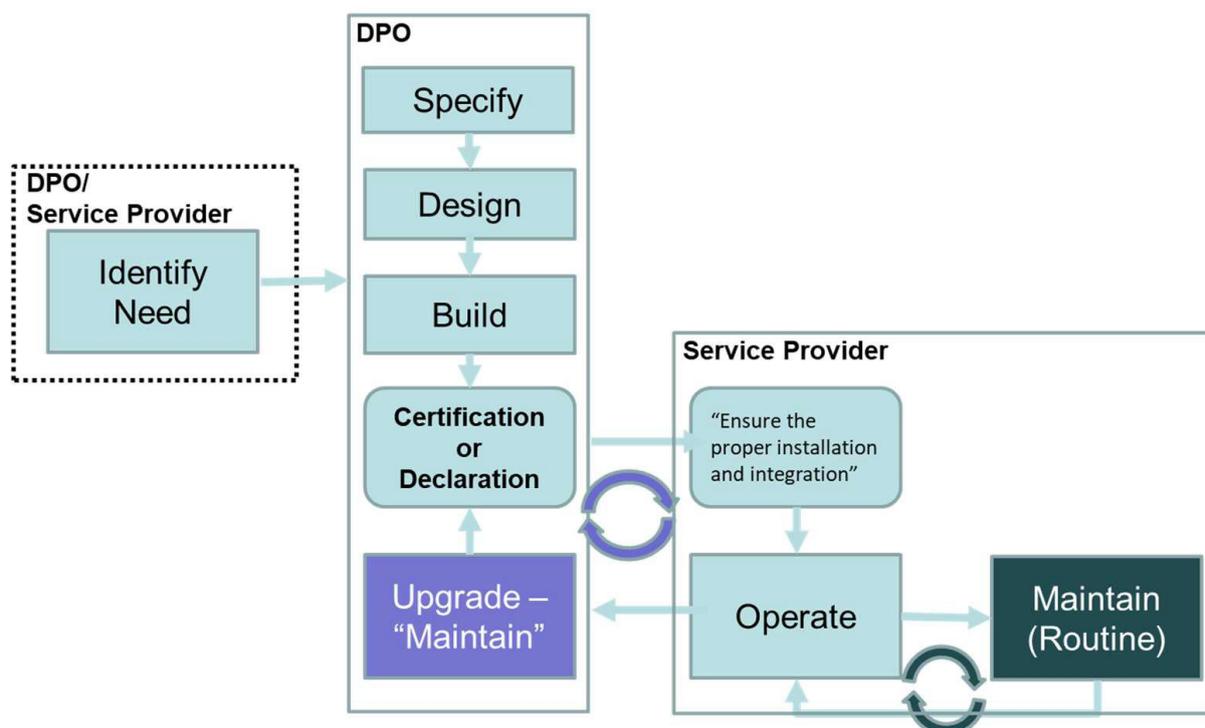
Maintenance is commonly understood as the act of keeping equipment in good condition by making repairs, correcting problems, etc. However, it could also be understood to refer to changes to equipment to reflect developments in requirements and standards. In order to cover these two potentially different meanings, the subject proposal differentiates routine maintenance from upgrades/evolution of existing equipment due to functional changes.

Routine maintenance is considered the performance of those tasks that are necessary to ensure that ATM/ANS equipment can continue to operate correctly to fulfil its operational function. The principles of the new conformity assessment framework will result in that this type of maintenance (i.e. routine maintenance) should only be performed in accordance with the instructions, guidance and requirements provided by the organisations involved in the design and/or production of ATM/ANS equipment in order to ensure the validity of the certificate or declaration of the particular ATM/ANS equipment. Such routine maintenance activities would be normally within the remit of ATM/ANS providers which perform them in accordance with the instructions of the relevant ATM/ANS equipment manufacturer.

Equipment upgrade is normally associated with a change to the functions, including the methods and the technology used. These changes/upgrades might affect the demonstration of compliance of the ATM/ANS equipment with its certification basis and, therefore, might have an impact on the validity of the related certificates or declarations. Under the principles of the new conformity assessment framework, the only type of organisation that could hold an equipment certificate or issue a declaration is an approved organisation involved in the design and/or production of ATM/ANS equipment and, therefore, these activities are to be carried out under the responsibility of the approved ATM/ANS equipment manufacturer.

Therefore, it could be determined that once the need for a functional change has been established, the organisation involved in the design and/or production of ATM/ANS equipment is responsible to specify, design, produce and certify/declare that ATM/ANS equipment. In doing so, the ATM/ANS equipment manufacturer should establish the maintenance requirements (procedures, periodicity, etc). Once the ATM/ANS equipment is certified/declared, the user (i.e. the ATM/ANS provider) should install and integrate it respecting the ATM/ANS equipment manufacturer's requirements and undertake the routine maintenance required to ensure that the equipment remains functional and operational. In this context, Figure 4 illustrates the links between 'upgrade' and 'routine maintenance'.

Figure 4



2.3.3. Transitional provisions

As explained in Section 2.1, Regulation (EC) No 552/2004 of the European Parliament and of the Council (the interoperability Regulation) was repealed by the Basic Regulation.

In this context, Article 140 'Transitional provisions' of the Basic Regulation prescribes that 'not later than 12 September 2023 the implementing rules adopted on the basis of Regulations (EC) No 216/2008 and (EC) No 552/2004 shall be adapted to this Regulation'. Meanwhile, the implementing rules adopted on the basis of Regulation (EC) No 552/2004 and certain articles of that Regulation and its related annexes remain applicable until the date of application of the implementing and delegated acts concerned and, in any case, not later than 12 September 2023. Consequently, the referenced regulations and associated requirements should be reviewed to enable the harmonised implementation of the future conceptual, technological, and operational changes introduced with a simplified regulatory framework.

The risk of a regulatory 'gap' could potentially incur after 12 September 2023, should the new regulatory framework not be in place and applicable on the date on which the current one ceases to

apply. Therefore, as already highlighted, the new framework on the attestation of ATM/ANS equipment establishes three instruments:

- certification by EASA of safety-critical ATM/ANS equipment;
- declaration by an approved manufacturer for some other critical ATM/ANS equipment; and
- statement of compliance issued by the ATM/ANS provider for all other ATM/ANS equipment, which constitutes a similar approach to the current EC declarations scheme based on the interoperability Regulation (Regulation (EU) No 552/2004).

As already detailed in Section 2.3.1.2, it is foreseen that after the entry into force of the new regulatory ATM/ANS equipment framework, all ATM/ANS equipment already deployed will be deemed to have been attested in accordance with the new rules. During the transitional period, all equipment will be subjected to a statement of compliance by the ATM/ANS service providers. Once the certification/declaration requirements become applicable, ATM/ANS equipment will be certified by EASA or declared by approved organisations involved in the design and/or production of ATM/ANS equipment respectively.

In conclusion, this approach would prevent a regulatory ‘gap’ from occurring after 12 September 2023 as well as ensure the necessary continuity of the activities leading to the deployment of new and upgraded ATM/ANS equipment.

2.3.4. Other associated deliverables

As an outcome of RMT.0161, EASA will issue an opinion during 2023/Q3 resulting from:

- the public consultation of this NPA (Subtask 1) by proposing:
 - an implementing act (IA) for the framework as regards the approval of organisations involved in the design and/or production of ATM/ANS equipment, including the associated privileges to that approval;
 - a delegated act (DA) on the ATM/ANS equipment certification/declaration scheme; and
 - an IA amending Regulation (EU) 2017/373 as regards ATM/ANS providers’ responsibilities in relation to ATM/ANS equipment before integration and deployment;
- the focused consultation of a second NPA (Subtask 2) proposing a revised ATM interoperability framework pursuant to the Basic Regulation, including the update and transposition of Regulation (EC) No 29/2009 on data link services for the single European sky¹³ (the data link services Regulation), instead of a respective stand-alone proposal. The objective of Subtask 2 is to review the SES interoperability rules (implementing the repealed Regulation (EC)

¹³ Commission Regulation (EC) No 29/2009 of 16 January 2009 laying down requirements on data link services for the single European sky (OJ L 13, 17.1.2009, p. 3) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R0029&qid=1658237670791>).

No 552/2004, Regulation (EC) 1032/2006¹⁴, Regulation (EC) No 262/2009¹⁵, Implementing Regulation (EU) No 1207/2011¹⁶, etc.) and adapt them to the EASA framework. This proposal with the draft amending regulations will be issued for consultation with the EASA Advisory Bodies during 2022/Q4; and

- The public consultation of a third NPA (Subtask 3) proposing a draft decision with the first set of the detailed (certification/declaration) specifications, acceptable means of compliance (AMC) and guidance material (GM) to establish the technical and operational conditions necessary to meet the essential requirements and relevant implementing rules, thus creating a presumption of conformity in terms of safety, interoperability, and performance. The rationale behind the publication of the draft detailed (certification/declaration) specifications and the associated AMC and GM with a separate NPA is to ensure a more focused consultation of the new regulatory framework.

One of the subjects that will be addressed at AMC level will be the classification of changes to ATM/ANS equipment, e.g. classification of ‘minor’ and ‘major’ changes.

Safety-related aerodrome equipment which does not fall under ATM/ANS systems and ATM/ANS constituents (i.e. ATM/ANS equipment) will be addressed in a separate NPA. That NPA will put forward a draft implementing act on the rules and procedures for the implementation of Article 36 *Implementing acts as regards aerodromes and safety-related aerodrome equipment* of and Annex VII *Essential requirements for aerodromes* to Regulation (EU) 2018/1139 with regard to safety-related aerodrome equipment.

2.4. What are the expected benefits and drawbacks of the proposed implementing and delegated acts?

The approval and continuing oversight of organisations involved in the design and/or production of ATM/ANS equipment, together with the introduction of the different methods of attestation and demonstration of compliance with the essential requirements applicable to ATM/ANS equipment are considered to provide the greatest benefits in terms of proportionality.

Furthermore, enhancing the harmonisation of the ATM/ANS equipment requirements will result in improved efficiency and lower costs for system procurement and maintenance and in improved operational coordination, thus reducing the fragmentation of the ATM/ANS equipment market and facilitating industry cooperation at European Union level.

For the detailed impact assessment (IA), please refer to Chapter 4.

¹⁴ Commission Regulation (EC) No 1032/2006 of 6 July 2006 laying down requirements for automatic systems for the exchange of flight data for the purpose of notification, coordination and transfer of flights between air traffic control units (OJ L 186, 7.7.2006, p. 27) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1032&qid=1658238186212>).

¹⁵ Commission Regulation (EC) No 262/2009 of 30 March 2009 laying down requirements for the coordinated allocation and use of Mode S interrogator codes for the single European sky (OJ L 84, 31.3.2009, p. 20) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R0262&qid=1658238395551>).

¹⁶ Commission Implementing Regulation (EU) No 1207/2011 of 22 November 2011 laying down requirements for the performance and the interoperability of surveillance for the single European sky (OJ L 305, 23.11.2011, p. 35) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R1207&qid=1658238565140>).

3. Proposed implementing and delegated acts

3.1. Draft regulations (draft EASA opinion)

3.1.1. Draft implementing act 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 (ATM/ANS equipment) (please refer to Appendix 1)

3.1.2. Draft delegated act laying 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 (ATM/ANS equipment) (please refer to Appendix 2)

3.1.3. Draft implementing act amending Implementing Regulation (EU) 2017/373 as regards the conformity assessment of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment) (please refer to Appendix 3)



4. Impact assessment (IA)

4.1. What is the issue

Please refer to Section 2.1.

4.1.1. Safety risk assessment

The need for certification or declaration of certain ATM/ANS equipment is not directly driven by safety events that have occurred. However, recognising that in the future the provision of ATM/ANS will rely more heavily on new digital technologies and ATM/ANS systems than today, action at European Union level is required to ensure the safety and interoperability of such systems. Moreover, ATM/ANS systems and ATM/ANS constituents (i.e. ATM/ANS equipment) are key and integral elements of the European ATM network (EATMN) and form a fundamental component to ensure safe flight operations within the single European sky (SES) airspace.

Failure to establish an EU framework for the attestation of certain ATM/ANS equipment may result in the implementation of technologies that are not mature to support the required operational improvements, thus compromising safety, performance and the necessary confidence in solutions supported by digital technologies and automation.

4.1.2. Who is affected

Mainly **manufacturers**, i.e. organisations involved in the design and/or production of ATM/ANS equipment.

ATM/ANS providers will remain responsible for the performance of maintenance and operational tasks as in the current scenario (i.e. 'business as usual'), but they will not perform any more activities in relation to the conformity assessment of the most critical ATM/ANS equipment, focusing only on the operational integration of the ATM/ANS equipment into the functional ATM/ANS system.

Moreover, according to the currently applicable requirements, especially point ATM/ANS.OR.B.015 *Contracted activities* of Annex III (Part-ATM/ANS.OR) to Implementing Regulation (EU) 2017/373, ATM/ANS providers shall ensure that when subcontracting any part of their activities to external organisations, the purchased system or constituent conforms to the applicable requirements, i.e. currently, ATM/ANS service providers oversee manufacturers as regards ATM/ANS equipment subject to purchase and this involves workload for both sides: for manufacturers to demonstrate compliance of the ATM/ANS equipment, and for ATM/ANS providers to oversee manufacturers.

In addition, similarly, the **responsibilities** of the ATM/ANS providers' **competent authorities** will be reduced and limited to the oversight of the integration and entry into service of the ATM/ANS equipment.

EASA will be required to act as the competent authority in relation to the certification and declaration of certain ATM/ANS equipment and for the approval of organisations involved in its design and/or production, on top of its current responsibility to act as the competent authority for pan-European and non-EU ATM/ANS providers.



4.1.3. How could the issue evolve

In the absence of appropriate, specific, and proportionate provisions on the attestation of ATM/ANS equipment, the currently applicable EC declaration scheme involving differing arrangements between regulated parties (e.g. national competent authorities, ANSPs, and manufacturers) across Europe will continue to apply without efficiently facilitating the coordinated introduction of new, EU-wide agreed and validated concepts of operation and/or technologies due to the following issues:

- the predominance of local (national) technical specifications used in procurement that has led to the fragmentation of the ATM/ANS equipment market and does not facilitate industry cooperation at European Union level; therefore, industry needs to considerably adapt its products to each market, which renders development and implementation of new technologies unnecessarily difficult and slows down the introduction of new operational concepts that are required to increase system capacity;
- multiple oversight of ATM/ANS equipment manufacturers by each ATM/ANS provider purchasing their products (i.e. ATM/ANS equipment) as well as by the national competent authority of the referenced providers.

In addition, currently, the fact that ATM/ANS providers do not take credit from the certification/declaration (i.e. attestation) process would lead to the continuation of the fragmentation of the systems market and the lack of industry cooperation at European Union Community level; as a result, the industry needs to considerably adapt its products to each national market due to the lack of harmonised standards for their products leading to delays in the development of new technologies and slowing down the introduction of new operational concepts that are required to increase system capacity.

Moreover, the current regulatory framework will continue to support the lack of a level playing field for the European industry as, currently, ATM/ANS equipment manufacturers do not have access to oversight credit, contrary to the practice followed in the other aviation domains (e.g. airworthiness).

Furthermore, if no action is taken, the requirements for the issue of EC declarations would cease to exist after 12 September 2023 and stakeholders would need to continue with the limited instructions and guidance developed and issued by their national competent authorities to ensure that the ATM/ANS systems and ATM/ANS constituents are interoperable and operationally suitable in a more and more complex and integrated ATM/ANS environment.

4.2. What we want to achieve — objectives

Please refer to Section 2.2.



4.3. How we want to achieve it — options

Table 2: Selected options

Option No	Short title	Description
0	Baseline (= do nothing)	<p>Do not implement the Basic Regulation.</p> <p>The interoperability framework on the basis of Regulation (EU) No 552/2004 ceases to exist, and stakeholders will need to continue with the limited instructions and guidance developed and issued by their national competent authorities to ensure that ATM/ANS systems and ATM/ANS constituents are interoperable and operationally suitable in a more and more complex and integrated ATM/ANS environment, consequently leading to multiple oversight.</p> <p>The requirements for ATM/ANS systems and ATM/ANS constituents would continue to apply in a non-coordinated and inconsistent manner to the manufacturers of ATM/ANS systems and ATM/ANS constituents.</p>
1	Introduction of the ATM/ANS equipment attestation scheme	<p>Introduction of the ATM/ANS equipment attestation scheme with the following instruments:</p> <ul style="list-style-type: none"> — only certain safety-critical ATM/ANS equipment subject to certification by EASA; — other safety-related ATM/ANS equipment subject to declaration by ATM/ANS equipment manufacturers; — other ATM/ANS equipment subject to statement of compliance by ATM/ANS providers. <p>With this approach, the essential requirements as regards safety, performance and interoperability would be met.</p>

Note to Option 1:

EASA proposes a single, harmonised and mutually recognised mechanism to attest the compliance of certain ATM/ANS equipment based on its intended purpose and for the safe and seamless operation of the EATMN for all phases of flight. The proposals resulting from this option would enable a holistic, end-to-end, performance-based approach to the provision of ATM/ANS in Europe, ensuring safety and interoperability.

The detailed (certification/declaration) specifications will be applicable to certain ATM/ANS equipment for the purpose of complying with the essential requirements set out in Annex VIII and, if applicable, in Annex VII to the Basic Regulation, and ensuring that the equipment is suitable for use.

Examples of ATM/ANS equipment for which certification is considered and the associated detailed (certification) specifications will be developed, consulted, and subsequently issued are:

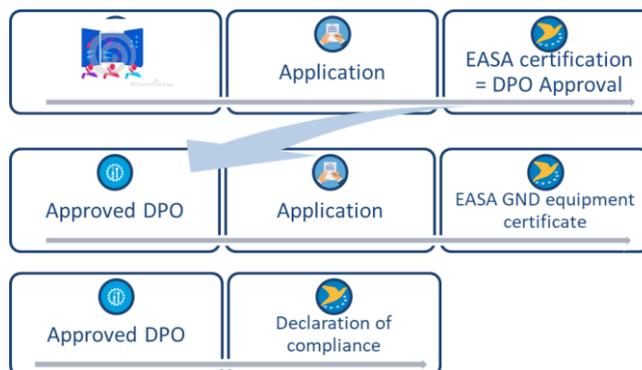
- flight data processing systems;
- surveillance data processing systems;



- central ATFM systems;
- certain integrations of these systems (e.g. remote tower system).

Consequently,

- ATM/ANS equipment certificates shall be issued by EASA after the applicant (an EASA-approved ATM/ANS equipment manufacturer) has demonstrated compliance with the applicable EASA detailed certification specifications;
- ATM/ANS equipment declarations shall be made by an EASA-approved ATM/ANS equipment manufacturer that holds an EASA approval with the respective privileges, attesting that the specific ATM/ANS equipment complies with the EASA detailed declaration specifications.



The ATM/ANS equipment certificates and declarations shall be recognised by all Member States without any further requirements or evaluation.

As per the requirements of the Basic Regulation, the use of such ATM/ANS equipment by the ATM/ANS providers shall only be allowed when a certificate or a declaration has been issued.

4.4. Methodology and data

4.4.1. Methodology applied

The methodology applied for this IA is the multi-criteria analysis (MCA), which allows to compare all the options by scoring them against a set of criteria.

The MCA covers a wide range of techniques that aim to combine a variety of positive and negative impacts into a single framework to allow an easier comparison of scenarios.

The MCA key steps in this IA include the following:

- establishing the criteria to be used for comparing the options (these criteria must be measurable, at least in qualitative terms);
- scoring how well each option meets the criteria; the scoring needs to be relative to the baseline scenario (Option 0); and
- ranking the options by combining their scores.

The criteria used to compare the options were derived from the Basic Regulation, and the guidelines for the IA were developed by the European Commission. The principal objective of the Basic Regulation, in accordance with its Article 1(1), is to ‘establish and maintain a high uniform level of civil aviation safety in the Union’. As additional objectives, the Basic Regulation identifies environmental, economic, proportionality, and harmonisation aspects, which are reflected below.

For the scoring of the impacts, a scale of –10 to +10 is used to indicate the negative and positive impacts of each option (i.e. from ‘very high’ to ‘very low’ negative/positive impacts). The

intermediate levels of benefits are termed 'high', 'medium' and 'low' with also a 'no impact' score possible.

Option 1 will be compared with Option 0, which assumes that:

- the current rules on the conformity assessment in the ATM/ANS domain shall apply **until 12 September 2023**;
- **after 12 September 2023**, if no action is taken, the requirements for the issue of EC declarations would cease to apply, and stakeholders would need to continue with the limited instructions and guidance developed and issued by their national competent authorities to ensure that ATM/ANS systems and ATM/ANS constituents are interoperable and operationally suitable in a more and more complex and integrated ATM/ANS environment.

Remark: Even if the assessment might show negative or positive elements for Option 0 (baseline scenario), the scores for Option 0 are set equal to 0 in order to allow a straightforward comparability across the options compared to the baseline scenario.

4.5. What are the impacts

4.5.1. Safety impact

Considering the nature and the risks associated with the operation of the Single European Airspace System (SEAS), all ATM/ANS equipment that supports the ATM/ANS functions and services listed in Annex VIII to the Basic Regulation and the organisations that design and produce such equipment should be subjected to a proportionate level of attestation. The attestation will be considered accomplished once the certificate that demonstrates compliance is issued or the declaration is made, based on the equipment's safety criticality and benefits for the relevant stakeholders, while the organisations involved in the design and/or production of certain ATM/ANS equipment are to be subjected to certification with the respective privileges.

In addition, the use and sharing of aeronautical data within the EATMN is paramount in ensuring safe and efficient operations. It is, therefore, fundamental that safety-relevant ATM/ANS equipment, and other ATM/ANS equipment on which the interoperability and safety of operations depend, conform to a common set of detailed specifications established by EASA.

With **Option 0**, the current situation will remain unchanged until 12 September 2023 while, thereafter, if no action is taken, stakeholders would need to deploy new technologies in a more complex and integrated ATM/ANS environment without ensuring in a standardised manner that the ATM/ANS equipment is safe and fit for the intended use. This might have negative consequences on safety.

With **Option 1**, ATM/ANS providers will establish robust processes for the deployment of new technologies that are conducive to safety. However, as a result of the new ATM/ANS equipment attestation scheme, an increase in the overall safety is foreseen to be 'low' positive (indicated as +4 in the Table 3).

The conformity assessment shall allow to demonstrate that ATM/ANS equipment meets the applicable requirements, thus ensuring that operational expectations are met with emphasis on safe and interoperable operations. It shall contribute to minimise technical failures or malfunctions which



may potentially have safety impacts (e.g. due to aircraft deviating from the safe flight path). Therefore, a formal process to check equipment suitability for use is considered essential.

Hence, Option 1 meets the following objectives as detailed in Section 2.2:

- **Minimise any undesirable implementation issues** that may compromise the operational functionalities, and promote technical interoperability through the use, where available, of detailed specifications.
- The appropriate implementation and operation of certain technologies (enablers) may be dedicated to obtaining particular safety gains.

For certain ATM/ANS equipment, the use of common requirements at EU level is beneficial where technical harmonisation can contribute towards meeting the safety goals, and necessary where there are interfaces with other systems. The proposed framework will enable enhanced harmonisation through the use of the EASA detailed specifications, and the concrete benefits will be evaluated whenever these detailed specifications are made available in support of a particular application.

Even if the lack of harmonised technical specifications has so far rarely led to safety issues, the desire to implement a distributed architecture implies greater interdependence between systems and organisations and, therefore, increased level of interoperability. Consequently, harmonised technical standards and formal attestation are significant enablers for the safe deployment of distributed architectures.

Moreover, Option 1 considers the integration of conformity assessment activities in the procedures which ATM/ANS providers have established already in order to manage and assess the safe deployment of ATM/ANS equipment.

In addition, Option 1 considers an increased and more streamlined role of the national competent authorities in the verification of ATM/ANS equipment before its integration into the ATM/ANS functional system that may be relevant for safety considerations. This should contribute to a more robust approach as regards oversight of ATM/ANS equipment.

- Facilitate the safe and interoperable **development and implementation of new technologies** by stakeholders, where such technologies are designed to have a positive impact in line with the European ATM Master Plan.

Option 1 supports the safe implementation of new technologies in two ways:

- It allows the accelerated deployment of new functionalities as enabled by the EASA detailed specifications (and the necessary standardisation material). The mandatory application of the EASA detailed specifications (as opposed to the voluntary use of Community specifications¹⁷) is also expected to reduce the potential for unsafe deployment.
- It ensures that deployment is subject to a streamlined assurance process, which is led by the ATM/ANS provider and proportionate to the potential safety impact of the changes to the ATM/ANS functional system.

¹⁷ [Community specifications \(europa.eu\)](https://europea.eu)



Table 3: Safety impacts

Option	Short title	Description	Score
0	Baseline (= do nothing)	Do not implement the Basic Regulation. The ultimate responsibility as regards safety will remain within the ATM/ANS providers' remit.	0
1	Introduction of the ATM/ANS equipment attestation scheme	Improved ability to introduce safety enablers. Improved ability to ensure the safe and interoperable deployment of new technologies. Improved oversight of the technical requirements and the related compliance demonstration processes.	+4

4.5.2. Environmental impact

n/a

4.5.3. Social impact

n/a

4.5.4. Economic impact

With **Option 0**, the current situation will remain unchanged until 12 September 2023 while, thereafter, if no action is taken, stakeholders (ATM/ANS providers and national competent authorities) would need to allocate more resources for the assessment of the integration of new technologies before deploying them in a more complex and integrated ATM/ANS environment, which could even lead to further fragmentation of the ATM/ANS equipment market.

With **Option 1**, one of the main impacts of the proposed regulatory framework, and the main area where the regulatory options can be differentiated, is in economic terms and in particular the effect on the cost of the associated equipment.

As regards the economic impact, the following objectives are considered:

- **promote cost-efficiency** by, inter alia, avoiding duplication and promoting effectiveness in the certification and oversight processes as well as the efficient use of related resources at European Union and national level by avoiding multiple oversight by the ATM/ANS providers that purchase ATM/ANS equipment and their competent authorities, and optimise the use of resources during the demonstration of compliance by reducing the administrative burden;
- **promote internal and external market opportunities** by ensuring fair competition and by facilitating the free movement of ATM/ANS equipment through the mutual recognition by the EU Member States of certificates or declarations, where applicable, without further evaluation.



PROMOTE COST-EFFICIENCY

Impact on ATM/ANS equipment manufacturers: Design and/or production organisations of ATM/ANS equipment are required to design and/or produce equipment in line with the respective applicable essential requirements. The proposed regulatory framework considers their nature and the associated risks and, therefore, all systems that support the ATM/ANS functions and services listed in Annex VIII *Essential requirements for ATM/ANS and air traffic controllers* to the Basic Regulation should not be subject to the same level of attestation, i.e. based on the risk of the particular activity and the benefits for the relevant stakeholders, certain ATM/ANS equipment should be subject to certification, while other ATM/ANS equipment should be subject to declaration, and other to no attestation at all.

Where formal attestation is required, the proposal does require the approval of the DPO by demonstrating compliance that should be commensurate with the complexity of its activities. Therefore, this option promotes the reuse of the ATM/ANS equipment manufacturer's processes whilst ensuring their adequacy.

ATM/ANS equipment manufacturers will face additional cost to adapt their working methods and procedures, as well as the organisational approval and ATM/ANS equipment certification cost. However, that cost would be compensated over time by the decrease in the workload for the applicant with the multiple oversight of the ATM/ANS providers that purchase the equipment and their competent authorities.

The option for organisations involved in the design and/or production of ATM/ANS equipment to make declarations on their own based on their associated privileges will simplify and streamline their coordination with the ATM/ANS providers.

Compared to Option 0, for ATM/ANS equipment subject to a Statement of Compliance (SoC), the coordination between ATM/ANS providers and ATM/ANS equipment manufacturers will not be affected. Indeed, even if no Declaration for Suitability for Use (DSU) or Declaration of Compliance (DoC) is formally required from ATM/ANS equipment manufacturers, ATM/ANS providers will need inputs and support from ATM/ANS equipment manufacturers to develop their SoCs.

The benefit of the proposed concept is the avoidance of oversight by those ATM/ANS providers that purchase equipment from ATM/ANS equipment manufacturers on the basis of evidence provided with the ATM/ANS equipment certificates and organisational approvals issued by EASA. In addition, when assessing the number of audits (and the related workload) of ATM/ANS equipment manufacturers by ATM/ANS providers, the total decrease in the workload and the associated cost could be quantified in the average of 10–15 %¹⁸ of the total cost for the acquisition of ATM/ANS equipment.

Impact on ATM/ANS providers: ATM/ANS providers involved in changes to ATM/ANS equipment, and their oversight authorities, are currently required to follow two assessment processes before putting equipment into service, which results from:

- the conformity assessment based on the interoperability Regulation (Regulation (EC) No 552/2004); and
- the management of change as per Implementing Regulation (EU) 2017/373.

Whilst these two assessment processes are different in terms of objectives, both require coordination as they impact on each other. The proposal simplifies the overall process and maximises

¹⁸ Based on feedback collected via interviews and surveys to some ATM/ANS providers and ATM/ANS equipment manufacturers.



the synergies with the rest of the activities concerning the verification of ATM/ANS equipment before it is put into operation/service.

ATM/ANS providers will benefit from the presumption of conformity afforded by the attestation, i.e. by a certificate or declaration, which reduces the effort required to gain technical approval (e.g. testing and equipment verification activities). In particular, ATM/ANS providers will be required to demonstrate compliance by benefiting from the ATM/ANS equipment attestation before integrating it into the ATM/ANS functional system instead of fully verifying the system and developing a technical file as required by the existing framework. The evidence for successful integration is provided by the documentation associated with the assurance of changes to ATM/ANS functional systems applicable to ATM/ANS providers. It is also anticipated that the approval and oversight of the organisations involved in the design and/or production of ATM/ANS equipment as well as the certificates and declarations of products will help ATM/ANS providers build greater trust with their suppliers and, hence, reduce the cost of testing and verification during the integration process.

In conclusion, compared to the existing framework, the new proposal is streamlined. ATM/ANS providers will be required to adapt their procedures, but this adaptation will translate into process simplification and enhanced coordination in the medium term. Overall, the new proposal will promote an overall harmonisation of the process and reduction in administrative burden that should in turn lead to lower cost in the medium term.

Impact on competent authorities, including EASA: The regulatory proposal concerns the establishment of common rules for ATM/ANS equipment within the EU, thus avoiding duplication and promoting effectiveness in the regulatory, certification and oversight processes as well as the efficient use of related resources at Union and national level. The oversight by the national competent authorities will focus on the integration of the ATM/ANS equipment; therefore, they will experience a cost reduction as all activities linked to the conformity assessment of the most critical ATM/ANS equipment will not be necessary any more at national level. On EASA's side, the implementation of Option 1 will require to plan well in advance the necessary resources for the initial certification and continuing oversight. However, the certification will fall under the Fees & Charges scheme to recover EASA's costs from the approved manufacturers as well as from the certification of the applicable ATM/ANS equipment. Consequently, the impact on EASA will be neutral.

PROMOTE INTERNAL AND EXTERNAL MARKET OPPORTUNITIES

Two key aspects are considered, namely the design and production cost and its potential impact on the price of the equipment, and the competitiveness of the respective market.

In terms of equipment design and production cost, there are several new requirements that ATM/ANS equipment manufacturers will have to meet such as the development and management of the related certification programme. Furthermore, for certain ATM/ANS equipment, the certification cost, where applicable, would also impact on the aggregated equipment design and production cost. Therefore, a higher production cost could imply pressure in the short term to increase the price of ATM/ANS equipment.

However, for cases where EASA detailed (certification/declaration) specifications have been established, it will ensure a level playing field as regards the product market while the level of the tailoring required will be driven by the local specificities, which in the medium term will have a positive impact by reducing the aggregated design and production cost.

For those cases where EASA detailed (certification/declaration) specifications have not been established, the related procurement specifications issued by the client will need to specify the related requirements to ensure that the delivered equipment meets the essential requirements. In this case, the lack of common specifications could lead to tailored products with higher design and production cost, similarly to today's scenario. As the proposed rules provide for the



certification/declaration of certain ATM/ANS equipment by its manufacturers, it is anticipated that this will greatly increase the commonality of equipment specifications and support the recognition of equipment by both EU and non-EU markets.

In the case an approved organisation has been granted the privilege to issue declarations, the cost is expected to be lower especially when ATM/ANS equipment manufacturers that provide a range of products are subject to the EASA declaration specifications since:

- the upfront cost of achieving organisation approval can be split over a greater range of products, especially if they are intended for long serial production; and
- the cost of liaising with EASA acting as the competent authority will be lower due to the promotion of a single authority for approval/certification and oversight.

Stakeholders	Economic impact
ATM/ANS equipment manufacturers	<p>Formal ATM/ANS equipment attestation required, as well as additional cost related to the approval of organisations involved in the manufacturing of the equipment concerned.</p> <p>Multiple positive economic impacts of equipment harmonisation in the medium term that could lead to cost reduction through efficient product policy implementation, reducing aggregated manufacturing cost and increasing the competitiveness of the EU industry.</p> <p>EASA organisational approval and ATM/ANS equipment certification/declaration would bring a positive economic impact as it will be mutually recognised both in EU and non-EU markets.</p>
ATM/ANS service providers	<p>Benefits from the presumption of conformity afforded by the attestation, certification or declaration by reducing the amount of effort required to demonstrate ATM/ANS equipment compliance before introducing changes to its functional system.</p> <p>Process simplification and coordination in the medium term.</p>
National competent authorities (NCAs)	<p>Reduced oversight scope with more focus on the service level approval, i.e. the approval of the change(s) to the functional system of the ATM/ANS providers.</p>
EASA	<p>Initial additional effort for EASA in relation to organisation approvals and ATM/ANS equipment certification activities that would be compensated by the Fees & Charges scheme implemented by EASA, i.e. the cost will be neutral.</p>

Illustrative examples of the potential economic benefits could be observed in the PRB Monitoring Report 2019, especially Annex IV – CAPEX report. The ATM/ANS equipment that could be subject to certification and cost saving could be related to the following:

- ATM systems: iCAS, iTEC, 4-Flight, Co-Flight, COOPANS, TopSky;
- Tower support systems: ASMGCS, AMAN, DMAN, ACDM, remote towers;
- Information services: AIM/AIS, MET.

Option 1 is considered to have a medium positive economic impact over time compared to the current scenario.



Table 4: Economic impact

Option	Short title	Description	Score
0	Baseline (= do nothing)	No change to the current practice	0
1	Introduction of the ATM/ANS equipment attestation scheme	While the additional cost for ATM/ANS equipment manufacturers and EASA would increase in the short term, in the medium to long term the overall design and/or production cost would decrease, and further economic benefits achieved from market development would be expected.	+6

Request to stakeholders

Stakeholders are invited to provide:

- *quantified justification elements on the possible impacts (e.g. economic and safety) of the options proposed, or alternatively propose a justified solution to the issue;*
- *any other information they may find necessary to bring to the attention of EASA; as a result, the relevant parts of the IA might be modified on a case-by-case basis.*

4.5.5. Proportionality issues

With respect to proportionality, it is considered whether the proposals would have a disproportionate impact on stakeholders such as, e.g., ATM/ANS equipment manufacturers and ATM/ANS providers. As today the process for demonstrating ATM/ANS equipment compliance is not subject to formal attestation, and compared to the current system, it is considered streamlined to some extent.

Option 1:

Impact on ATM/ANS equipment manufacturers. As discussed under the economic impact, there is an additional cost for ATM/ANS equipment manufacturers in establishing and following a certification programme under the supervision of EASA. It is also noted that a new applicant would benefit from the guidance the interaction with EASA will offer, as it would ensure that the process put in place to develop its products is adequate for certification. It offers the ability for ATM/ANS equipment manufacturers to simplify and at the same time upgrade their processes for complex equipment to attract more customers.

Impact on ATM/ANS providers. The development of harmonised equipment subject to formal attestation is likely to have a more positive impact on non-complex ATM/ANS providers as they will benefit more from the availability of certified/declared products. This is particularly true for AFIS providers as the possibility to procure ATM/ANS equipment that is already certified or declared by an approved organisation involved in its design and/or production would ease the demonstration of compliance with the essential requirements for both AFIS providers and their competent authorities, which in turn would provide for cost-efficiency and a reduction in human resources needs.

Compared to the current scenario, the implementation of Option 1 is considered to have a positive impact (+4) as regards proportionality.



Conclusions regarding proportionality**Table 5: Proportionality impact**

Option	Short title	Description	Score
0	Baseline (= do nothing)	No change to the status.	0
1	Introduction of the ATM/ANS equipment attestation scheme	The availability of certified/declared ATM/ANS equipment would benefit small and non-complex ATM/ANS providers, and possibly aerodrome operators, due to the reduced implementation cost. Equipment certification/organisation approval would support new entrants in ensuring their processes are fit for purpose.	+4

4.6. Conclusion

The summary of the impacts for each option is provided in Table 6.

Table 6: Comparison of the options

Option	Short title	Safety	Economic	Proportionality	Overall
0	Baseline (= do nothing)	0	0	0	0
1	Introduction of the ATM/ANS equipment attestation scheme	+4	+6	+4	+14

The approval and continuing oversight of ATM/ANS equipment manufacturers (Option 1), together with the introduction of the different methods of attestation and demonstration of compliance with the essential requirements applicable to ATM/ANS equipment is the preferred option since it provides the greatest benefits in terms of proportionality.

Furthermore, enhancing the level of common, harmonised system requirements would result in greater efficiency and lower cost for system procurement and maintenance and in improved operational coordination thus reducing the fragmentation of the ATM/ANS equipment market and facilitating industry cooperation at European level.

4.7. Monitoring and evaluation

As this NPA introduces a certification and declaration scheme for certain ATM/ANS equipment that will apply to new and updated ATM/ANS equipment designs, the monitoring of the effects produced by the new measures will consist of the following:

- (a) feedback from future ATM/ANS equipment certification projects; and
- (b) in the long term, the trend of the issues encountered with the ATM/ANS equipment during the investigation of accidents and incidents, as well as other feedback from ATM/ANS equipment manufacturers, ATM/ANS service providers, and oversight authorities.



Item (a) depends on the applications received after the adoption and applicability of the proposed regulatory framework as well as the issue and publication of the EASA detailed certification/declaration specifications.

Further to monitoring, an evaluation might be performed in the long term but in any case not earlier than 5 years after the date of applicability of the detailed certification/declaration specifications issued by EASA, and it would require the availability of experience gained from several ATM/ANS equipment certification projects.

Item (b) would be available once new ATM/ANS equipment designs have entered into service and sufficient experience has been gained with their operation, which would require several years.



5. Proposed actions to support implementation

EASA will consider the most appropriate method to support the implementation of this proposal by applying one of the following actions, as appropriate:

- Focused communication for Advisory Body meeting(s) (MAB/SAB/TeB/TEC/COM)
(Advisory Body members)
- Detailed explanation with clarifications on the EASA website
(Primarily targeted audience: industry, competent authorities)
- Dedicated thematic workshop/session
(Primarily targeted audience: industry, competent authorities)



6. References

6.1. Related EU regulations

- Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1)
- 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)

6.2. Related EASA decisions

n/a

6.3. Other references

- 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)

7. Quality of the NPA

To continuously improve the quality of its documents, EASA welcomes your feedback on the quality of this NPA with regard to the following aspects:

7.1. The regulatory proposal is of technically good/high quality

[Please choose one of the options below and place it as a comment in CRT; if you disagree or strongly disagree, please provide a brief justification.]

Fully agree / Agree / Neutral / Disagree / Strongly disagree

7.2. The text is clear, readable and understandable

[Please choose one of the options below and place it as a comment in CRT; if you disagree or strongly disagree, please provide a brief justification.]

Fully agree / Agree / Neutral / Disagree / Strongly disagree

7.3. The regulatory proposal is well justified

[Please choose one of the options below and place it as a comment in CRT; if you disagree or strongly disagree, please provide a brief justification.]

Fully agree / Agree / Neutral / Disagree / Strongly disagree

7.4. The regulatory proposal is fit for purpose (capable of achieving the objectives set)

[Please choose one of the options below and place it as a comment in CRT; if you disagree or strongly disagree, please provide a brief justification.]

Fully agree / Agree / Neutral / Disagree / Strongly disagree

7.5. The impact assessment (IA), as well as its qualitative and quantitative data, is of high quality

[Please choose one of the options below and place it as a comment in CRT; if you disagree or strongly disagree, please provide a brief justification.]

Fully agree / Agree / Neutral / Disagree / Strongly disagree

7.6. The regulatory proposal applies the 'better regulation' principles^[1]

[Please choose one of the options below and place it as a comment in CRT; if you disagree or strongly disagree, please provide a brief justification.]

Fully agree / Agree / Neutral / Disagree / Strongly disagree

7.7. Any other comments on the quality of this NPA (please specify)

Note: Your comments on this Section will be considered for internal quality assurance and management purposes only and will not be published in the related CRD.

^[1] For information and guidance, see:

- https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en
- https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en
- https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox/better-regulation-toolbox_en

8. Appendices

8.1. Appendix 1: DRAFT COMMISSION IMPLEMENTING REGULATION (EU) .../... 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

DRAFT COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **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 EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,
Having regard to [...] ¹⁹, and in particular Article [...] thereof,
Whereas:

- (1) [Initial capital...].
- (2) [Initial capital...].
- (3) The measures provided for in this Regulation are in accordance with the opinion of the [...] committee, [for acts adopted after consultation of a committee under the examination procedure],

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down, pursuant to Articles 42(1)(b) and 43(1) of Regulation (EU) 2018/1139, 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 (ATM/ANS equipment).

Article 2

Definitions

For the purpose of this Regulation, ‘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.

¹⁹

OJ L [...], [...], p. [...].

Article 3

Competent authority requirements

1. For the purposes of this Regulation, the competent authority responsible for the issue of approvals to organisations involved in the design, and/or production of ATM/ANS equipment and for the oversight and enforcement in respect of those organisations, shall be the Agency pursuant to Article 80(1)(c) of Regulation (EU) 2018/1139.
2. The Agency shall fulfil the detailed requirements laid down in Annex I (Part-ATM/ANS.EQMT.AR) to Delegated Regulation (EU) .../... [*delegated act on the attestation of ATM/ANS equipment*] when conducting certification, investigations, inspections, audits and other monitoring activities necessary to ensure the effective oversight of organisations involved in the design, and/or production of ATM/ANS equipment subject to this Regulation.

Article 4

Organisations involved in the design, and/or production of ATM/ANS equipment

An organisation involved in the design, production or maintenance of ATM/ANS equipment shall demonstrate its capability in this regard in accordance with the Annex (Part-DPO.OR) to this Regulation.

Question 8.1 #1

At present, EASA has not established any bilateral working arrangements to address technical ATM/ANS equipment issues. However, it is proposed to establish such bilateral working arrangements and offer the possibility for derogation from the provisions of the above-mentioned Article 4.

Stakeholders are invited to comment on the proposal and, where they believe it is not sufficient, make additional proposals, including justifications.

E.g. ‘By way of derogation from point 1, an organisation whose principal place of business is in a non-Member State, may demonstrate its capability by holding a certificate issued by that State for the organisation involved in the design, production or maintenance of ATM/ANS equipment, for which it applies, provided that the Agency has determined that the system of that State includes the same independent level of checking of compliance as provided for by this Regulation, either through an equivalent system of approvals of organisations or through the direct involvement of the competent authority(ies) of that State.’

Article 5

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

**REQUIREMENTS FOR ORGANISATIONS INVOLVED IN THE DESIGN AND/OR PRODUCTION OF ATM/ANS EQUIPMENT
(Part-DPO.OR)**

SUBPART A — GENERAL REQUIREMENTS (DPO.OR.A)

DPO.OR.A.001 Scope

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 and/or production of ATM/ANS equipment.

DPO.OR.A.005 Eligibility

Any natural or legal person who has demonstrated, or is in the process of demonstrating, their capability to design and/or produce ATM/ANS equipment in accordance with point DPO.OR.A.010, may apply for a design and/or production organisation approval under the conditions laid down in this Annex.

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

- (a) An application for an approval under this Regulation 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 and/or production of ATM/ANS equipment shall comply with the requirements set out in this Annex where those requirements are applicable to the activities the organisation involved in the design and/or production of ATM/ANS equipment performs or intends to perform.

DPO.OR.A.015 Organisation exposition

- (a) An organisation involved in the design and/or production of ATM/ANS equipment shall establish and maintain an exposition, which provides the following information:
 - (1) statement signed by the accountable manager who confirms that the organisation exposition and any associated manuals, which describe how the organisation implements the provisions of this Regulation, are complied with at all times;
 - (2) the title(s) and name(s) of the key manager(s);
 - (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 that shows the associated chains of responsibility of the managers;
 - (5) a general description of the organisation's human 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) .../... [*delegated act on the attestation of ATM/ANS equipment*] and has no unsafe 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 has been issued in accordance with Implementing Regulation (EU) .../... [*implementing act on the approval of DPOs*], as applicable;
 - (10) the procedure 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 procedures;
 - (13) a list of the contracted organisations referred to in point DPO.OR.B.015 of this Annex.
- (b) The 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 exposition.

DPO.OR.A.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 its delegated and implementing acts.
- (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 its delegated and implementing acts.

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) to point ATM/ANS.EQMT.AR.A.020 of Annex I (Part-ATM/ANS.EQMT.AR) to Delegated Regulation (EU) .../... [*delegated act on the attestation of ATM/ANS equipment*].

PDO.OR.A.020 Continued validity of an organisation approval

- (a) An organisation's approval shall remain valid for an unlimited period of time provided that:
 - (1) the organisation remains compliant with the applicable requirements of this Regulation;
 - (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.

DPO.OR.A.025 Facilitation and cooperation

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.

DPO.OR.A.030 Findings and corrective actions

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

- (a) identify the root cause of the non-compliance;
- (b) define a corrective action plan; and
- (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 ATM/ANS.EQMT.AR.C.020 of Annex I (Part-ATM/ANS.EQMT.AR) to Delegated Regulation (EU) .../... [*delegated act on the attestation of ATM/ANS equipment*].

DPO.OR.A.035 Immediate reaction to a safety and interoperability problem

An organisation involved in the design and/or production of ATM/ANS equipment shall implement any safety measures, including ATM/ANS equipment directives, mandated by the Agency in accordance with point ATM/ANS.EQMT.AR.025 of Delegated Regulation (EU) .../... [*delegated act on the attestation of ATM/ANS equipment*].

DPO.OR.A.040 Failures, malfunctions, and defects

- (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; and
- (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 (a)(1) and on 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 mandatory and voluntary occurrence reporting and follow-up that meet the requirements of Regulation (EU) No 376/2014 and of Regulation (EU) 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 or underperformance 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.

DPO.OR.A.045 Approval transferability

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

SUBPART B — MANAGEMENT (DPO.OR.B)

DPO.OR.B.001 Management system

- (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 a 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 certain 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:
 - (i) control procedure(s) for the design of ATM/ANS equipment, and for changes to its design;

- (ii) 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; and
 - (iii) procedure(s) for 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) staff involved in the design of ATM/ANS equipment are of sufficient numbers and have considerable experience, and have been authorised to discharge their allocated responsibilities;
 - (v) assurance that there is close and efficient coordination between departments and within departments;
- (10) as regards production activities, control 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 products, parts, materials and equipment, including the supply of new items or items used by product 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, jigs, 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 and/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 and/or production of ATM/ANS equipment shall establish a function 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 and/or production of ATM/ANS equipment and the complexity of its activities, taking into account the hazards and associated risks inherent in those activities.

DPO.OR.B.005 Change management

- (a) Following the issue of an organisation's certificate, any change to the management system that is significant for the demonstration of compliance shall be approved by the Agency before it is implemented.
- (b) Each change made to the ATM/ANS equipment shall be notified to the Agency by following the approved procedure, defining the classification of the changes to the ATM/ANS equipment and describing how such changes will be notified and managed.

DPO.OR.B.010 Facility requirements

An organisation involved in the design and/or production of ATM/ANS equipment shall ensure that its 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

- (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 the organisation's supervision. An organisation involved in the design and/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 and/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 and/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.

DPO.OR.B.020 Personnel requirements

- (a) An organisation involved in the design and/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 postholders, in particular of management personnel in charge of safety-, quality-, security-, finance- and human-resources-related functions, as applicable, shall also be defined.

DPO.OR.B.025 Record-keeping

- (a) An organisation involved in the design and/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 of this Annex.
- (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 and/or production of ATM/ANS equipment shall maintain a register of the ATM/ANS users that deploy its ATM/ANS equipment.

SUBPART C — TECHNICAL REQUIREMENTS (DPO.OR.C)**DPO.OR.C.001 Organisations involved in the design and/or production of ATM/ANS equipment**

- (a) An applicant for, and a holder of, a design and/or production organisation approval for ATM/ANS equipment shall be entitled to hold or apply to be issued a certificate for the design and/or production of ATM/ANS equipment.
- (b) As regards design activities, an organisation shall:
 - (1) issue a declaration of design for certain ATM/ANS equipment, as applicable;
 - (2) issue data and information under its authority within the scope of its terms of approval as established by the Agency with the following statement: 'The technical content of this document is approved under the authority of EASA.AOA.GND.[XXXX]';
 - (3) prepare and maintain, for each model of each product for which an ATM/ANS equipment declaration has been issued, a current file of complete technical data and records.
- (c) As regards production activities, an organisation shall:
 - (1) manufacture each article ensuring that the completed product conforms to its design data and is safe for installation;
 - (2) prepare and maintain, for each model of each product for which an ATM/ANS equipment declaration has been issued, a current 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 product;
 - (4) make available to the users of the product, and to the Agency on request, those instructions for continued suitability necessary for the use and maintenance of the product, 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 to, within the scope of its terms of approval, determine that each completed ATM/ANS equipment conforms with the applicable design data and is in a condition for safe operation before issuing a statement of conformity that the ATM/ANS equipment it has manufactured has been produced in accordance with the applicable requirements of this Regulation and with the applicable design data.
- (e) The statement of conformity 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) its part number;
 - (3) its serial number;
 - (4) a statement that the ATM/ANS equipment has been manufactured in conformity to the applicable design data and is in a condition for safe operation;
 - (5) a reference to the declaration of design.

DPO.OR.C.005 Coordination

An organisation involved in the design and/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 proper support of the continued suitability of the ATM/ANS equipment, as applicable;
- (c) the proper support to the ATM/ANS equipment design activity with regard to its continued suitability of the ATM/ANS equipment.

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

When an ATM/ANS equipment directive has to be issued by the Agency, the organisation involved in the design and/or production of ATM/ANS equipment shall:

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

8.2. Appendix 2: DRAFT COMMISSION DELEGATED REGULATION (EU) .../... laying 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

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

of XXX

laying 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

THE EUROPEAN COMMISSION,

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

Having regard to [...] ²⁰, and in particular Article [...] thereof,

Whereas:

(4) [Initial capital...].

(5) [Initial capital...],

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down, pursuant to Article 47 of Regulation (EU) 2018/1139, 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:
 - (a) the identification of ATM/ANS equipment subject to certification, declaration, or a statement of compliance;
 - (b) the issue of certificates for ATM/ANS equipment;
 - (c) 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;
 - (d) 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;
 - (e) the issue of ATM/ANS equipment directives by the Agency.

²⁰

OJ L [...], [...], p. [...].

Article 2

Definitions

For the purpose of this Regulation, ‘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.

Article 3

Competent authority

3. 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 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 I to this Regulation.
4. 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 that processes and delivers data for the purpose of the provision of ATM, including equipment that is necessary for the purpose of 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 II 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 compliance of the ATM/ANS equipment with its certification basis; 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 which 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 II 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.

Question 8.2 #1

Stakeholders are invited to comment on whether sensors (for example, PSR/SSR radars, ADS-B receivers or MLAT equipment) used for surveillance should be subject to declaration by approved design and/or production organisations, including a justification.

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.020 of Annex I as a result of the following:
 - (a) the ATM/ANS equipment no longer complies 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 shall be issued with a statement of compliance by the ATM/ANS provider in accordance with point (g)(3) of point ATM/ANS.OR.A.045 of Regulation (EU) 2017/373 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 by the Agency; 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.A.050(e).

Article 7

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 552/2004²¹ 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, 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, 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 point 1(a) and (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, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation.

²¹ 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)

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 and that has been manufactured from [the date of entry into force of this Regulation] until [12 September 2028] shall be 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 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, 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 compliance 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 (c) that such ATM/ANS equipment does not ensure a level of safety, 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 point 3(a) and (b) until [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, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation.

Article 8

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

REQUIREMENTS FOR THE AGENCY (Part-ATM/ANS.EQMT.AR)

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

ATM/ANS.EQMT.AR.A.005 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 II and III to this Regulation with regard to:

- (a) the issue, maintenance, amendment, limitation, suspension or revocation of certificates for ATM/ANS equipment;
- (b) the acceptance of declarations for ATM/ANS equipment;
- (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.010 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.015 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.020 Means of compliance

- (a) The Agency shall develop acceptable means of compliance (AMC) that may be used by persons or organisations to demonstrate compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis. When the acceptable means of compliance is/are complied with, the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis shall be deemed to have been met.
- (b) Other, alternative means of compliance (AltMoC) may be used by an organisation involved in the design and/or production of ATM/ANS equipment to establish compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis.
- (c) 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 ATM/ANS provider.
- (d) When the Agency finds that the AltMoC proposed by an applicant is/are sufficient to establish compliance with the applicable requirements, it shall without undue delay notify the applicant that the proposed AltMoC may be implemented and, if applicable, amend the approval of the applicant accordingly.

ATM/ANS.EQMT.AR.A.025 Immediate reaction to a safety 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 and interoperability information.
- (b) Upon receiving the information referred to in point (a), the Agency shall take appropriate measures to address the safety and/or interoperability problem, including the issue of ATM/ANS equipment directives in accordance with point ATM/ANS.EQMT.AR.A.025.
- (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]*. When joint action is required, the competent authorities of the ATM/ANS providers concerned shall also be notified.

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

- (a) ‘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 condition that has been identified and restore the performance and interoperability of that ATM/ANS equipment when evidence shows that the safety, performance or interoperability of that particular equipment may otherwise be compromised.

- (b) The Agency shall issue an ATM/ANS equipment directive when:
- (1) an unsafe, 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.
- (c) When an ATM/ANS equipment directive is issued to correct the condition referred to in point (b), the holder of the ATM/ANS equipment certificate or the declarant of the declaration of compliance of the ATM/ANS equipment design shall, unless otherwise determined by the Agency in case urgent action is needed:
- (1) propose appropriate corrective action and submit details of that proposal to the Agency for approval;
 - (2) following the approval by the Agency of the proposal referred to in point (1), make available to all known users of the equipment and, on request, to any person required to comply with the ATM/ANS equipment directive, appropriate descriptive data and accomplishment instructions.
- (d) 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.
- (e) The verification of compliance of the organisations with the applicable ATM/ANS equipment directives shall be ensured by the competent authorities of the ATM/ANS providers that use the affected ATM/ANS equipment, as applicable.

ATM/ANS.EQMT.AR.A.035 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 certification specification 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.A.040.
- (b) The inclusion of additional features, characteristics or functions not initially included in the certification basis shall be agreed by the Agency.
- (c) 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 useability of the ATM/ANS equipment.

ATM/ANS.EQMT.AR.A.040 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 II to this Regulation;
 - (2) declare compliance of ATM/ANS equipment in accordance with Annex III 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 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.

ATM/ANS.EQMT.AR.A.045 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 the Agency finds necessary to ensure the appropriate level of performance of the ATM/ANS equipment equivalent to that required by the applicable certification specifications.

ATM/ANS.EQMT.AR.A.050 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 it 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 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.055 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.A.050, 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.A.060 Declaration of compliance of the ATM/ANS equipment design

- (a) Upon receiving a declaration of compliance for ATM/ANS equipment design from an organisation involved in the design of ATM/ANS equipment approved by the Agency in accordance with Implementing Regulation (EU) .../... [*implementing act on DPO approval*] and which has the privilege under that approval to make such declarations, the Agency shall verify that:
 - (1) the declaration contains all the information specified in point ATM/ANS.EQMT.DEC.010;
 - (2) 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 recorded 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.
- (d) The Agency shall register the declaration provided that the requirements in points (a) to (c) are met. The Agency shall maintain a register of all valid compliance declarations as regards ATM/ANS equipment submitted to it in accordance with this Regulation.

ATM/ANS.EQMT.AR.A.065 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 Annex II, III or 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.

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, 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].

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)(4) cover all the tasks performed on its behalf by the qualified entity(ies).

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 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)(2);

- (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:
 - (1) applications for the issue of approvals;
 - (2) approvals issued to organisations involved in the design and/or production of ATM/ANS equipment, including the associated privileges and any changes to them;
 - (3) ATM/ANS equipment certificates issued, including any changes to them;
 - (4) declarations of compliance of ATM/ANS equipment design;
 - (5) the Agency's continuing oversight programme, including all assessment, audit and inspection records;
 - (6) a copy of the oversight programme listing the dates when audits are due and when audits were carried out;
 - (7) copies of all formal correspondence;
 - (8) 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;
 - (9) any assessment, audit or inspection report;
 - (10) copies of all organisation handbooks, procedures and processes or manuals and amendments to them;
 - (11) 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 kept for a minimum period of 5 years, 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 — OVERSIGHT, CERTIFICATION AND ENFORCEMENT
(ATM/ANS.EQMT.AR.C)

ATM/ANS.EQMT.AR.C.001 Initial oversight investigation

- (a) Upon receiving a declaration of compliance of the ATM/ANS equipment design from an organisation involved in its design and/or production, 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 III to this Regulation.
- (b) The Agency shall acknowledge the receipt of the declaration, including the assignment of an individual declared production organisation reference number to the declarant.

ATM/ANS.EQMT.AR.C.005 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 III to this Regulation;
- (c) there are no unresolved issues in accordance with point ATM/ANS.EQMT.AR.C.001.

ATM/ANS.EQMT.AR.C.010 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 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.010.

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.020 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.015 Changes to declarations

- (a) Upon receiving a notification of changes in accordance with point ATM/ANS.EQMT.DEC.015, the Agency shall verify the completeness of the notification in accordance with point ATM/ANS.EQMT.AR.C.001.
- (b) When the change(s) affects (affect) any aspect of the declaration that is registered in accordance with point ATM/ANS.EQMT.AR.C.005, 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.020 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.A.025.

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.025;
 - (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, 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.



ANNEX II
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, 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 compliance

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.A.030;
 - (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.A.050; 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)(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.A.030 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.A.030 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 if the Agency finds that 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.A.030, 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.AR.A.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.EQPT.CERT.015(a)(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.A.050(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.035, 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.

ATM/ANS.EQMT.CERT.030 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.035 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.040 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.045 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.050 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.055 Changes to the ATM/ANS equipment certification basis

- (a) 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’.
- (b) All other 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.A.035.
- (c) By way of derogation from point (b), 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. 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].
- (d) The part number scheme defined by the approved design organisation shall allow the part number evolution resulting from the introduction of changes as per point (c).

ATM/ANS.EQMT.CERT.060 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).

ANNEX III

DECLARATION OF COMPLIANCE OF THE ATM/ANS EQUIPMENT DESIGN**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 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 Declaration of changes to the design of ATM/ANS equipment

- (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.001 to determine its compliance shall require the assignment of a new model designation to the equipment.

ATM/ANS.EQMT.DEC.020 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.025 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.030 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.035 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).

8.3. Appendix 3: DRAFT COMMISSION IMPLEMENTING REGULATION (EU) .../... amending Implementing Regulation (EU) 2017/373 as regards the conformity assessment of ATM/ANS systems and ATM/ANS constituents

DRAFT COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Implementing Regulation (EU) 2017/373 as regards 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 [...]²², and in particular Article [...] thereof,

Whereas:

- (6) Implementing Regulation (EU) 2017/373 lays down common requirements for the provision of air traffic management and air navigation services ('ATM/ANS') and other air traffic management network functions ('ATM network functions') for general air traffic and their oversight.
- (7) With the adoption of Commission Implementing Regulation (EU) .../... [*implementing act on DPO approval*], ATM/ANS systems and ATM/ANS constituents ('ATM/ANS equipment') shall be subject to certification or declaration by organisations involved in the design and/or production of ATM/ANS equipment. To ensure the appropriate installation, on-site testing and safe entry into service of such equipment, Implementing Regulation (EU) 2017/373 should be amended to include the necessary requirements on ATM/ANS providers.
- (8) In order to ensure the proper implementation of this Regulation, Member States and the affected stakeholders should be given sufficient time to adapt their procedures to the new regulatory framework before this Regulation becomes applicable.
- (9) The European Union Aviation Safety Agency has proposed measures in its Opinion No XX/202X²³ in accordance with Articles 75(2)(b) and (c) and 76(1) of Regulation (EU) 2018/1139.
- (10) Implementing Regulations (EU) 2017/373 should, therefore, be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

²² OJ L [...], [...], p. [...].

²³ <https://www.easa.europa.eu/document-library/opinions>

Article 1

Amendments to Implementing Regulation (EU) 2017/373

Annex II to Implementing Regulation (EU) 2017/373 is amended as follows:

1. point (a) of point ATM/ANS.AR.A.020 is amended as follows:

‘(a) The competent authority shall without undue delay notify the Agency in case of any significant problems with the implementation of the relevant provisions of ~~Regulation (EC) No 216/2008 and its implementing rules~~ Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis or of Regulations (EC) No 549/2004, (EC) No 550/2004, and (EC) No 551/2004 and ~~Regulation (EC) No 552/2004~~ of the European Parliament and of the Council ⁽¹⁾ applicable to service providers.’;

[...]
2. point (a)(4) of ATM/ANS.AR.C.005 is amended as follows:

‘(a) Within the ~~scope framework~~ of point ATM/ANS.AR.B.001(a)(1), the competent authority shall establish a process in order to verify:

[...]

~~(4) implementation of safety objectives, safety requirements and other safety-related conditions identified in declarations of verification of systems, including any relevant declaration of conformity or suitability for use of constituents of systems issued in accordance with Regulation (EC) No 552/2004;~~

(4) the implementation of safety and interoperability objectives, applicable requirements and other conditions identified in the statement of compliance for ATM/ANS equipment; technical and performance limitations and conditions identified in ATM/ANS equipment certificates and/or ATM/ANS equipment declarations; and of safety measures, including ATM/ANS equipment directives, mandated by the Agency in accordance with point ATM/ANS.EQMT.AR.A.025 of Annex I to Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment];’;
3. points (c), (d) and (e) of point ATM/ANS.AR.C.050 are amended as follows:

‘(c) A level 1 finding shall be issued by the competent authority when any serious non-compliance is detected with the applicable requirements of ~~Regulation (EC) No 216/2008 and its implementing rules~~ Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis as well as Regulations (EC) No 549/2004, (EC) No 550/2004, and (EC) No 551/2004, and ~~(EC) No 552/2004~~ and their implementing rules, with the ~~service~~ ATM/ANS provider’s procedures and manuals, with the terms ~~and of~~ conditions of ~~the~~ certificate ~~or certificate~~, with the designation act, if applicable, or with the content of a declaration which poses a significant risk to flight safety or otherwise calls into question the service provider’s capability to continue operations.

Level 1 findings shall include but ~~are~~ not ~~be~~-limited to:

- (1) the promulgation of operational procedures and/or provision of providing a service in a way which introduces a significant risk to flight safety;
 - (2) the obtaining or maintenance maintaining of the validity of the service provider's certificate through the submission of falsified by falsification of submitted documentary evidence;
 - (3) evidence of malpractice or fraudulent use of the service provider's certificate;
 - (4) the lack of an accountable manager.
- (d) A level 2 finding shall be issued by the competent authority when any other non-compliance is detected with the applicable requirements of ~~Regulation (EC) No 216/2008 and its implementing rules~~ Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis, as well as Regulations (EC) No 549/2004, (EC) No 550/2004, and (EC) No 551/2004, and ~~(EC) No 552/2004~~ and their implementing rules, with the service ATM/ANS provider's procedures and manuals or with the terms and of conditions of the or certificate, or with the content of a the declaration.
- (e) When a finding is detected, during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by ~~Regulation (EC) No 216/2008 and its implementing rules~~ Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis, as well as Regulations (EC) No 549/2004, (EC) No 550/2004, and (EC) No 551/2004 and ~~(EC) No 552/2004~~ and their implementing rules, communicate the finding to the service provider in writing and require corrective action to address the non-compliance(s) identified.
- (1) In the case of level 1 findings, the competent authority shall take immediate and appropriate action, and may, if appropriate, limit, suspend or revoke in whole or in part the certificate while ensuring the continuity of services provided that safety is not compromised, and in the case of the Network Manager, it shall inform the Commission. The measures taken shall depend upon the extent of the finding and shall remain in force until successful corrective action has been taken by the service ATM/ANS provider.
 - (2) In the case of level 2 findings, the competent authority shall:
 - (i) grant the service provider 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 service provider, 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 service provider fails to submit a corrective action plan that is acceptable to the competent authority in the light of the finding, or where the service provider fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding may be raised to a level 1 finding, and action shall be taken as laid down in point (1).
- (f) Where the competent authority detects that ATM/ANS equipment is not integrated into the ATM/ANS functional system as per point (x) of point ATM/ANS.OR.A.045, it shall, with due regard to the need to ensure the safety and continuity of operations, take all measures necessary to restrict the area of application of the ATM/ANS equipment concerned or prohibit its use by the ATM/ANS providers under its oversight.

- (g) For those cases that do not require level 1 and 2 findings, the competent authority may issue observations.’;
4. the following points (g) and (h) are added to point ATM/ANS.OR.A.045:
- ‘(g) Before integrating ATM/ANS equipment into the ATM/ANS functional system, the ATM/ANS provider shall ensure that:
- (1) new or modified ATM/ANS equipment is certified by the Agency in accordance with Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment] and manufactured by an approved ATM/ANS equipment organisation pursuant to Implementing Regulation (EU) .../... [implementing regulation on DPO approval]; or
 - (2) new or modified ATM/ANS equipment is declared by an approved design organisation pursuant to Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment] and manufactured by an approved ATM/ANS equipment organisation pursuant to Implementing Regulation (EU) .../... [implementing act DPO approval]; or
 - (3) by way of derogation from points (1) and (2), when the ATM/ANS equipment is neither subject to certification nor to declaration pursuant to Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment], the ATM/ANS provider shall make a statement of compliance for the ATM/ANS equipment to declare its compliance with the applicable technical standards established in accordance with Article 6(1) of Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment]; and
 - (4) the particular ATM/ANS equipment has been verified to comply with the equipment manufacturer’s specifications, including installation and on-site test(s).
- (h) When the ATM/ANS provider puts the ATM/ANS equipment into service, it shall ensure that the ATM/ANS equipment, or the modified one, is deployed according to the conditions of use, as well as to any prescribed limitations, and meets all the applicable requirements that stem from the safety assessment or the safety support assessment.’.

Article 2

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
[...]

