

**3. CRD table of comments and responses**

**Individual comments and responses referring to the relevant discussion topics**

In responding to the comments, the following terminology is applied to attest EASA’s position:

- (a) **Accepted** — EASA agrees with the comment and any proposed change is incorporated into the text.
- (b) **Partially accepted** — EASA either partially agrees with the comment or agrees with it but the proposed change is partially incorporated into the text.
- (c) **Noted** — EASA acknowledges the comment, but no change to the text is considered necessary.
- (d) **Not accepted** — EASA does not agree with the comment or proposed change.

<b>(General Comments)</b>	-
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comment	33	comment by: <i>German NSA (BAF)</i>	<p>It is not clear what is covered in principle from ATM/ANS equipment.</p> <p>According to Regulation 2018/1139 ATM/ANS consists of ATS, C, N, S, MET, AIS, ASM, ATFM, DAT, FPD and ATM network functions.</p> <p>NPA 2022-09 addresses only ATS, C, N, S, ATFM equipment.</p> <p>Please clarify in the text whether the other services/functions - especially MET - are covered as well. Otherwise NSAs and EASA will run into discussions for which ATM/ANS equipment Statements of Compliance have to be delivered.</p>
response			<p><i>Accepted</i></p> <p>Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.</p>

comment	34	comment by: <i>German NSA (BAF)</i>	<p>Regarding the draft regulation for certification and declaration of compliance of ATM/ANS equipment, and EASA's responsibilities, there should be the possibility for interested NSA to take over activities regarding certification/declaration of ATM/ANS equipment.</p> <p>BAF proposes to insert a provision that EASA can delegate the responsibility to the NSAs.</p>
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response

*Partially Accepted*

The comment is welcomed, and the commentator is kindly invited to note that the legal basis for such joint certification, oversight and enforcement system is already laid down in CHAPTER IV of the EASA Basic Regulation (EU) 2018/1139. All further details are defined in the partnership agreements with the national competent authorities. In conclusion, the comment is noted, and it is considered that the issue is already addressed at the EASA Basic Regulation and there is no necessity for further details at implementing and delegated acts level.

comment

67

comment by: CAA CZ

First, we would like to thank the Agency for its efforts in preparing the new regulatory framework, which fundamentally changes the set tasks of service providers and national supervisory authorities when it comes to ensuring compliance of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment) in future.

After reviewing the Notice of Proposed Amendment 2022-09, we would like to make the following questions and recommendations that may have a major impact on the implementation of the new regulatory framework:

1. What will be the procedure if the ATM/ANS equipment is in operation at an ATM/ANS service provider and the DPO ceases to hold the DPO approval?
2. Why is the minimum content of the Statement of Compliance (SoC) not specified in the draft regulation when there are ones for EASA certificates and DPO declarations? We are strongly asking for establishing further details and a description of what such a document must contain, e.g. the minimum content of the SoC, or and the form, set for uniform implementation within the EU, at least through the AMC. It is unclear if CAs have to check SoC without this required AMC.
3. On what basis will the ATM/ANS service providers issue SoCs during the transition period if they do not have updated DSUs or EASA specifications at that time? How will the ATM/ANS service providers keep their DoVs updated, if manufactures do not update their DSU during the transition period? What will be the procedure during the transition period when modifying ATM/ANS equipment manufactured before 12 SEP 2023 in the form of various patches or releases? We consider the manufacturer will not be obliged to update the DSU, which forms a part of the Technical file belonging to the certain DoV
4. The new regulation requires that for a period of 5 years from September 2023, the CAs have to provide relevant DoV (TF) and SoC to EASA. However, this will produce an additional burden for the CAs with no visible benefit, as both the DoV and the SoC are self-declarations from the ANSP. We propose to cancel this obligation also with regard to various language mutations.
5. We recommend placing Presentation systems (WS presenting the output from FDP systems and from SDP systems to ATCO) among the most critical ATM/ANS equipment. These should be listed separately as they may not form a coherent whole with FDP systems or with SDP systems, but they are also most critical for the provision of ATS services.

6. We recommend placing COM/NAV/SUR equipment, having already setup appropriate standards among the middle critical ATM/ANS equipment, requiring DPO declaration. These are mainly covered by ICAO SARPS.
7. We recommend that if the ATM/ANS equipment is not subject to EASA certification or DPO declaration, it is possible to issue special conditions according to ATM/ANS.EQMT.AR.A.045 (Special Conditions) also via the CA responsible for the oversight. In this case, the respected CA has to inform about issuing of the special conditions the Agency EASA, which must be finally confirmed by the Agency. We request this addition mainly because a situation may arise where, based on local conditions, it will be necessary to accept a deviation from the issued specifications for this category of ATM/ANS equipment attestation (third level).
8. The new regulation has introduced new requirements for ATM/ANS service providers in the framework of functional system change management (draft amendment to Regulation (EU) 2017/373 point ATM/ ANS.OR.A.045: new items (g) [especially (4)] and (h)). These amendments to Regulation 2017/373 can be supported, but we recommend issuing AMC/GM for their uniform implementation.
9. We recommend considering the possibility of obliging the manufacturer of certain ATM/ANS equipment to ensure their professional installation (such as ILS, etc.). The installation could then be carried out as contracted activities on behalf of the manufacturer of the affected ATM/ANS equipment in cooperation with the concerned ATM/ANS provider.
10. Since recording systems for legal record of voice communication and surveillance situation on ATCO screens are not listed in Article 3.1 of Annex VIII to the Basic regulation, should we not consider them as ATM/ANS equipment?

Other general questions considering the Agency future tasks:

1. Will the Agency also evaluate AltMoC proposed by an organisation involved in the design and/or production of ATM/ANS equipment (DPO) for ATM/ANS equipment that are neither subject to certification by EASA nor subject to declaration made by DPO?
2. Will the Agency publicly announce a list of accepted individual declarations made by DPOs for ATM/ANS equipment?
3. Will the Agency publicly announce a list of the approved DPO?
4. Does EASA intend to entrust the CA to act on behalf of EASA to fulfil certain tasks in the field of DPO approval and ATM/ANS equipment certification, as in the case of airworthiness certification?
5. To whom will the costs of the joint oversight visits according to ATM/ANS.EQMT.AR.A.015 (b) carried out by the CAs of the Member States and the Agency be charged?

Contact person: Josef Kopp ([kopp@caa.cz](mailto:kopp@caa.cz)), ANS Department Director & ATM/ANS sectorial focal point for EASA

response

*Noted*

Following the order of the comments, the commentator is invited to note the following:

1. Please refer to topic 'DPO approval discontinuation'.
2. Taking into account the comment, the development of the associated AMC/GM is under consideration.
3. Please refer to topic 'Transitional provisions'.
4. Please refer to topic 'Transitional provisions'.
5. Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.
6. Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.
7. The comment is noted and the proposal is considered as not acceptable as the 'special conditions' principle applies when the equipment is subject to certification only. This principle is not applicable when the equipment is subject to declaration. Furthermore, the statement of compliance is also a kind of declaration and is subject to oversight only and not to approval.
8. The proposal is well received and will be considered in the context of the activities of RMT.0161 Subtask 3.
9. Taking into account the comment, the development of the associated AMC/GM is under consideration.
10. Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

As regards the other general questions:

1. If the manufacturer would be an approved organisation and depending on the privileges of the approval, the answer is affirmative; if this is not the case, the answer is negative.
2. The answer is affirmative.
3. The answer is affirmative, which is also the case for approved ATM/ANS providers.
4. The answer is affirmative.
5. The answer depends on the scope of the visit.

comment 68

comment by: ASD

*ASD welcomes the opportunity to provide comments on the EASA NPA 2022-09 and fully supports the approach taken which will ease the reference to the new regulatory framework and will enable the necessary harmonisation of the requirements of interoperability, security, performance and safety. We would like to thank EASA for the efforts delivered to achieve this objective. We would also like to offer the following high-level comments in support of the development of the AMC & GM and the detailed specifications, which are planned to be prepared in sub part 3 and which are of key importance for the proper implementation of this new regulation:*

- *The transition phase should be set up to ensure a smooth implementation of the new requirements taking into consideration contractual obligations;*
- *The rule should ensure a fair and proper implementation of the regulation with regards to Design and Production Organisations' approval, oversight and equipment certification;*
  - *e.g. Clearly define the roles, responsibilities of the 'qualified entities' as well as the associated EASA oversight and the given level of delegation;*
- *The certification maintenance requirements should be commensurate with the level of change undertaken on an ATM/ANS equipment;*
  - *e.g. Enable the management of minor changes by Design and Production Organisations, without requiring a new certificate to ensure an efficient certification maintenance process.*

*Those 3 points should be duly considered for an efficient certification/declaration program deployment supporting a level playing field in Europe.*

response *Accepted*

Following the order of the comments:

- Please refer to topic 'Transitional provisions';
- Please refer to topic 'Roles and responsibilities of the different actors';
- Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment *69*

comment by: *Deutscher Wetterdienst*

The Notice of Proposed Amendment 2022-09 may replace the Articles of the Interoperability Regulation (EU) 552/2004 that are still applicable without repeating neither the systems of the EATMN nor a definition of EATMN at all which is already a lack of the Basic Regulation (EU).

In March 2011 at the 18th meeting of the Conformity Assessment Task Force (CATF#18), the SES Framework Unit presented the document 'Application of Conformity Assessment to EATMN systems for the use of meteorological information'. The interconnections between MET services and systems in the ATM/ANS environment were already pointed out in that report which seem to have not taken into account. Further, it is surprising and dissapointing that the amendments proposed therein to clarify and specify the applicable regulations seem to have been hardly or not at all considered in the preparation of this NPA. On the contrary, the formulations, which were already identified as too vague at that time and clarification was proposed and provided, were softened even further and therefore offer even more scope for different interpretations and inhomogeneous implementations.

response

*Noted*

The commentator is kindly invited to refer to the final proposal presented in Opinion No 01/2023 resulting from:

- the public consultation of Notice of Proposed Amendment (NPA) 2022-09 titled ‘Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment)’<sup>1</sup> developed under Subtask 1 of RMT.0161; and
- the consultation with the EASA Advisory Bodies (ABs)<sup>2</sup>, in accordance with Article 6(2) of MB Decision No 01-2022, through NPA 2022-107 titled ‘Simpler interoperability framework for the single European sky airspace’, developed under Subtask 2 of RMT.0161.

The latter proposal addresses the repeal of the 8 interoperability regulations adopted on the basis of the already repealed SES IOP Regulation (EC) No 552/2204.

comment

70

comment by: *Thales Land and Air Systems*

Thales thanks EASA and the RMT.0161 members for the work accomplished to develop NPA 2022-09. Thales welcomes the opportunity given to provide comments on this draft regulation which introduces a paradigm shift in the European ATM community and fully supports the approach taken which will enable harmonization of interoperability, performance, security and safety requirements applicable to the ATM/ANS equipment.

The organization of the RMT.0161 activities is well understood, nevertheless as AMC/GM and Detailed Specification will be developed in a later stage (during subtask#3), it remains difficult to anticipate all the aspects of this new regulation implementation.

We would like to offer our comments with the objective to continue to improve this new regulation and provide support for the upcoming development of the AMC & GM and the detailed specifications.

Those comments focus on the following key attention points:

- The rule should ensure a fair and proper implementation of the regulation with regards to Design and Production Organisations’ approval, oversight and equipment certification;
  - o e.g. Clearly define the roles, responsibilities of the ‘qualified entities’ as well as the associated EASA oversight and the given level of delegation;
- Scope of applicability of the regulation
  - o Scope of DPO activities subject to approval should be clarified with regards to maintenance and production. Where the NPA context and summary seems clear in paragraph 2 & 3, the regulatory requirements introduce inconsistencies that should be addressed

<sup>1</sup> [NPA 2022-09 - Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and ATM/ANS constituents \(ATM/ANS equipment\) \(Subtask 1\) | EASA \(europa.eu\)](#)

<sup>2</sup> ADR TeB, ADR.TEC, Air Crew TeB, Air Ops TeB, ATM/ANS TeB, ATM/ANS.TEC, FS.TEC, GA TeB, GA.COM, MAB, SAB, SAB MB, and SM TeB.

- o The definition of ATM/ANS equipment subject to certification or declaration shall be based on the equipment criticality, impact on interoperability and be consistent with the regulation objective and expected benefits described in the NPA paragraph 2 & 3.
- The transition phase should be set up to ensure a smooth implementation of the new requirements taking into consideration contractual obligations;
- The certification maintenance requirements should be commensurate with the level of change undertaken on an ATM/ANS equipment;
  - o e.g Enable the management of minor changes by Design and Production Organisations, without requiring a new certificate to ensure an efficient certification maintenance process.
- Regulation Impact Assessment should be updated to take into consideration the fees and charges applicable to the DPO approval and the certification of equipment. It is also noted that Regulation 2019/2153 defining the fees and charges should be updated in order to align with the activities introduced by this new regulation.

Those comments and above key points should be duly considered for an efficient certification/declaration program deployment supporting a level playing field in Europe.

*Detailed comments are provided in the corresponding sections of the NPA 2022-09.*

response *Noted*

The comment is well received.

comment **182**

comment by: *CANSO*

General Positions:

CANSO has consulted the proposed Notification of Proposed Amendment (NPA) 2022-09 on the Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and constituents.

On a holistic view, CANSO understands and in principle supports the intentions expressed and proposed by the NPA. We are confident that this approach has the potential to allow defragmenting the equipment market and allow for an accelerated and more efficient implementation of standardised architectures leading to a successful implementation of upcoming operational concepts.

Standards are necessary for the harmonization of systems in Europe.

In our opinion, systems are hardware, software and procedures. It is important that the regulations currently being established allow a modular design of the ATM systems in this sense and that the certification requirements do not refer to complete systems.

In the process of drafting the AMC/CS, those stakeholders are to be involved who have the necessary know-how for the respective functions in question; these are, in particular, the ANSP for Procedures issues.

With a standardization of systems on the basis of technical requirements and administrative procedures in Europe, a genuine supplier market will potentially emerge, if the certification requirements for DPOs do not represent a prohibitive barrier to market entry for smaller market participants.

It is clear that this regulation needs to enable a noticeable reduction in costs and a significant gain in flexibility.

CANSO is supportive with regard to the goal of establishing a Europe-wide interoperability of systems and equipment in order to achieve the above-mentioned goals. The comments that follow are constructive and critical with reference to achieving this goal and are made in the following categories:

- Regulations that contradict the objectives are objected to in a clear manner (with reference to the objective)
- Regulations that need to be reworded to be clear, and
- Regulations that are missing are addressed accordingly.

Interoperability is supported, but the NPA should be modified to be clear on the content and include areas that presently are not affected.

A level playing field should be supported by emphasizing standardization in Europe.

About the proposed transition period (5 years since 13.09.2023) the objective is understood but how to deal with and implement the changes during the transition shall be further specified.

The EASA proposal raises quite a few questions that need to be clarified in advance. The comments therefore reflect whether the objectives of the NPA can be achieved and support the basic position. Such as:

- Will it lead to a harmonized European ANS infrastructure? Will future systems be modular and standardized?
- Will interfaces be open and modular system developments possible?
- Will interoperability of systems be ensured?
- Are the regulations specific enough to ensure a true competition of certified system providers?
- Will the NPA help overcome the current fragmented landscape of proprietary systems; why, how?
- Is there any evidence, or at least logical rationale, that the NPA will lead to lower cost for the ANS System as a whole, and for ANSPs in particular?



- Regarding supplier competition: How can it be ensured that the NPA does not hinder new system suppliers and thus restrict competition?
- How is modularity introduced by the NPA (a reference to overall systems such as COOPAN S Topsky is given)?
- Some essential details and definitions are not included but should be considered.
- The responsibility of the "Statement of Compliance" for systems is passed on to the ANSPs. This should be left with the system suppliers
- A transition period of 5 years seems too short and, in this respect, unrealistic. It is clear that legacy systems must be adapted to the new standards over time. If this is imposed in too short a period, it can lead to premature depreciation and thus sunk costs. In the interests of renewing the European air traffic control infrastructure, the reduction of residual costs by replacing legacy systems must be regulated throughout Europe and financed in a fee-neutral manner, and this must also be taken into account in the performance and charging system in RP 4.
- What contingency arrangements (if any) will be put in place should demand exceed supply as a result of a more limited number of suppliers in the market?

Proposed Change:

Clarify ambiguous sections of the draft proposal and address regulations to ensure the goal of the NPA is supported.

The final regulatory proposals need to align to the high-level expectations of the EASA Steering Group for an efficient and harmonised approach as expressed in the pre-NPA discussions and acknowledged by EASA.

response

*Noted*

The comment is well received.

The Agency believes that the most of your general concerns are addressed in the topics presented in Section 2 of the CRD 2022-09, which have been duly considered in the Opinion:

In case CANSO sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between CANSO and the Agency or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

184

comment by: CANSO

The NPA represents only a part of the overall package. Essential details and definitions are not included in the proposed Draft Implementing/Delegated Acts. Thus, related acceptable means of compliance (AMC) and guidance material (GM) as well as EASA detailed specifications (DSs) as Certification Specifications or as Certification Basis are still missing.

AMCs are to be regarded as mandatory in practice, since AltMoCs are extremely costly. AMCs are only planned for Q3/2023.

Propose change:

AMCs, GMs and DSs shall be released together with the regulatory framework requirements entry into force.

For ANSP's, AMC's for creation of Statement of Compliance are essential.

response

*Noted*

EASA is working on the development of the associated draft acceptable means of compliance (AMC) and guidance material (GM) and the first set of detailed specifications. These draft AMC and GM will be aligned with the final text of the subject EU regulation and will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

For further details please refer to RMT.0161 Subtask 3.

comment

185

comment by: *CANSO*

It is not defined by the regulation which systems/constituents fall under which regime (Certification/Declaration/Statement of Compliance). The examples given in the cover letter raise the next question. If flight data processing systems or surveillance data processing systems require certification, does this apply only to this component (CSCI) or to the entire ATM system (such as Topsky)?

The systems subject to this regulation shall be more closely defined as directly contributing to the safe provision of ATS.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

186

comment by: *CANSO*

The implications for ANSPs in the context of conformity assessment regarding "Statement of Conformity" are not foreseeable. Concrete definitions are missing.

The requirements should be clarified accordingly.

response

*Noted*

All feedback provided is welcomed and considered in the preparation of the Opinion and subsequent phases.

comment

187

comment by: *CANSO*

The software assurance obligations of the ANSPs, based on VO2017/373, are not addressed.

An adaptation of the AMC's is required.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

194

comment by: *CANSO*

Once a product is certified, what happens if customization (due to natural technology evolution or patch) is needed? Is there a need to re-trigger the certification process? It would be important to define the criteria to discriminate minor upgrades from major upgrades and evolutive maintenance.

response

*Noted*

The comment is well received and agreed with.

The subject and the concept of minor/major changes for the ATM/ANS equipment will be further defined at the level of AMC.

comment

195

comment by: *CANSO*

Clarify if the design of the ATM/ANS system, which is constituted by certified components, is in the scope of this NPA.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

196

comment by: *CANSO*

Clarify if maintenance organization will fall under the certification requirements.

response

*Noted*

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, this proposal should differentiate 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 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.

In conclusion, the answer is negative, provided that the activity between the routine maintenance and upgrades/evolution is clearly allocated between the ATM/ANS providers and the ATM/ANS equipment manufacturer.

In addition, please refer to topic 'Roles and responsibilities of the different actors'.

comment

197

comment by: *CANSO*

Request to clarify on which document/regulation the criteria to discriminate equipment requiring certification from declaration ones will be described.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

257

comment by: *CANSO*

This is a general comment about a number of issues not covered by the NPA regarding practicalities in creating attestation.

If a certified organization with a certified equipment cease to exist or cease to maintain/upgrade an equipment what will that mean to ANSP:s using such equipment?

How will the regulation be applied at combined Civil/Military ATS units where military is providing ATM/ANS equipment to the combined civil/military ANSP?

When changes are made in interoperability specifications (ASTERIX format for example) how shall updates then be identified? Is it a supplier task or an ANSP task, and how fast is adaptation required?

In what way can ANSPs assume what responsibility is moved to DPOs, and what contractual matters between ANSPs and DPOs can be removed/reduced due to attestations from the Agency?

There are no exemptions due to various service locations. A very small ATS unit might be forced to accept a very expensive ATM/ANS equipment from a large DPO since a small DPO might not be able to meet all requirements for attestation. This will have the effect that it will be very costly for small ATS/Airports.

In case a DPO become bankrupt or declare an ATM/ANS equipment End Of Life, will it be possible for an ANSP to themselves do something with the ATM/ANS equipment to keep it alive? How is such a situation resolved? Can the ANSP choose themselves how long they can use the equipment, or how quickly must such an equipment to be replaced

response

*Noted*

Following the order of the questions raised by the commentator, the following should be considered:

1. Please refer to topic 'DPO approval discontinuation';
2. The commented proposed framework is DA/IA to the EASA Basic Regulation; thus, air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military should be excluded from the scope of this Regulation. However, Member States should ensure, in accordance with their national law, that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 of the European Parliament and of the Council applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139;
3. Taking into account the comment, the development of the associated AMC/GM is under consideration;
4. Please refer to topic 'Roles and responsibilities of the different actors';
5. Please refer to topic 'DPO approval discontinuation'.

comment

284

comment by: ENAIRE

First of all, from ENAIRE side, we would like to stress our support to the new attestation method proposed in the NPA aiming at providing improvements in the field of safety, interoperability and fostering efficiency of European air transport and air navigation services provision.

It is necessary to provide, even at this step in the regulatory process, more details on a technical level and specifically on the required coordination between affected stakeholders, to establish the basis on which to build future detailed rules.

We would also like to insist on the need to implement this new method carefully, ensuring that the final result is cost effective, that is, the cost of DPO approvals (costs on manufactures and EASA) must be balanced with real benefits in the processes followed by NSAs and ANSPs (in economic terms but also in terms of time needed to put a new system or a system modification into operation). This effectiveness might be reflected in proper CBA studies at European and local levels.

response

*Noted*

The comment is duly considered.

comment

285

comment by: ENAIRE

The new regulations should establish (even if only at high level) the supervision tasks to be carried out by NSAs in order to avoid the current disparity of criteria among different NSAs.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

The commentator is kindly invited to note that Article 3(2) defines that '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.'. In other words, the oversight activities of NCAs are addressed in Implementing Regulation (EU) 2017/373.

comment

286

comment by: ENAIRE

The new regulations should also provide more detailed information on how to deal with **additional requirements** (coming from ANSP) on systems whose certification or Declaration do not include these additional requirements.

If these "additional requirements" have impact on the certificate or on the Declaration, then a re-certification might be needed, implying costs and extra time.

If these "additional requirements" do not have impact on the certificate or on the Declaration, then it is not clear how to deal with the EASA certified/Declared part of the equipment and the SoC supervised by the NSA.

In other words, will the ANSP be limited to the procurement of only "certified" functionalities or systems with "Declaration" and thus....limited to what the DPOs are able or wish to manufacture?

response

*Noted.*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

287

comment by: *ENAIRE*

The new regulations should provide more detailed information/guidance on what is a "**new functionality**" requiring certification or re-certification in an ATM system or not. Currently the ATM systems suffer continuous evolutions/modifications and the process should be clear and fast enough to avoid an ANSP not being able to improve their systems.

response

*Noted*

The subject and the concept of minor/major changes for the ATM/ANS equipment will be further defined at the level of AMC.

comment

288

comment by: *ENAIRE*

The new regulations should also provide more detailed information/guidance on the process to **modify ATM systems / functionalities** taking into account the interaction between manufacturer and ANSP, as it is the case of operational validations (before, after or during the certification process). This might have an important and negative effect of the time needed to implement operational changes.

response

*Noted*

The subject and the concept of minor/major changes for the ATM/ANS equipment will be further defined at the level of AMC.

Furthermore, the associated AMC/GM to Regulation EU 2017/373 will be amended to address how the evidence of compliance is to be managed by the ATM/ANS providers, and when relevant, presented to their respective competent authority.

comment 289

comment by: ENAIRE

The new regulations should clarify the impact of the certification of new functionalities in the **continuous evolution of ATM systems** (required time, changes in ATM SW systems...).

response *Noted*

The subject and the concept of minor/major changes for the ATM/ANS equipment will be further defined at the level of AMC.

Furthermore, the associated AMC/GM to Regulation EU 2017/373 will be amended to address how the evidence of compliance is to be managed by the ATM/ANS providers, and when relevant, presented to their respective competent authority.

comment 290

comment by: ENAIRE

The new regulations should clarify and establish the process to be followed with NON-EU (i.e. GBAS) systems.

response *Noted*

Taking into account the comment, the text of the delegated act is amended; please refer to Article 7.

comment 291

comment by: ENAIRE

The new regulations should clarify and establish the **standardization framework** against which the certification/declaration are issued (MOPS, ICAO, doc, etc).

response *Noted*

Please refer to Annex II and Annex IV to the proposed delegated act.

comment 292

comment by: ENAIRE

The new regulations should clarify the implications on, for example, **iTEC developments**.



response	<p><i>Noted</i></p> <p>The comment is duly considered.</p>
comment	<p>293 <span style="float: right;">comment by: <i>ENAIRE</i></span></p> <p>The new regulations should clarify/establish the documentation to be requested by the NSAs to the ANSP for the <b>operational integration of certified/Declared systems</b>. This is crucial to avoid the repetition of current disparity of criteria among different NSAs.</p>
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>
comment	<p>294 <span style="float: right;">comment by: <i>ENAIRE</i></span></p> <p>The new regulations should clarify/establish at least some guidance on the <b>documentation to be included in the SoC</b>. Otherwise different NSAs will apply different criteria and we will end up again with a disparity of criteria among different NSAs.</p>
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>
comment	<p>301 <span style="float: right;">comment by: <i>CANSO</i></span></p> <p>When all criteria and specifications are defined and equipment and DPO are certified / approved, can it be assume that all equipment are equivalent and the only difference is the price? How will the ANSP be able to distinguish the quality of equipment / suppliers?</p> <p><b>Proposal:</b> Access to certification documentation / reports shall be available to stakeholders.</p>
response	<p><i>Noted</i></p> <p>Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'. The comment is well received and, therefore, taking into account the comments, the development of the associated AMC/GM is under consideration.</p>

comment

358

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**General, page 6**

Organisations of Maintenance was a part of the ToR. It is not part of the NPA ?

response

*Noted*

The comment is acknowledged. The commentator is invited to note that 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, this Regulation should differentiate 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 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.

Furthermore, please refer to topic 'Roles and responsibilities of the different actors'.

comment

363

comment by: *Tern Systems*

Tern Systems agrees with the general objectives of the NPA. Tern Systems is not against more regulation of DPOs and sees many opportunities for DPOs. Detailed specifications could potentially increase quality and reduce costs. Guidance provided by a competent regulator could improve design and development processes more efficiently than nowadays where DPOs get varying feedback from different customers. An approval and attestation that is valid throughout the EEA also would most certainly be very beneficial, in contrast to dealing (indirectly through our customers) with national regulatory bodies of varying competence when it comes to ATM/ATS equipment. If well implemented and acknowledged throughout Europe, such an EASA approval/attestation has the potential to become a world-wide acknowledged sign of quality.

On the other hand, the NPA leaves many questions open and introduces risks for DPOs that make it impossible and in places doubtful that those benefits can be achieved. For the potential to be reached, the NPA needs considerable improvements and uncertainties need to be removed.

In general, we agree with the very detailed comments made by Eurocontrol and CANSO that we were fortunate enough to receive through one of our customers.

response *Noted*

comment 375

comment by: *Tern Systems*

In general, we agree with the very detailed comments made by Eurocontrol and CANSO that we were fortunate enough to receive through one of our customers.

response *Noted*

comment 450

comment by: *NAV Portugal E.P.E*

**NAV Portugal** welcomes the opportunity to comment this NPA 2002-09, on the "*Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and constituents*".

Whilst we understand EASA's motivation in developing this NPA, it is our opinion that there are several aspects that have not been considered or sufficiently pondered in its development, and, as such, we urge EASA to consider the comments arising from this consultation process like those of CANSO.

**NAV Portugal** has some specificities, amongst them the fact that it provides air navigation services, in several units, using a non-European ATM system, developed in house; this system will be used as a fall back to the new TOPSKY system, common to the other Members of COOPANS Alliance.

In this light, there are practical questions to which this NPA does not answer and that, in the particular case of NAV Portugal, may prove to be serious hurdles to the proposed benefits.

General comments/questions about a number of issues not clear in the Proposed NPA.

**#1/**

In our understanding the work that is shifted from the ANSP is mostly the paper work to assemble all the technical files using documentation from various sources (regulation / standards, call for tender, supplier, procedures, safety assessments, training records, etc.) The assessment of all supplier documentation and the production of the internal documentation

by the ANSP will continue to be needed. In conclusion, there will be no significant burden relieve on the resources (time, effort, cost) required from the ANSPs' sides.

**Recommendation:** Review CBA taking into account feedback from stakeholders.

**#2/**

When all criteria and specifications are defined and equipment and DPO are certified / approved, can it be assume that all equipment are equivalent and the only differentiating factor will be the price?

How will the ANSP be able to distinguish the quality of equipment / suppliers?

**Recommendation:** Access to certification documentation / reports shall be available to stakeholders.

**#3/**

From our point of view, it appears clear that EASA will increase its powers by defining system specifications, approve suppliers and certify equipment. In that sense, there is a significant risk of restricting the number of approved suppliers (in EU case the big ones) and impair innovation and competition. How will Innovation be ensured?

**Recommendation:** The mechanisms distribute authority and involve stakeholders in this process, including ANSPs and NSAs, should be clearly defined.

**#4/**

EU Regulation 2017/373 distinguishes between Safety Assessments and Safety Support Assessments depending on the impacted services. Will the fact that an equipment is certified by EASA give the necessary evidence that the system behaves and will continue to behave only as specified in the specified context?

**Recommendation:** EASA to clarify the liability perimeter of the Certification and DPO declarations.

**#5/**

From NAV Portugal perspective, for this major "change" in regulation to be applied there is still a lot to be defined / clarified, e.g. the criteria for DPO approval, the systems that will be subject certification or the systems that may be subject to Statement of Compliance.

**Recommendation:** To include a complete roadmap covering the development and validation of the required supporting documentation, including the items mentioned in the comment.

response *Noted*

Following the order of the comments:

1. Please refer to topics: 'Roles and responsibilities of the different actors' and 'Impact assessment'.
2. Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'. The comment is well received and, therefore, taking into account the comments, the development of the associated AMC/GM is under consideration.
3. The comment is welcomed, and the commentator is kindly invited to note that the legal basis for joint certification, oversight and enforcement system is already laid down in CHAPTER IV of the EASA Basic Regulation (EU) 2018/1139. All further details are defined in the partnership agreements with the national competent authorities. In conclusion, the comment is noted, and it is considered that the issue is already addressed at EASA Basic Regulation and there is no necessity for further details at implementing and delegated acts level.
4. Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.
5. Please refer to Section 1.2 'The next steps' of Opinion No 01/2023.

comment

457

comment by: *CANSO*

**General Comment**

The Essential Requirements of (EU) 2018/1139 are generally applicable at a System level (and many of the current IR/CS requirements are end-to-end and/or can be implemented across multiple Constituents) and full compliance is only demonstrable by the ANSP; noting that the Safety (Support) Assessments under (EU) 2017/373 do not fully cover compliance with the ERs, etc. (but conversely, the current TFs should cover Safety), the proposed framework provides no mechanism for an ANSP to demonstrate their compliance, and national differences may emerge. Further, the loss of the requirement for independent verification of ANSP compliance (which is now being placed on DPOs) is a concerning omission from the proposed framework.

- (EU) 2017/373 can be amended to capture the need for an ANSP to produce and maintain Technical Files to demonstrate compliance of their Systems with the ERs (and any associated detailed rules which are applicable at the System level). These TFs should form the basis for NSA auditing of the Systems and approval of change, and the inclusion of a requirement for ANSP declarations based on independent verification of compliance would provide a mechanism for the implementation of minor changes (not subject to NSA review).

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The associated AMC/GM to Regulation EU 2017/373 will be developed to address how the evidence of compliance is to be managed by the AMT/ANS providers, and when relevant, presented to their respective competent authority.

comment

458

comment by: *CANSO*

**General Comment**

The future direction of ATM systems is to make use of common **IT infrastructure**, data centres, etc. which would not by themselves perform any ATM function; the ANSP would procure software products from DPOs and host them on these platforms. There is still "equipment", but it would not be in scope of the certification, and the provider would not be a DPO; to make this architecture work under the proposed framework, it is likely that ANSPs will need to certify as DPOs.

- (EU) 2017/373 should be updated to ensure ANSPs retain responsibility for ER compliance of the System, which should be demonstrated through Technical Files.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The associated AMC/GM to Regulation EU 2017/373 will be developed to address how the evidence of compliance is to be managed by the AMT/ANS providers, and when relevant, presented to their respective competent authority.

comment

461

comment by: *ENAIRO*

The new regulations should elaborate more on issues such as:

- Particular systems / functionalities that will finally require "certification"
- Particular systems / functionalities that will finally require "Declaration"
- Clarification on systems that will not require "certification" nor "Declaration" nor SoC.

This will avoid misunderstandings with the NSAs.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

483

comment by: DGAC (French CAA)

The deadline (30<sup>th</sup> of September) for answering the NPA is way too short and unacceptable for such an important regulatory subject, especially as it was issued mid-August during the summer break. That being said, the 7 days additional period was most welcome.

response

*Noted*

The comment is well received.

comment

484

comment by: DGAC (French CAA)

The proposal of the NPA (introduction of a regulatory framework for the certification of certain ATM/ANS equipment as well as approval of DPO) is supported by DGAC (NSA + regulator), however clarifications are needed and this is the purpose of the following comments.

There are many uncertainties about this new regulatory framework, including the undetermined real economic impact of the new measures (i.e. cost of DPO certification, whole cost of getting the equipment certified or of issuing a declaration of compliance, and its weight in the buyers' costs, taking into account that GE are produced in very limited series); the foreseen difficulties with regards to the availability in due time of the technical standards and specifications for every concerned ATM/ANS GE; time induced in the process of developing new systems, and changes; avoiding deterring effects on developments of new systems/equipment/functions or enhancements of existing ones; and whether and how data services (including possible new common services like SWIM) would be affected.

Hence due care should be taken for each next step, with a view to keep heavy processes limited to what is strictly necessary, and it should be ensured that all parties can participate and provide their feedback at all next steps of the rulemaking process and standardisation. In this respect, one such step should be to consider determining lists of what type of GE – or GE function - should be subject to a certificate, or to a declaration by the DPO, or to a statement by ATM/ANS providers (or even to none of those).

In view of the foregoing, a clear strategy should be thoughtfully agreed with all stakeholders and involved authorities and established to define priorities taking into account interoperability needs and safety criticality of ATM/ANS GE. Finally, proportionality in the application and oversight of this new regulatory framework should be planned for.

response

*Noted.*

The comment is well received.

Please refer to topics 'Impact assessment' and 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

Please refer to topic 'Impact assessment'.

comment

493

comment by: *Karl Óli Lúðvíksson*

Isavia ANS, (Icelandic Air Navigation Service Provide) general comment to this NPA is to refer to and support the comments made by Eurocontrol and CANSO regarding this NPA

response

*Noted*

comment

503

comment by: *Naviair*

General comments:

Naviair hereby gives its preliminary general comments to the proposed Notification of Proposed Amendment (NPA) 2022-09 on the Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and constituents.

In overall terms Naviair understands the intentions expressed in the NPA and are confident that the establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and constituents will have a long term advantage. However, the NPA also raises some uncertainties and specific questions, which we would like EASA to elaborate on in further details. In this regard we also want to refer to the comments made by Eurocontrol as we share some of the same concerns.

Naviairs comments only have an overall general character, while we want to referrer to more detailed questions outlined in the comments made by CANSO.

First and foremost, Naviair foresees a high risk that the anticipated cost related to this NPA will be high in the beginning of its implementation. Given the current economic situation in the ATM industry we want to highlight the need for an economic impact assessment for the introduction of this new regulatory framework at this current time and the need to consider cost-efficiency. We therefore encourage EASA, in the drafting of AMC/CS, that relevant stakeholders are to be involved who have the necessary know-how for the respective functions in question and the related efficiency it might contribute to.

The NPA considers EASA to act as the competent authority, in this regard Naviair would like more specific information on how EASA will ensure the sufficient personnel, expertise and capacity to enforce this role, in order to prevent any back locks or interruptions for certification of ATM-systems?



In the ATM world, the systems and the constituents are not specified in a similar manner as airborne equipment and are not operated in a close defined environment. The system can be easily carried from the airborne side to the navigation and surveillance equipment, however communication systems cannot be assimilated directly, operating in various models such as voice or data communication. For Naviair it is uncertain whether the approach in the NPA is suitable for all ATM/ANS-equipment and the justification hereof?

Finally, we seek clarification on the joint Civil and Military infrastructure, systems and services used for civil aviation and how it will be handled in the regulation regarding certification/declaration?

Naviair wants to thank for the opportunity to comment on this NPA and is confident that the questions mentioned above and the additional questions mentioned by CANSO can be answered and thereby provide the necessary clarity.

response

*Noted*

The comment is well received.

As stated in Opinion No 01/2023, in parallel with the European Commission adoption process, EASA will continue working on the development of the associated draft AMC, GM and DSs. EASA will adapt these draft AMC and GM to the potential changes that may be introduced in the final text of the subject EU regulations during the regulatory process on the adoption of the regulations. The ED Decision(s) containing the associated AMC, GM and DSs will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

In addition, please refer to topic 'EASA acting as the competent authority for all DPOs'.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

As regards the final comment, the commented proposed framework is DA/IA to EASA Basic Regulation; thus, air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military should be excluded from the scope of this Regulation. However, Member States should ensure, in accordance with their national law, that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 of the European Parliament and of the Council applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

comment

525

comment by: *Copenhagen Airports*

Copenhagen Airports wants to thank for the opportunity to comment on this NPA and is confident that the questions entered can be answered and thereby provide the necessary clarity.

In overall terms Copenhagen Airports understand the intentions of the NPA, and believe the establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and constituents will have a long term advantage.

However, the NPA also raises some questions and uncertainties, which we would like EASA answer and clarify.

response

*Noted*

The comment is well received.

comment

546

comment by: *Austro Control*

**Comment:**

General Positions:

Standards are necessary for the harmonization of systems in Europe.

In our opinion, systems are hardware, software and procedures. It is important that the regulations currently being established allow a modular design of the ATM systems in this sense and that the certification requirements do not refer to complete systems.

In the process of drafting the AMC/CS, those stakeholders are to be involved who have the necessary know-how for the respective functions in question; these are, in particular, the ANSP for Procedures issues.

With a standardization of systems on the basis of technical requirements and administrative procedures in Europe, a genuine supplier market will potentially emerge, if the certification requirements for DPOs do not represent a prohibitive barrier to market entry for smaller market participants.

It is the clear expectation of ANSPs that this regulation will enable a noticeable reduction in costs and a significant gain in flexibility.

Austria is supportive with regard to the goal of establishing a Europe-wide interoperability of systems and equipment in order to achieve the above-mentioned goals. The comments are therefore constructive and critical comments are made with reference to the objectives in the following categories:

- Regulations that contradict the objectives are objected to in a clear manner (with reference to the objective).

- Regulations that need to be reworded to be clear, and

- Regulations that are missing are addressed accordingly.

Interoperability is supported, but the NPA should be modified to be clear on the content and include areas that presently are not affected.

A level playing field should be supported by emphasizing standardization in Europe.

The EASA proposal raises quite a few questions that need to be clarified in advance. The comments therefore reflect whether the objectives of the NPA can be achieved and support the basic position. Such as:

- Will it lead to a harmonized European ANS infrastructure? Will future systems be modular and standardized?

- Will interfaces be open and modular system developments possible?

- Will interoperability of systems be ensured?

- Are the regulations specific enough to ensure a true competition of certified system providers?

- Will the NPA help overcome the current fragmented landscape of proprietary systems; why, how?

- Is there any evidence, or at least logical rationale, that the NPA will lead to lower cost for the ANS System as a whole, and for ANSPs in particular?

- Regarding supplier competition: How can it be ensured that the NPA does not hinder new system suppliers and thus restrict competition?

- How is modularity introduced by the NPA (a reference to overall systems such as COOPANS Topsy is given)?

- Some essential details and definitions are not included but should be considered.

- The responsibility of the "Statement of Compliance" for systems is passed on to the ANSPs. This should be left with the system suppliers.

- A transition period of 5 years seems too short and, in this respect, unrealistic. It is clear that legacy systems must be adapted to the new standards over time. If this is imposed in too short a period, it can lead to premature depreciation and thus sunk costs. In the interests of renewing the European air traffic control infrastructure, the reduction of residual costs by

replacing legacy systems must be regulated throughout Europe and financed in a fee-neutral manner, and this must also be taken into account in the performance and charging system in FP 4.

**Proposed Change:**

Clarify ambiguous sections of the draft proposal and add missing regulations to ensure the goal of the NPA is supported.

**Classification:**

Major/conceptual

response

*Noted*

The comment is well received.

The Agency believes that the most of your general concerns are addressed in the topics presented in Section 2 of the CRD 2022-09, which have been duly considered in the Opinion.

In case Austro Control sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between Austro Control and the Agency, or to be included in the agenda of the most relevant EASA Advisory Body.

comment

547

comment by: *Austro Control*

**Comment:**

The NPA represents only a part of the overall package. Essential details and definitions are not included in the proposed Draft Implementing/Delegated Acts. Thus, related acceptable means of compliance (AMC) and guidance material (GM) as well as EASA detailed specifications (DSs) as Certification Specifications or as Certification Basis are still missing.

AMCs are to be regarded as mandatory in practice, since AltMoCs are extremely costly. AMCs are only planned for Q3/2023.

**Proposed Change:**

AMCs, GMs and DSs shall be released together with the regulatory framework requirements entry into force.

For ANSP's, AMC's for creation of Statement of Compliance are essential.

**Classification:**

Major/conceptual

response

*Accepted*

As stated in No Opinion 01/2023, in parallel with the European Commission adoption process, EASA will continue working on the development of the associated draft AMC, GM and DSs.

EASA will adapt these draft AMC and GM to the potential changes that may be introduced in the final text of the subject EU regulations during the regulatory process on the adoption of the regulations. The ED Decision(s) containing the associated AMC, GM and DSs will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

comment

548

comment by: *Austro Control*

**Comment:**

It is not defined by the regulation which systems/constituents fall under which regime (Certification/Declaration/Statement of Compliance). The examples given in the cover letter raise the next question. If flight data processing systems or surveillance data processing systems require certification, does this apply only to this component (CSCI) or to the entire ATM system (such as Topsky)?

**Proposed Change:**

The systems subject to this regulation shall be more closely defined as directly contributing to the safe provision of ATS.

**Classification:**

Major/conceptual

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

549

comment by: *FOCA Switzerland*

The NPA states that it covers ATM/ANS equipment but in the explanations and the draft regulations only ATS, C, N, S ATFM are addressed. That could lead to confusion between the stakeholder (manufacturer/ANSP/NSA). We believe it is necessary to have a clear regulation and to know exactly which ANS/ATM-Services/Functions are covered. This would avoid future discussions e.g. between ANSPs and NSAs concerning equipment that has to be subject to a statement of conformity (Statement of conformity replaces in principle the DoV).

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

550

comment by: *Austro Control*

**Comment:**

The implications for ANSPs in the context of conformity assessment regarding "Statement of Conformity" are not foreseeable. Concrete definitions are missing.

**Proposed Change:**

The requirements should be clarified accordingly.

**Classification:**

Major/conceptual

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the associated AMC/GM is under consideration.

comment

551

comment by: *Austro Control*

**Comment:**

The software assurance obligations of the ANSPs, based on VO 2017/373, are not addressed.

**Proposed Change:**

An adaptation of the AMC's is required.

**Classification:**

Major/conceptual

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

552

comment by: *Austro Control*

**Comment:**

The draft regulations constitute a deterioration for systems/constituents requiring a Statement of Compliance (issued by the ANSP) compared to the current regime, as now the ANSP is solely responsible for demonstrating compliance with all technical standards, whereas currently the manufacturer must provide the evidence in Declarations (DoC, DSU).

**Proposed Change:**

The status quo should be maintained as it is effective and proportionate.

**Classification:**

Major/conceptual

response

*Not Accepted*

Please refer to topic 'Impact assessment'.

comment

621

comment by: *ERA a.s.*

ERA a.s. is multilateral / ADS-B manufacturer delivering its products worldwide. Only 36% of ERA ATC business is in EU. ERA is focused to be certified against worldwide standards – ISO 9000, 14000, 27000, Eurocae ED-109A, ED-117A, ED-142, ED-129B, ETSI...

EASA certifies the company/product for EU market only, therefore ERA does not consider being certified by EASA as a competition advantage. ERA asks to simplify this framework in the way it could be replaced by international standards for usage on EU market.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, the commentator is invited to note that when offering the product outside the EU market, the commented requirements do not apply.

comment

626

comment by: *Finnish Meteorological Institute (FMI) - MET SP*

Throughout the NPA it is stated that the proposed requirements concerning various levels of ATM/ANS system specifications are intended to serve an equal market environment.

However, some MET systems used for service provision are not even available from the market and in-house developed systems are quite widely used. Additionally, possible oversized declaration (or even certification) requirements for MET systems would certainly limit the availability of suitable systems, add significantly costs and possibly even have negative impact on the quality of MET service.

Worst case scenario would be that not all required MET services can be provided due to lack of suitable systems; in many cases systems also need to fit into MET providers' general MET service configuration (internal interoperability). As is well known, many European MET providers have also responsibilities related to their national weather services and e.g. same servers and other infrastructure is commonly used to serve both aviation and public needs.

Even without this forthcoming regulation, fully compliant and interoperable MET service is provided for aviation users and e.g. changes for ATM/ANS functional systems are duly handled by MET SP and national CA, following change management rules set in (EU) 2017/373. All ATM/ANS providers impacted by this future regulation are certified and provide services under CA's oversight.

MET systems and equipment are used to supply services and those services are associated more with the quality of service rather than safety. MET Services are seen as provision of information and data and not as provision of ATM/ANS systems and equipment.

The added value for e.g. declaration (or even certification) for MET systems is very unclear and not referenced in the NPA at all. The proposed applicability to MET SP is seen not to reflect SES principles of proportionality and cost-efficiency.

Considering all mentioned only the lowest level of conformity requirements (*a statement of compliance*), if any, would be justified for MET systems and equipment.

From MET SP perspective, proper and exhaustive impact assessment is not provided in the NPA.

Also AMC and GM texts would be needed to evaluate all impacts. Public consultation is certainly needed for drafted AMC and GM, as well.

response

*Noted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Impact assessment'.

comment

660

comment by: POL CAA LOZ-4

The document should clear up any doubts about small local companies and their inability to compete with the big giants. Small companies should not be closed off from offering their products.

response

*Noted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Access to the market'.

comment

668

comment by: IAA ANSP

IAA ANSP supports NPA 2022-09 and has the following questions:



1. Request clarification on the process to be used in the event no detailed specifications are developed for a system?
2. Request detail on the level of input that ANSP's will have in the development of detailed specifications?
3. Request detail on requirements when connectivity of systems will be with agencies outside the EU?
4. Requests clarification on the 2017/373 SW assurance obligations placed on ANSPs and if changes are proposed to 2017/373 and its AMC to address this base on what is proposed in this NPA?
5. Requests clarification on the timeframe proposed in ATM/ANS.EQMT.DEC.030 Maintenance instructions, point B for the delivery to "users and interested parties" of changed maintenance instructions/manuals?
6. Requests details on what basic Security requirements have been or are being considered as part of this NPA?
7. Request clarification regarding what kind of maintenance dataset updates are considered to be. Clearly, there are minor dataset updates such as adding a route point or tuning a coordination timer which could easily be seen as 'routine'. But there are also major dataset updates where how the technical system is used can be modified – could these be seen as 'upgrade' maintenance requiring the manufacturer to be involved in deployment? Or maybe they are seen as integration activities where the ANSP has the responsibility?
8. Request clarification regarding the patching of Operating Systems (particularly in the context of security vulnerabilities). Can this be considered to be a routine maintenance activity?

response *Noted*

The comments are duly considered in the Opinion.

The Agency believes that the most of your concerns are addressed in the topics presented in Section 2 of the CRD 2022-09.

In case IAA ANSP sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between IAA ANSP and the Agency, or to be included in the agenda of the most relevant EASA Advisory Body.

comment 704

comment by: Aviation Division

1. Draft regulations are very unclear in which of the equipment is subject to certification, and which equipment shall be issued with a declaration of design compliance. The list of equipment for both cases need to be clearly specified at detailed specification and AMC level. Otherwise that will certainly lead to confusion between DPOs, SPs, and CAs.

2. Minimum content of a statement of compliance is not specified in the draft regulations. Further details of what such document must contain need to be determined.
3. According to the draft regulation, the Agency shall evaluate the ATM/ANS equipment that has been manufactured or put in operation before the date of entry into force of the draft regulation. CAs shall provide the Agency with the relevant information to facilitate this evaluation. However, this will produce an additional burden for the CAs with no visible benefit.

response *Noted*

Following the order of the comments:

1. Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment';
2. Taking into account the comment, the associated AMC is under development;
3. Please refer to topic 'Transitional provisions'.

comment 752

comment by: *POL CAA LOZ-4*

Will the template of Appendix 1 to PANS-ATM/ANS.AR (ANSP certificate template) also be the template documents referred to in the draftee? This seems reasonable from the point of view of regulatory harmonization.

response *Noted*

The commented referenced template is certificate for the ATM/ANS provider, while the template of ATM/ANS equipment certificate should address different elements as it serves a different purpose. Thus, the answer is negative.

comment 756

comment by: *POL CAA LOZ-4*

Comment from PANSA:

Currently, the certification of ATM/ANS equipment relies on locally determined rules, which on the one hand allows for the consideration of specific local risks and considerations and the involvement of the NSAs, but on the other hand creates additional costs and burdens for ANS service providers, NSAs and manufacturers. The proposed rules significantly change the current regulatory framework and it is necessary to obtain confirmation that they will fulfil the objectives behind their creation.

Some of the proposed changes can be interpreted in two ways, such as:

- limiting the role of national aviation authorities in the certification process may, on the one hand, result in a harmonised approach at EU level and a reduction of the burden and therefore

of costs at local level; on the other hand, it may result in a reduction of the role of local authorities and an increase in bureaucracy and costs at EU level;

- the change is intended to harmonise systems at European level, but may also be considered as a limitation of innovation and use of solutions at local level.

The topic of the NPA currently being consulted is very important for the ANSP community in Europe. I would therefore like to inform you that an ad hoc European CANSO CEO Conference (EC3) meeting was held on 6 September 2022 to discuss the proposed new legislation.

Further specific issues which - also as a result of the discussions at the above-mentioned meeting - in PANSAs opinion should be highlighted during the current open consultation are presented below. At the same time, it should be noted that PANSAs considers that it is not possible to make a comprehensive assessment of the proposed solutions without draft implementing documents, in particular AMC (Acceptable Means of Compliance) and GM (Guidance Material).

1. It is necessary to clarify which equipment will be subject to ANSP declarations and to clarify which documents navigation service providers are to rely on when developing their declarations (Statement of Compliance) in the interim period, i.e. between 12 September 2023 and the date of introduction of the new regulations.

This is because the Statements of Verification (DoV) currently being developed by ANSPs are made on the basis of, among other things, documentation received from manufacturers (Declaration of Suitability - DoS, Declaration of Conformity - DoC, technical documents) and FAT/SAT documentation,

The proposed legislation implies that documents confirming compliance with certain standards and requirements (e.g. DoS or DoC) issued by manufacturers before 12 September 2023 for certified products will remain valid, however, clarification is required as to whether and what documents confirming compliance with interoperability requirements manufacturers will be required to provide with the equipment offered during the transition period preceding the implementation of EASA certification requirements.

2. an EASA expert attended the EC3 meeting and declared the possibility to use EU funding coordinated by SESAR during the transition period to comply with the regulation. The question of the possible object and scope of the financial contribution from SESAR initiatives for the transitional period of the new regulations (in particular whether SESAR DM or SESAR JU is to be the lead) needs to be clarified. In this context, it would be advisable to support the launch of pilot projects, in cooperation with EASA and SESAR, during the transition period.

3 Aspects that may negatively affect costs and fair treatment of stakeholders should be monitored. Attention should also be paid to whether the new rules will stifle innovation by unduly increasing the influence of certain manufacturers and forming an oligopoly,

4. Articles 42(1)(b) and 43(1) of Regulation (EU) 2018/1139 concern (in the English version) "Organisations involved in the design, production or maintenance of ATM/ANS systems and ATM/ANS constituents". The Explanatory Memorandum to the draft (page 21 of the NPA) explains that 'maintenance' - depending on its meaning - falls either in the production of equipment or in the provision of ATM/ANS services. Consequently, it is understandable that both in the title of the implementing regulation (p. 42 et seq.) of the NPA, to be issued on the basis of Articles 42(1)(b) and 43(1) of Regulation (EU) 2018/1139, and in principle in its content, there is a reference to "organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents ("ATM/ANS equipment") without indicating "maintenance". However, in Article 4 it appears "organisation involved in the design, production or maintenance of ATM/ANS equipment" which is to be considered an

inconsistency as the context seems to indicate that this is the same as "organisation involved in the design, and/or production of ATM/ANS equipment".

(5) From the point of view of the PANSA in its further work, it is important to define precisely the application of the provisions to software and services and to define the responsibilities of the ANSP.

response

*Noted*

The comments are duly considered in the Opinion.

The Agency believes that the most of your concerns are addressed in the topics presented in Section 2 of the CRD 2022-09.

In case POL CAA LOZ-4 sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between POL CAA LOZ-4 and the Agency, or to be included in the agenda of the most relevant EASA Advisory Body.

comment

757

comment by: *EUROCONTROL*

We understand that there is a need for a regulation to replace the temporary provisions of the BR in regards of conformity assessment however, EUROCONTROL cannot support the proposed regulation of NPA 2022-09 on conformity assessment of ATM/ANS equipment.

Except where it is specified that the EUROCONTROL comments are limited to NM or MUAC, all other comments apply to all EUROCONTROL stakeholders.

We recognize that the

- The new Basic Regulation repealed IOP regulation so per 12 Sept 2023 a new framework needs to be set-up.
- There may be lessons learned / best practices from air certification processes which could be of value to the ground side
- The current IOP regulation shows inefficiencies in the oversight done by NSAs and as well between NSAs and EASA for pan-European ATM-equipment
- There is a fragmentation of ground equipment although we want to underline that this is frequently due to different underlying operational concepts and procedures
- There is a need to move the whole ATM industry towards an Open Architecture, digitalization and service orientation whilst moving away from equipment focus.
- The Military is out of scope in accordance with the EASA Basic Regulation
- However, there are four scenarios where this NPA may affect the Military as they:

- voluntary apply 552/2004 methodology;

- provide service to civil traffic;
- data is shared with civil aviation or
- (CNS) infrastructure is shared with civil aviation.

- There is increasing demand and political will to share military infrastructure and/or data to enable CNS rationalization, increase efficiency and safety and decrease energy and spectrum usage.
- The Military also self-certify some of their assets and in the absence of opt-in as per EASA BR, they may not accept third party certification.

Disclaimer: The military specific comments reflect only expert-level views from Agency experts and do not represent a formal military position which only national military authorities can develop.

response *Noted.*

The comment(s) is(are) duly considered.

comment 758

comment by: *EUROCONTROL*

**Scope:**

o The scope of the proposal is very unclear and left open to significant interpretation and uncertainty. The use of terms as “safe” or “safety critical” is inconsistent with what is defined in EU.2017/373.

- Where only Air Traffic Services (ATS) are considered to be safety related as per the definition of safety risk (accident with harmful effect).
- And where “service providers other than ATS providers” are subject to performance and quality assessments only.

In that context, we do not understand why ATFM systems are explicitly mentioned in the explanatory text as being included in the scope of certification in this NPA.

- Detailed specifications, specific criteria and associated AMCs are missing. This does not help understand which system and constituents would fall in each of the three categories proposed.
- Not including military at all will significantly and negatively impact harmonization and interoperability in aviation. With a smart approach military aviation should be encouraged to apply this methodology, without falling under the responsibility of EASA. As there is a case prescribed in the Preamble of the EASA Basic Regulation

where the military should apply respective regulation, it should be legally possible to include also the military in the scope of this regulation.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

As stated in Opinion No 01/2023, in parallel with the European Commission adoption process, EASA will continue working on the development of the associated *draft* AMC, GM and DSs. EASA will adapt these draft AMC and GM to the potential changes that may be introduced in the final text of the subject EU regulations during the regulatory process on the adoption of the regulations. The ED Decision(s) containing the associated AMC, GM and DSs will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

The commented proposed framework is DA/IA to EASA Basic Regulation; thus, air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military should be excluded from the scope of this Regulation. However, Member States should ensure, in accordance with their national law, that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 of the European Parliament and of the Council applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

comment

759

comment by: *EUROCONTROL*

**Services vs. equipment approach:**

- Surprisingly, there is no specific consideration in the proposed regulation regarding the evolution and modernization (digitalization) of the ATM/ANS domain. Digitalization trends like Cloud, AI, 'service versus equipment' approach are not addressed.
- Assuming they would fall in the scope of this regulation, this could lead to significant cost increase on public IT architectures providing Infrastructure as a service (IaaS, i.e. virtualisation) and industry standard IP network infrastructure and services. This is leading to increased cost of services and possible unavailability of operational services in case current providers refuse to follow the new heavy DPO process.

response

*Noted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Impact assessment'.

comment

760

comment by: *EUROCONTROL*

**Costs, delays and business risks**

- The impact assessment is insufficient. It must be redone, completed and provide the demonstration that the transition is cost neutral and there is a tangible benefit compared to today's situation. Without this we are at a high risk not to meet RP4 cost efficiency target.

**For Service Providers (as per (EU)2017/373)**

- Additional costs in modifying and managing current equipment procurements
- Additional costs for future procurements (10-15%)
- Costs of the need for becoming an approved DPO (many SP develop parts of their equipment)
- Cost of the associated oversight (as DPO and in relation to contracts)
- No consideration in the case a manufacturer chooses not to become DPO (impact on current contracts and operations)
- No considerations in the case the manufacturer fails to retain its DPO approval
- Planned transitional measures address only the practicalities of the oversight and not potential operational impact
- The non-existence of clear criteria for the allocation of a certain equipment to a certain category (subject to (1) certification, (2) declaration of compliance or (3) statement of compliance) and the impact those decisions may have on current and future operations
- Although not identified in this NPA but as a consequence of it and by analogy with the onboard regulatory framework, we foresee that ATSEP would have to be licensed, which could have a significant cost for the ATSEPs (order of magnitude 100M€).
- Specifically for MET SP, equipment that was not subject to (EC)552/2004 would be subject to this new regulatory framework (with the associated cost and no details on transition)

**For EUROCONTROL**

- The NPA considers an additional cost of at least 10-15% of development; it represents about 50 M€ for iNM and potential years of delays.
- There will be other negative impacts on the dozens of tools and services offered by EUROCONTROL to its Member States and operational stakeholders for free or at a low price. As an example, to adapt ARTAS and SDDS to the new certification scheme compared to current DSU process would multiply the cost by a factor of four due to the maintenance activities. Overall costs on our tools and services is estimated between 5 to 10 M€.
- EUROCONTROL common services could also be at risk and as a minimum would come with additional cost due to the DPO new requirements as well as the additional requirements for the Service Provider with the risk that current equipment providers may not accept to become DPOs, notably those outside the EU (e.g. British Telecom for NewPENS).
- We foresee a high risk on our European Air Transport Innovation Network with new costs associated to their industrialization phase.
- For a service provider as MUAC, the impact is considered to be in the order of 4M€/year

#### For SDM/Innovation

- We foresee several years of delay for CP1 programme, issues with additional resources required and additional cost on all SESAR deployment activities (past deployment and future ones). These have not been anticipated in the EC call for the new SDM.
- The heavy conformity assessment needs will further stifle the already closed ATM market and kill innovation.

#### o For Military

- The interoperability with military aviation and ATM and Air Defense in particular is not considered at all in the NPA.
- The use of military infrastructure/equipment by civilian SPs is not addressed. We understand the content of the NPA will apply indirectly to military equipment through the application of Art. ATM/ANS.OR.B.015.
- Also regulation (EU) 2018/1139 asks Member States to ensure, in accordance with their national law, that military aerodromes, when opened to the public, and that military ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 of the European Parliament and of the Council applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in the regulation.



- Considering national prerogatives related with military certification, what is to be expected in terms of ‘certification’ or ‘declaration of compliance’ of military equipment for scenarios as described above?
- How will the methodology be applied to systems for which the military would be considered the DPMO?
- Considering national prerogatives for military, what is expected in terms of the related ‘oversight’ on the military in such cases?
- Considering national prerogatives for military, what is expected in terms of the related ‘oversight’ on the military in such cases by the civilian ANSP (e.g.: it’s currently already difficult to access precision, availability data/information of those infrastructures.)
- We expect that the proposed regulation will have an impact on the price of equipment and procurement , especially for military specific systems offered by non-EU manufacturers
- In more and more cases the military airbases are shared with civil providers and open to civil traffic. How will this methodology applied especially in those cases?

For EASA

Although all those associated costs will be cascaded down to the DPOs, SPs and airspace users, the NPA does not provide any detail on EASA's plan and associated cost:

- To recruit, train staff in sufficient (high) number and in such a short timeframe;
- To assess the cost of the oversight for the “approval” as DPO and the related oversight for getting CERT and DoC for concerned equipment;
- To continuously oversee all those considerations.

§

response

*Noted*

Please refer to topic ‘Impact assessment’, especially ‘Certification costs and impacts on the market’.

comment

761

comment by: *EUROCONTROL*

Beyond all these additional costs, the proposal is far more complex than current oversight arrangements and does not demonstrate quantifiable benefits for ATM, and for the NM system which is unique there will be no benefit.

There is a high risk to jeopardize interoperability and harmonization by not including the military in a smart and open approach.

Understanding that all those issues will take time to resolve, we are open to work with EASA on an acceptable alternative proposal that meets the deadline of the 13 Sept 2023 but can only be one that would help meet SES performance targets.

Alternatively, and knowing that this deadline is very tight; we suggest that EASA carries-over the provisions of 552/2004 (that everyone knows) to demonstrate compliance to the essential requirements/regulations which would provide the time to deliver a new regulatory framework resolving the mentioned issues.

response

*Noted*

The comment is duly considered.

comment

762

comment by: *EUROCONTROL*

Overall, the NPA and its justification material make the claim for major improvement in the domain of ATM/ANS:

- **Harmonization of certification and oversight:**

If the proposed centralized approach is applied in the same manner as widely seen nowadays through the current “standardization inspections”, the interpretation of the detailed specifications could differ from one inspector to the other thus hindering the harmonisation of the certification and oversight.

-

**Reduction of cost:**

This claim is not supported by evidence; no cost benefit analysis is presented specifically in the domain of the cost of the approval of the DPOs, the certification and declaration of design compliance processes of the concerned ATM/ANS equipment and cost of the associated oversight

-

**Economy of scale:**

This claim is inappropriate; there are not so called “long serial production” (§4.5.4) in the domain of ATM/ANS equipment subject to certification:

- The FDPS or RDPS examples provided in the NPA are not build in big serial number.
- **There is only one NM system for one user, therefore we fail to understand why this rationale should apply.**

**“ One size fits all”:**

Equipment in the domain of ATM/ANS are highly adapted to their context and local reality; different data sets in 2 ATSU of the same ANSP would trigger different needs for demonstrations of compliance. Even in the context of COOPANS, the local realities require specific modules for the different ATSPs. Development of new functionalities are triggered by different local realities and contexts, the content of this NPA would drastically impair the associated innovations and competitions.

-

**Trust in certificate and DoC:**  
 This claim is inappropriate as SPs remain accountable for the service they provide; there will be no relieving factor on the resources (time, effort, cost) required from the SPs' sides.

**Copy/pasting from the airborne side**  
 No evidence is provided that the approach that has been taken in the airborne domain is valid and applicable in the ATM/ANS domain.

Proposed action: EASA should review completely those claims and provide the associated evidence.

response

*Noted*

In addition to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment', it should be highlighted that the proposal does not prevent the integration of different modules/products by the ATM/ANS providers. When such modules/products contain functionalities subject to certification or declaration, they should be designed and produced by approved DPOs in order they place free their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and the business cases. Additionally, it is important to highlight that any ATM/ANS provider could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

763 comment by: EUROCONTROL

Inconsistency with EU.2017/373:  
 The ATM/ANS equipment subject to 'Certification' are referred to as "safety critical"; ATM/ANS equipment subject to 'Declaration of Compliance' are referred to as "other critical" and "other safety critical" (this needs consistency!).

**In the context of EU.2017/373, safety refers to risk and is excluded from the scope of "SPs other than ATSPs". Therefore, we fail to understand the criteria which lead to the decision that flight data processing, surveillance data processing systems and central ATFM systems fall under the certification as mentioned in the NPA text.**

Proposed actions:  
 It should be refrained from using safety criticality and refer to performance and context of use.  
 Equipment is not "safe" or "unsafe"; it is what is done with them in a certain context that could be "safe" or "unsafe".

The regulatory framework should apply only to manufacturers providing equipment to safety-critical operations, i.e. ATM/ANS/ATS providers and not non-ATS providers e.g. AIS that by definition do not affect safety.

This is not only a proposal but it could also be an interpretation of the NPA; the question to be asked to EASA is whether this regulatory interpretation would be acceptable by EASA.

Define criteria for equipment allocation between Certification/ Declaration and Statement of Compliance is essential as not all equipment are known today, and therefore only a few detailed specifications or AMCs can be developed today

response *Noted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Impact assessment'.

comment 764

comment by: *EUROCONTROL*

Unavailability of what is inconsistently refer to as "EASA measures", "Design Specifications", "Certification Specifications", "AMC", "GM".

Without those, this NPA represents a framework proposing a solution that is at best immature and that is equivalent to a "blank cheque".

Considering the tight timeline that EASA has defined for itself, the subsequent NPAs (on those "EASA measures") will more than likely be rushed, enforcing a framework that is not demonstrated as valid.

Question: isn't "certification specifications" an old trace of copy/pasting from the airborne side?

Proposed action:

Delay the "proposal to the Commission" and subsequent acts related to this framework and extend the validity of the current regulatory framework (incl. (EC) 552/2004 in order to have a clarified situation (including the criteria to associate each equipment to a CERT, DOC, SOC type (art 4, 5 and 6 of Appendix 2))

response *Noted*

The comment is duly considered.

NPA 2022-107 titled 'Simpler interoperability framework for the single European sky airspace' was consulted with the EASA ABs. 490 comments from 21 commenters were received with the following shares by stakeholder category: 38 % from NCAs, 34 % from the industry (22% from the ANSPs and 12% from others than ANSPs), and 28 % from other organisations and social partners. The consultation did not indicate any controversial issues.

Furthermore, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Impact assessment'.

comment

765

comment by: EUROCONTROL

Fair competition

The cost and effort on administrative and bureaucratic aspects will remove some actors from the competition.

Many if not all SPs will have to become DPOs as they are designing or developing parts of their own ATM/ANS equipment. The ones not willing to follow that path will have to depend on the industry at higher costs.

The competition will only be fair for the ones (SPs or equipment providers) that get the DPO approval; the other will disappear from the scene; prices will go higher.

The above is not considered at all in the NPA which in part 4. Impact assessment (IA) only anticipates for positive impact.

Proposed action:

Impact assessment on the cost or revenues for all ATM stakeholders and users (travelers, DPOs, SPs, National CAs and impact on employment should be provided and supported by evidence).

response

*Noted*

Please refer to topics 'Impact assessment', especially 'Certification costs and impacts on the market'.

comment

766

comment by: EUROCONTROL

About DPOs:

No consideration provided on what happens to the concerned equipment CERT or DEC when the DPO loses its approval or disappears (including during the transition periods); the CERT or DEC would become invalid and the SPs will have to remove the concerned equipment from operations (ref to new ATM/ANS.OR.A.045(g) and (h) that are part of this NPA); and then...

Would there be an opportunity for demonstrating that the risk on underperformance or on safety would be better controlled with the equipment in operation?

What happens if the equipment suppliers are not based in the EU? Are we expecting that those comply with the regulation? If they don't, will they be excluded? What will be the impact on the competition and the prices?

The example (E.g.) proposed in question (8.1#1) is not realistic. Could we expect the USA, Canada, India, China... to seriously consider this proposal?

Proposed action:

EASA should develop those considerations and make them available for commenting

response

*Noted*

Please refer to topics 'DPO approval discontinuation' and 'Access to the market'.

comment

767

comment by: EUROCONTROL

What if the design specifications (or other wording used in an inconsistent way through the NPA) are not demanding enough?

What would happen if there were an event where the CERT or DEC equipment is identified as being the root cause for a major incident or even an accident? Who will bear the responsibility? EASA?

In accordance with EU.2017/373, SPs are responsible for the service they provide. Are all actors ready to believe the statement of the CERT or DEC?

Once this framework will be in place, DPOs will limit themselves on the demonstration of the design specifications (or other wording used in an inconsistent way through the NPA). Changing DPO will not provide better evidence to the SPs.

Proposed action:

The proposed regulation should clarify this type of event.

response

*Noted*

In addition to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability', it is suggested to acknowledge topic 'Roles and responsibilities of the different actors'.

comment

768

comment by: EUROCONTROL

Responsibilities of the SPs,

SPs remain accountable for the service they provide through their Compliance Monitoring and compliance with ATM/ANS.OR.B.015 (contracted activities). All the processes for demonstration of compliance with requirements (regulatory, technical, functional, non-functional, SW...) on the procured equipment will need to remain

response

*Noted*

AMC/GM to Regulation EU 2017/373 will be developed to address how the evidence of compliance is to be managed by the ANSPs, and when relevant, presented to their respective competent authority.

Changes to an ATM/ANS equipment are either to be done under the control of the DPO responsible for its certificate and oversight. This does not prevent those certain changes (e.g. under maintenance instruction, in the frame of configurable elements) from being implemented by the user (ANSP), but always under the conditions prescribed by the DPO in the relevant manuals.

comment

773

comment by: *DFS Deutsche Flugsicherung GmbH*

DFS welcomes and supports the new regulatory approach that is provided by this NPA and that is based on the vision discussed in the EASA ATM Ground Equipment Steering Group. We have submitted clarification requests that are meant to help EASA address possible discrepancies between the text proposed and the intentions desired. Finally, it is important for us that the application of the rules is designed and introduced in a way that doesn't jeopardize a continued ATM/ANS service (unjustified cost increases for maintaining legacy systems or missing alternatives for new equipment due to market entry barriers need to be avoided).

response

*Noted*

EASA welcomes the comment and the commitment expressed.

comment

795

comment by: *ENAV*

General Positions:

On a holistic view, ENAV understands and in principle supports the intentions expressed and proposed by the NPA. We are confident that this approach has the potential to allow defragmenting the equipment market and allow for an accelerated and more efficient implementation of standardised architectures leading to a successful implementation of upcoming operational concepts.

Standards are necessary for the harmonization of systems in Europe.

In our opinion, systems are hardware, software and procedures. It is important that the regulations currently being established allow a modular design of the ATM systems in this sense and that the certification requirements do not refer to complete systems.

In the process of drafting the AMC/CS, those stakeholders are to be involved who have the necessary know-how for the respective functions in question; these are, in particular, the ANSP for Procedures issues.

With a standardization of systems on the basis of technical requirements and administrative procedures in Europe, a genuine supplier market will potentially emerge, if the certification requirements for DPOs do not represent a prohibitive barrier to market entry for smaller market participants.

It is clear that this regulation needs to enable a noticeable reduction in costs and a significant gain in flexibility.

ENAV is supportive with regard to the goal of establishing a Europe - wide interoperability of systems and equipment in order to achieve the above-mentioned goals. The comments that follow are constructive and critical with reference to achieving this goal and are made in the following categories:

Regulations that contradict the objectives are objected to in a clear manner (with reference to the objective)

Regulations that need to be reworded to be clear, and Regulations that are missing are addressed accordingly.

Interoperability is supported, but the NPA should be modified to be clear on the content and include areas that presently are not affected.

A level playing field should be supported by emphasizing standardization in Europe.

About the proposed transition period (5 years since 13.09.2023) the objective is understood but how to deal with and implement the changes during the transition shall be further specified.

The EASA proposal raises quite a few questions that need to be clarified in advance. The comments therefore reflect whether the objectives of the NPA can be achieved and support the basic position. Such as:

Will it lead to a harmonized European ANS infrastructure? Will it be modular and standardized?

Will interfaces be open and modular system developments possible? Will interoperability of systems be ensured?

Are the regulations specific enough to ensure a true competition of certified system providers?

Will the NPA help overcome the current fragmented landscape of systems; why, how?

Is there any evidence, or at least logical rationale, that the NPA will lead to lower cost for the ANS System as a whole, and for ANSPs in particular?

Regarding supplier competition: How can it be ensured that the NPA does not hinder new system suppliers and thus restrict competition?

How is modularity introduced by the NPA (a reference to overall system)?

Some essential details and definitions are not included but should be considered.

The responsibility of the "Statement of Compliance" for systems is passed on to the ANSPs. This should be left with the system suppliers

A transition period of 5 years seems too short and, in this respect, unrealistic. It is clear that legacy systems must be adapted to the new standards over time. If this is imposed in too short a period, it can lead to premature depreciation and thus sunk costs. In the interests of renewing the European air traffic control infrastructure, the reduction of residual costs by legacy systems must be regulated throughout Europe and financed in a fee-neutral manner, and this must also be taken into account in the performance and charging system in FP 4.

Proposed Change:

Clarify ambiguous sections of the draft proposal and add missing regulations to ensure the goal of the NPA is supported

response

*Noted*



The comment is well received.

The Agency believes that the most of your general concerns are addressed in the topics presented in Section 2 of the CRD 2022-09, which have been duly considered in the Opinion.

In case ENAV sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between ENAV and the Agency, or to be included in the agenda of the most relevant EASA Advisory Body.

comment

797

comment by: ENAV

The NPA represents only a part of the overall package. Essential details and definitions are not included in the proposed Draft Implementing/Delegated Acts. Thus, related acceptable means of compliance (AMC) and guidance material (GM) as well as EASA detailed specifications (DSs) as Certification Specifications or as Certification Basis are still missing.

AMCs are to be regarded as mandatory in practice, since AltMoCs are extremely costly. AMCs are only planned for Q3/2023.

Propose change:

AMCs, GMs and DSs shall be released together with the regulatory framework requirements entry into force.

For ANSP's, AMC's for creation of Statement of Compliance are essential.

response

*Accepted*

EASA is working on the development of the associated draft acceptable means of compliance (AMC) and guidance material (GM) and the first set of detailed specifications, which will be publicly consulted with EASA stakeholders.

These draft AMC and GM will be aligned with the final text of the subject EU regulations and will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

comment

798

comment by: ENAV

It is not defined by the regulation which systems/constituents fall under which regime (Certification/Declaration/Statement of Compliance). The examples given in the cover letter raise the next question. If flight data processing systems or surveillance data processing systems require certification, does this apply only to this component (CSCI) or to the entire ATM system (such as Topsy)?

The systems subject to this regulation shall be more closely defined as directly contributing to the safe provision of ATS.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

800

comment by: ENAV

The implications for ANSPs in the context of conformity assessment regarding "Statement of Conformity" are not foreseeable. Concrete definitions are missing.

The requirements should be clarified accordingly.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

812

comment by: EUROCONTROL

**Document quality:**

Passive form should be avoided in requirements as it is sometimes not clear to whom the requirement applies. It may also help to categorise if the requirement is OR or AR.

Proposed action:

Remove passive form from requirements and clarify who is responsible.

response

*Accepted*

The comment is duly considered during the finalisation of the proposal.

comment

816

comment by: EUROCONTROL

**SESAR deployment and OEP**

The text below is an extract from the NPA text as for the time being no information on this could be identified in the proposed regulation. However, it could lead to significant impacts on the network once the proposed regulation is in place:

*“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 to manage their activities and achieve their objectives. “*

This text gives EASA total freedom to act on any network deployment even those that have taken place. Moreover, we are at risk that any future, not yet identified deployment would fall under such certification scheme. Note that such risk on the SDM has not been anticipated in the EC SDM call.

Finally, there is a risk that any equipment already successfully deployed could be reconsidered by EASA during the next 5 years of transition.

**All these elements show that there is a significant risk of additional cost, delay and potentially disruption of operation for the network.**

Similarly, the network operational stakeholders are fully committed to deliver early benefits through the Operational Excellence Programme, such activities are not identified in the NPA, we expect that they will not be included in this regulation as we see a significant risk to the network in terms of cost and delays.

As a minimum EASA shall provide additional information on the following points: which criteria will be applied to identified equipment concerned? Which deployment project is concerned?

As a minimum EASA shall adapt the proposed regulation to ensure that any consideration on the deployment programme would come as a minimum with a zero- impact compared to the existing regulation. Ideally only equipment required in deployment projects demonstrating a positive cost benefit for the network should be considered under this new certification scheme.

Proposed actions:

**Provide more clarity and define the criteria that EASA will apply to the equipment for the deployment of certain Single European Sky ATM Research (SESAR) projects.**

Before any commitment on this regulation can be made, **full clarity should be made on the cost, delay and potential disruption that this regulation could have on SESAR deployment projects.** Update the impact assessment accordingly.

**Propose an acceptable way forward to ensure a zero impact on the network in terms of cost and operations compared to the current regulatory framework for any of the deployment program (SESAR or OEP ) that you may consider in this regulation.** Ideally only equipment required in deployment projects demonstrating a positive impact for the network should be considered under this new certification scheme.

response *Noted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment ' and 'Impact assessment'.

comment 822

comment by: *skeyes*

#### **Current situation with EU 2018/1139 repealing EU 552/2004**

In the process scheme of an ANSP, the execution of the verification of systems is triggered by the change management process

A change can introduce a new equipment or introduce evolutions to an already verified equipment The change management is covering all aspects from the initial idea of the change itself, passing by specification of the solution, design of the solution, implementation/production of the solution including introduction/evolution of equipment, validation of the equipments, validation of the solution (integration concept) until the entry into service.

It is supported by different risk analysis's (safety, security, and a structured process keeping in mind that design and production of an equipment is only a part of the change/solution.

Most of ANSP equipments are provided by manufacturers, therefore with a DSU or a DoC (when community specifications are available). Then the verification of conformity is done by ANSP and a DoV (similar to a statement of Compliance) is produced. The main grey zone with this approach is the quality of the DSU/DoC that can be different from one manufacturer to another ( the structure of this document is defined by the regulation, but not the content).

For internal developments, no DSU/DoC is produced as an ANSP is not a (recognized) manufacturer. Nevertheless, the end to end verification is similar and summarized in a DoV.

The main drawback of the current approach is that the oversight activities are not (explicitly) regulated for the manufacturer part. This puts the entire responsibility of the conformity assessment on the shoulders of the ANSP under the supervision of the competent authority (usually the NSA).

The main advantage of this solution is that it works for manufacturers COTS product solution, as well as for bespoke solutions (even if they are developed inside the ANSP)

### **Introducing proposed amendment 2022/09**

The NPA 2022/09 mainly deal with the grey zone on manufacturers activities and oversight. It introduces:

- A concept of certification of the manufacturer by EASA, aligning all manufacturers on a common baseline in terms of design and production aspects of an equipment.
- A concept of equipment certificates delivered by approved/certified manufacturer.

This makes a huge formal shift of responsibilities to the equipment manufacturer for all what concern the design and production of the equipment itself.

Nevertheless, the integration of the equipment as part of a change/solution in the context of the ANSP remains the sole responsibility of the ANSP. This means that all activities linked to the production of a statement of compliance (formerly the DoV) are still applicable. The administrative and oversight burden might be lighter thanks to the standardized equipment certificate provided by approved manufacturer.

For all generic functions of an ANSP that can be supported by standard COTS equipment, this is a real added value.

For bespoke solutions sometimes needed for site specific implementation within a specific ANSP, this can become a real problem. If the equipment manufacturer for the bespoke solution is an approved one, this might be easy, but if the ANSP is developing internally a solution, this is a new grey zone after 2023.

The question that is raised here is the following (for an internal development): Can an ANSP be considered as a manufacturer, and therefore shall the ANSP request for certification to be granted to approve its own equipment? Or is a statement of compliance covered by NSA oversight still sufficient?

Furthermore, the recent introduction of EU 2018/1139 regulation, extending the scope of conformity assessment to MET and AIS domain, has raised a lot of question for MET and AIS service providers, as well as for equipment manufacturers in their domain (traditionally not concerned by interoperability regulation).

Seen the certification requirements for all ATM/ANS service providers is there already, a further level of certification or declaration will most probably only result in additional workload and additional costs without ultimate benefits like increased flight safety.

A transition period of 5 years (between 2023 and 2028) is foreseen but will be rather short to setup the entire certification mechanism for manufacturers at the level of EASA, and to solve issues introduced by the NPA.

### **Added values of the NPA**

End to end standardization of the conformity assessment process.

Light but not significant improvement in the administrative burden of statement of compliance for the ANSP

**Drawbacks of the NPA**

For manufacturers, being approved and granted to deliver certificates for their equipment will have an additional cost (that will most probably billed indirectly to the ANSP's).  
Introduction of a grey zone for internal development

response *Noted*

The comment is duly considered.

comment

826

comment by: ENAV

The software assurance obligations of the ANSPs, based on VO 2017/373, are not addressed.  
An adaptation of the AMC's is required.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

827

comment by: ENAV

Once a product is certified, what happens if customization (due to natural technology evolution or patch) is needed? Is there a need to re-trigger the certification process?  
It would be important to define the criteria to discriminate minor upgrades from major upgrades and evolutive maintenance.

response *Noted*

The drafting suggestions are noted, and concrete comments in the regulatory draft are incorporated when appropriate.

Furthermore, the subject and the concept of minor/major changes for the ATM/ANS equipment will be further defined at the level of AMC.

comment

828

comment by: ENAV

Clarify if the design of the ATM/ANS system, which is constituted by certified components, is in the scope of this NPA.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment.

Furthermore, the certification basis applicable will be defined including applicable certification specifications (this will depend on the functionalities 'comprised' by the product).

comment

829

comment by: ENAV

Clarify if maintenance organization will fall under the certification requirements.

response

*Noted*

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, this proposal should differentiate 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 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.

In conclusion, the answer is negative, provided that the activity between the routine maintenance and upgrades/evolution is clearly allocated between the ATM/ANS providers and the ATM/ANS equipment manufacturer.

In addition, please refer to topic 'Roles and responsibilities of the different actors'.

comment

830

comment by: ENAV

Request to clarify on which document/regulation the criteria to discriminate equipment requiring certification from declaration ones will be described.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment.

Furthermore, the certification basis applicable will be defined including applicable certification specifications (this will depend on the functionalities 'comprised' by the product).

comment

831

comment by: ENAV

This is a general comment about a number of issues not covered by the NPA regarding practicalities in creating attestation.

If a certified organization with a certified equipment cease to exist or cease to maintain/upgrade an equipment what will that mean to ANSP:susing such equipment?

How will the regulation be applied at combined Civil/Military ATS units where military is providing ATM/ANS equipment to the combined civil/military ANSP?

When changes are made in interoperability specifications (ASTERIX format for example) how shall updates then be identified? Is it a supplier task or an ANSP task, and how fast is adaptation required?

In what way can ANSPs assume what responsibility is moved to DPOs, and what contractual matters between ANSPs and DPOs can be removed/reduced due to attestations from the Agency?

There are no exemptions due to various service locations. A very small ATS unit might be forced to accept a very expensive ATM/ANS equipment from a large DPO since a small DPO might not be able to meet all requirements for attestation. This will have the effect that it will be very costly for small ATS/Airports.

In case a DPO become bankrupt or declare an ATM/ANS equipment EndOf Life, will it be possible for an ANSP to themselves do something with the ATM/ANS equipment to keep it alive? How is such a situation resolved? Can the ANSP choose themselves how long they can use the equipment, or how quickly must such an equipment to be replaced

response

*Noted.*

Following the order of the issues:

- please refer to topic 'DPO approval discontinuation';
- The commented proposed framework is DA/IA to EASA Basic Regulation; thus, air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military should be excluded from the scope of this Regulation. However,



Member States should ensure, in accordance with their national law, that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 of the European Parliament and of the Council applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139;

- please refer to topic ‘ATM/ANS equipment change management’;
- please refer to topic ‘Roles and responsibilities of the different actors’;
- please refer to topic ‘Certification costs and impacts on the market’;
- please refer to topic ‘DPO approval discontinuation’.

comment

832

comment by: ENAV

When all criteria and specifications are defined and equipment and DPO are certified / approved, can it be assume that all equipment are equivalent and the only difference is the price? How will the ANSP be able to distinguish the quality of equipment / suppliers?

**Proposal:**

Access to certification documentation / reports shall be available to stakeholders.

response

*Noted*

Please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’. The comment is well received and, therefore, taking into account the comments, the development of the associated AMC/GM is under consideration.

comment

833

comment by: ENAV

The Essential Requirements of (EU) 2018/1139 are generally applicable at a System level (and many of the current IR/CS requirements are end-to-end and/or can be implemented across multiple Constituents) and full compliance is only demonstrable by the ANSP; noting that the Safety (Support) Assessments under (EU) 2017/373 do not fully cover compliance with the ERs, etc. (but conversely, the current TFs should cover Safety), the proposed framework provides no mechanism for an ANSP to demonstrate their compliance, and national differences may emerge. Further, the loss of the requirement for independent verification of ANSP compliance (which is now being placed on DPOs) is a concerning omission from the proposed framework.

(EU) 2017/373 can be amended to capture the need for an ANSP to produce and maintain Technical Files to demonstrate compliance of their Systems with the ERs (and any associated

detailed rules which are applicable at the System level). These TFs should form the basis for NSA auditing of the Systems and approval of change, and the inclusion of a requirement for ANSP declarations based on independent verification of compliance would provide a mechanism for the implementation of minor changes (not subject to NSA review).

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

834

comment by: ENAV

The future direction of ATM systems is to make use of common **IT infrastructure**, data centres, etc. which would not by themselves perform any ATM function; the ANSP would procure software products from DPOs and host them on these platforms. There is still "equipment", but it would not be in scope of the certification, and the provider would not be a DPO; to make this architecture work under the proposed framework, it is likely that ANSPs will need to certify as DPOs.

(EU) 2017/373 should be updated to ensure ANSPs retain responsibility for ER compliance of the System, which should be demonstrated through Technical Files.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The associated AMC/GM to Regulation EU 2017/373 will be developed to address how the evidence of compliance is to be managed by the AMT/ANS providers, and when relevant, presented to their respective competent authority.

comment

944

comment by: NATS

NATS accepts that the framework provided by (EC) No 552/2004 does not provide sufficient detail to ensure that the oversight of manufacturers is standardised across Member States, nor does it allow one NSA to make use of market surveillance activities performed by another NSA, or for manufacturers to benefit from organisational certification. The current framework would also benefit from a more formal mechanism for making minor amendments to Constituents, and it needs to be better integrated with the requirements for notification and approval of change provided in (EU) 2017/373.

Noting these deficiencies, NATS support the intent to improve the current Conformity Assessment framework. However, although this NPA may address some of the issues with the current framework, NATS are concerned that – as written – it may introduce a number of new issues, in particular:

- ANSPs are not analogous to Airline Operators: In such an analogy, most ANSPs actually “build the aircraft” and the distinction between the System (as assembled by the ANSP, i.e. the aircraft) and Constituents (as produced by the DPOs, for integration into the System) is still relevant in ATM/ANS, unless the expectation / end result is that ANSPs need to certify as DPOs.
- Essential Requirement Compliance: Compliance with most of the ERs (and many technical specifications) can only be demonstrated by the ANSP. The proposed framework seemingly removes the features intended to ensure consistency in how an ANSP addresses them (Technical Files and Declarations of Verification), which could lead to further national differences in how these are handled. Noting that the safety (support) assessments required under (EU) 2017/373 do not cover the full scope of the ERs, the Technical Files provide a robust mechanism for capturing and auditing ANSP compliance with the ERs (including safety), and the requirement for a DoV based on independent verification provides a mechanism which could be used for ANSPs to deploy “minor” changes not subject to NSA approval.
- Flexibility: It appears that each piece of “ATM Equipment” will fall into one of the three categories (Certification, Declaration, or Statement of Conformity) depending on its function, which means there is only a single path to market for any given product. Two of the categories necessitate organisational approvals, and the third places no obligations on the manufacturer. The proposed framework presents significant barriers to entry for SMEs & non-EU manufacturers; a more flexible framework (providing options for each category of product) would allow DPOs to choose the most appropriate path for their circumstances, allowing more competition and innovation, and would ideally provide a mechanism for an ANSP to verify the conformity of products where the manufacturer was for some reason unable.
- Bespoke products: The reality of ATM/ANS today means that many products must be designed specifically to account for the wider context of a particular ANSP’s System; such products are unlikely to benefit from the proposed scheme, and it may make it harder for ANSPs to procure the Constituent that they actually need for their particular environment/circumstances. Although the framework may be more effective at some future date when ATM/ANS is significantly more standardised, attempting to force such standardisation prematurely will likely result in more problems/costs/delays/incidents/etc. and any new framework needs to better allow for the approval of today’s bespoke products.
- New Architectures: The proposed framework seems to be based on the idea that an ANSP procures a “full stack” (hardware, OS, software, etc.) from a supplier, but ANSPs are fast moving towards new concepts from the IS domain (clouds, data centres, virtualisation, SoA,). The proposed framework could limit the allowable architectures and stifle innovation, and/or the certification may prove largely meaningless as ANSPs re-host and verify software in their own environments.
- Conformity Assessment: The most critical equipment will be subject to EASA certification, and the ANSP is expected to perform no further verification, but this certification will be based on audit activities rather than independent verification. Many specifications contain end-to-end requirements, and even when they align neatly with the product, ambiguities in these specifications could lead to

implementations which pass internal testing by even the most competent organisation, but which fail to work in the way anticipated by ANSPs. The new framework needs to better acknowledge the extent of engineering performed by ANSPs and their role in ER compliance (without forcing them into DPO certification, which seems superfluous given their (EU) 2017/373 certification... notwithstanding that the changes proposed appear to fall short of ensuring ER compliance).

- Impact on ANSP Operations: The validity of ATM Equipment certification/declaration seems dependent on valid organisational approval, which raises concerns on the implications for ANSPs if e.g. a DPO's approval is withdrawn or they choose to withdraw from the market. Additionally, the need for some categories of ATM Equipment to be certified by EASA may create a bottleneck, potentially delaying the delivery of important changes.

Although the airworthiness framework may work well in that domain, the ATM/ANS domain is small and makes more use of bespoke products (noting that the New Legislative Framework was previously considered overly burdensome for an industry of this size), with a close relationship between the supplier and the ANSP – who is ultimately responsible for the design and implementation of the overall System – and the proposed framework may not be the most efficient for the ATM/ANS domain, potentially having the opposite effect to the stated objectives. NATS would ask that EASA carefully consider the comments raised against this NPA and whether the industry may be better served by more flexibility in the framework to provide more options for DPOs to get products to market and ensure consistency in how ANSPs demonstrate compliance of their Systems. We believe it is possible to avoid the above issues while still abiding by the framework set out by (EU) 2018/1139 but appreciate that this would require extensive changes to the text of the NPA.

response

*Noted*

The comment is well received.

The Agency believes that the most of your general concerns are addressed in the topics presented in Section 2 of the CRD 2022-09, which have been duly considered in the Opinion.

In case NATS sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between NATS and in another forum.

comment

1044

comment by: *Fintraffic Air Navigation Services*

- We support the general idea and principle of the initiative.

response

*Noted.*

The comment is well received.

comment

1045

comment by: *Fintraffic Air Navigation Services*

- It is mentioned that further detailed specifications will be published later. It is important that AMCs/GM are clearly defined and valid regardless of the operating environment which differ in various parts of Europe. Thinking of ATM systems all functionalities necessary in certain operating environments may not be needed in other areas.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, as stated in the Opinion No 01/2023, in parallel with the European Commission adoption process, EASA will continue working on the development of the associated *draft* AMC, GM and DSs. EASA will adapt these draft AMC and GM to the potential changes that may be introduced in the final text of the subject EU regulations during the regulatory process on the adoption of the regulations. The ED Decision(s) containing the associated AMC, GM and DSs will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

comment

1046

comment by: *Fintraffic Air Navigation Services*

- The planned implementation schedule (date of entry into force) is very challenging to both suppliers/manufacturers and ANSP's. The schedule should be reconsidered. Enough time should be available for EASA to create AMC/GM.

response

*Noted*

The date is set up by the legislator in Regulation (EU) 2018/1139. The proposed transitional period (5 years) caters initially for that risk.

In addition, as stated in the Opinion No 01/2023, in parallel with the European Commission adoption process, EASA will continue working on the development of the associated *draft* AMC, GM and DSs. EASA will adapt these draft AMC and GM to the potential changes that may be introduced in the final text of the subject EU regulations during the regulatory process on the adoption of the regulations. The ED Decision(s) containing the associated AMC, GM and DSs will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

comment

1047

comment by: *Fintraffic Air Navigation Services*

- There is a risk that the legislation as a whole will cause additional costs for the air traffic services supply chain due to manufacturers' certification requirement, EASA's additional personnel cost while ANSP's cost reductions are negligent. Local verification and testing etc. are still required and necessary.

response

*Noted*

Please refer to topic 'Impact assessment', especially 'Certification costs and impacts on the market' as well as to 'Transitional provisions'.

The proposed transitional period (5 years) caters initially for that risk.

comment

1048

comment by: *Fintraffic Air Navigation Services*

- There is a risk that the legislation as a whole will cause additional costs for the air traffic services supply chain due to manufacturers' certification requirement, EASA's additional personnel cost while ANSP's cost reductions are negligent. Local verification and testing etc. are still required and necessary.

response

*Noted*

Please refer to topic 'Impact assessment', especially 'Certification costs and impacts on the market' as well as to 'Transitional provisions'.

The proposed transitional period (5 years) caters initially for that risk.

comment

1049

comment by: *Fintraffic Air Navigation Services*

- The document should describe exceptions from the regulation (eg. certification continuity in case of bankruptcy of the supplier).

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

1052

comment by: *DGAC (French CAA)*

The summary of the NPA is not consistent with the article 4 of appendix II "*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*" defining "*Certification of ATM/ANS equipment*"

Indeed, the summary first introduces the need to better manage interoperability (chapter 2.2 of the NPA) and then states the need to certify "certain safety-critical ATM/ANS systems" (page 15/82 of the NPA) without being very clear whether it is a function that would be certified or a piece of equipment and without being precise on what is considered by EASA as "safety-critical". Finally, Appendix 2 article 4 does not restrict the scope of certification so that "“ATM/ANS equipment that processes and delivers data for the purpose of the provision of ATM, shall be issued with a certificate by the Agency as specified in Annex II to this Regulation”"; in other words, any equipment contributing to a function which delivers data for the purpose of ATM should be certified (which is very broad) ...

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1114

comment by: *Romanian CAA*

General comments:

- a) - The use of terms as "safe" or "safety critical" is inconsistent with what is defined in Regulation (EU) 2017/373. The ATM/ANS equipment subject to 'certification' are referred to as "safety critical"; ATM/ANS equipment subject to 'Declaration of Compliance' are referred to as "other critical" and "other safety critical". Safety critical "equipment" needs to be defined / rephrased - According to Regulation (EU) 2017/373 safety refers to risk and it is only within the scope of ATSP (no other service providers are using it).
- b) - The term „equipment" introduced for ATM/ANS does not exist in the Regulation (EU) 2018/1139, which refers to systems and constituents.
- c) - There is no definition for EATMN. The only place where EATMN is defined is in Regulation (EC) 552/2004. Parts of this regulation have already been repealed and what is remaining of it will be repealed by the result of this NPA.

response

*Noted*

The categorisation of the equipment is based on the nature and risk of the activities supported/enabled by such equipment. This is not exclusively based on safety criticality. In this context, the text of the Opinion is made more consistent, avoiding references to safety criticality, which might be imprecise.

As the commentator mentions, the ATM/ANS equipment is not defined, and therefore, Article 2 of the delegated act defines the term used in the Regulation.

Taking into the comment, the definition is introduced.

comment

1127

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Austria supports the goal of interoperability, but the NPA should be modified to be clear on the content and the scope, which must be proportionate with regard to the purpose of achieving adequate safety and interoperability of systems directly contributing to the provision of ATS.

response

*Noted*

The comment was duly considered.

comment

1130

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

The proposal must address a modular approach to system design by focussing the certification efforts on building blocks and their interfaces rather than large, monolithic systems. Only then real competition on the market and an efficient system architectures from a technical point of view can be achieved.

response

*Accepted*

In addition to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment', it should be highlighted that the proposal does not prevent the integration of different modules/products by the ATM/ANS providers. When such modules/products contain functionalities subject to certification or declaration, they should be designed and produced by approved DPOs in order they place free their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and the business cases. Additionally, it is important to highlight that any ATM/ANS provider could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

1132

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

The drafting of the AMCs and CSs supplementing the Regulations of this proposal will determine the usefulness and the economic impact of the proposal. It must be ensured that all regulatory as well operational stakeholders are fully involved in this process.

response

*Accepted*

As stated in Opinion No 01/2023, in parallel with the European Commission adoption process, EASA will continue working on the development of the associated draft AMC, GM and DSs. EASA will adapt these draft AMC and GM to the potential changes that may be introduced in the final text of the subject EU regulations during the regulatory process on the adoption of



the regulations. The ED Decision(s) containing the associated AMC, GM and DSs will be published by EASA following the publication of the aforementioned EU regulations by the European Commission. So, in the development of the associated AMC, GM and DSs, subject matter experts from the industry are involved in addition to the RMG for RMT.0161.

comment 1133 comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

· With a standardization of systems on the basis of technical requirements and administrative procedures in Europe, a genuine supplier market will potentially emerge, if the certification requirements for DPOs do not represent a prohibitive barrier to market entry for smaller market participants.

response *Noted*

Please refer to topic 'Access to the market'.

comment 1169 comment by: *Finnish Transport and Communications Agency*

Traficom requests EASA to consider a proportionate approach, so that the new provisions would not lay down excessive requirements on small size organisations, especially on MET organisations who use in-house developed, non-commercial systems only by itself nationally.

response *Accepted*

The comment is duly considered.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 1177 comment by: *Deutscher Wetterdienst*

It is repeated throughout the NPA that the proposed requirements for the various levels of system certification are intended to serve an equal market environment. There is a feeling that the proposed implementing regulations and delegated act might be used by some system providers to exert a dominant position in the market.

response *Noted*

The proposed transitional period (5 years) caters initially for that risk.

The evolution of the market then should be observed in the frame of the monitoring of the effectiveness of the new framework.

The commentator is invited to further clarify why the new framework would negatively impact availability of alternative suppliers of equipment in the market, compared to the current framework.

comment

1178

comment by: *Deutscher Wetterdienst*

Due to the certification requirement concerning all ATM/ANS service providers already established by the EU - and here systems/equipment used are already subject to supervision by the national competent authority (CA) via the implementation of the Functional System - a further level of attestation is to be classified as superfluous and will most probably only result in additional workload and unjustifiable additional costs without any demonstrable positive influence on flight safety.

(s. IA cost efficiency)

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1179

comment by: *Deutscher Wetterdienst*

In all the explanations no reference to the risk that certain services could no longer be provided at all due to a complete and utter lack of available certified or declared equipment is not addressed at all.

response

*Noted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

On the other hand, the categorisation of the equipment is based on the nature and risk of the activities supported/enabled by such equipment.

comment

1180

comment by: *Deutscher Wetterdienst*

There is a lack of information what will happen to the operational equipment of a service provider, depending on its systems to provide stable and robust services if the certification / declaration of the equipment will be revoked or suspended. If the equipment is not allowed to be operated without a valid certificate/declaration that would result in an immediate stop of the provision of important MET information services for the European airspace users and aviation community.

response *Noted*

Please refer to topic 'DPO approval discontinuation'.

Furthermore, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

On this specific case, the MET equipment is proposed to be a subject to a statement of compliance issued by the ATM/ANS provider.

comment *1181*

comment by: *Deutscher Wetterdienst*

The current text gives room for different interpretations and therefore inevitably will result in non-homogenous implementation and thus contradicts the fundamental principles of the EU legislature. A clear declaration on IR level (e.g. in an annex) is absolutely required stating that only ATM/ANS equipment of the EATMN but not any equipment to support information services to support the provision of ATM functions are affected.  
Missing definition/ adoption of the systems definition from 552/2004.

response *Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

## 1.1. How this NPA was developed

p. 4

comment *136*

comment by: *COULON FR SAA*

The basic *régulation*(BR) and Interoperability (IOP) distinguish clearly the case of military stakeholders as non binded by the regulations, if it is successfully argued the non ATS nature of the services.

Will it be the same here?

Can we draw a strait conclusion that the Implementing rule (IR) drafted here by for ATM/ATS services could non apply to military non ATS services/systems?

response

*Accepted*

The proposal puts forward the establishment of a framework on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military. In addition, in accordance with Article 1(2) of the framework Regulation (EC) No 549/2004, the regulatory framework for the creation of the single European sky does not cover State aircraft (including military, customs and police aircraft) during operations and training.

Taking into account these principles, the recitals for the proposed Regulations address these subjects.

comment

157

comment by: DSNA

**#1** -subtask 2  
comment : will the 6 ATM functionalities of CP1 (2021/116) be included in this subtask 2 ?

**#2** -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 specifications (4).*

Comment: RMT061 is not currently adequate to deliver Detail Specifications, as it is a demanding task and all stakeholders are not represented. Proposal: This task shall be assigned to another body, or RMT061 needs to be enlarged to all stakeholders.

response

*Noted*

Following the order of the comments:

- Regulation (EU) 2021/116 is not an SES IOP implementing rule and is not required to be adapted to the new framework. Therefore, it is not within the scope of Subtask 2 of RMT.0161.
- Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'. In addition, as stated in Opinion No 01/2023, during the committee procedure for the adoption of the proposed implementing and delegated acts, EASA will continue the work preparing the issue of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specifications (DSs), which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DSs

will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

comment 203 comment by: *CANSO*

Subtask 2  
Comment : will the 6 ATM functionalities of CP1 (2021/116) be included in this subtask 2 ?

response *Noted*

Regulation (EU) 2021/116 is not an SES IOP implementing rule and is not required to be adapted to the new framework. Therefore, it is not within the scope of Subtask 2 of RMT.0161.

comment 204 comment by: *CANSO*

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 specifications (4) .  
Comment: RMT061 is not currently adequate to deliver Detail Specifications, as it is a demanding task and all stakeholders are not represented.

Proposal: This task shall be assigned to another body, or RMT061 needs to be enlarged to all stakeholders.

response *Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, as stated in Opinion No 01/2023, during the committee procedure for the adoption of the proposed implementing and delegated acts, EASA will continue the work preparing the issue of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specifications (DSs), which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DSs will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

Furthermore, EASA also shares the view regarding the need for inclusiveness of the ATM stakeholder community in large.

comment

835

comment by: ENAV

Subtask 2

Comment : will the 6 ATM functionalities of CP1 (2021/116) be included in this subtask 2 ?

response

*Noted*

Regulation (EU) 2021/116 is not an SES IOP implementing rule and is not required to be adapted to the new framework. Therefore, it is not within the scope of Subtask 2 of RMT.0161.

comment

836

comment by: ENAV

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 specifications (4) .

Comment: RMT061 is not currently adequate to deliver Detail Specifications, as it is a demanding task and all stakeholders are not represented.

Proposal: This task shall be assigned to another body, or RMT061 needs to be enlarged to all stakeholders.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, as stated in Opinion No 01/2023, during the committee procedure for the adoption of the proposed implementing and delegated acts, EASA will continue the work preparing the issue of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specifications (DSs), which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DSs will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

Furthermore, EASA also shares the view regarding the need for inclusiveness of the ATM stakeholder community in large.

comment

233

comment by: *Indra Navia*

In general, we welcome this initiative as it is in our common interest to have a level playing-field and common understanding and practice around requirements related to safety, quality, interoperability and performance of the equipment and services in the ANS/ATM domain. However, there is a concern that cost of approvals is not scoped and not possible to predict. It is therefore not possible to budget for it, or take it into account in proposals to customers. It is also not defined who pays for EASAs effort.

There is concern about the fact that it cannot be expected that EASA has competence on all types of systems. It must be avoided that the first applicant for a particular equipment type has to fund EASA familiarization with that particular type of equipment. EASA must ensure that there is sufficient internal budget for this, independent of who pays for their effort in reviewing material and issuing certificates.

Also, EASAs level of involvement in equipment attestations must stay on the level of detail that corresponds to the EASA auditors level of expertise on that particular type of system at the start of the audit process. The industry cannot afford the burden of assisting in raising EASAs representatives' level of expertise on the particular product type. This limitation should be covered in the regulation, in order to help resolve any potential conflicts that may arise.

response

*Noted*

Please refer to topic 'Impact assessment' and in particular 'Certification costs and impacts on the market'.

It is well acknowledged that this proposal would potentially affect EASA's resources. Therefore, the Commission should ensure that the Agency has the necessary resources and capabilities, taking into account all relevant factors, including an assessment carried out by the Agency to determine the resources needed for the exercise of its newly assigned tasks under this proposal. The implementation of the proposal will require the Agency to plan in advance the necessary resources for the initial certification and continuing oversight of the organisations involved in the design and/or production of ATM/ANS equipment as well as for the certification and registry of the declarations of ATM/ANS equipment, including their continuous oversight. However, this oversight by the Agency will fall under the Fees & Charges scheme.

As regards the comment on the level of involvement in equipment attestations, it will be considered during the development of the associated AMC/GM in the context of the activities of RMT.0161 Subtask 3.

comment

308

comment by: *Nils PALMQVIST*

Please note that many (or even most) of the comments from LFV might also have been taken on board by CANSO, and entered by them as duplicates in case CANSO have agreed with an LFV comment. LFV have entered our own comments just to be sure that all of our comments have been entered in CRT.

response *Noted*

comment 309

comment by: *Nils PALMQVIST*

This is a general comment about a number of issues not covered by the NPA regarding practicalities in creating attestation.

**1.** If a certified organisation with a certified ATM/ANS equipment cease to exist, or cease to maintain/upgrade an equipment what will that mean to ANSPs using such equipment? Will it be possible for an ANSP to themselves do something with the ATM/ANS equipment to keep it alive? How is such a situation resolved? Can the ANSP choose themselves how long they can use the equipment, or how quickly must such an equipment to be replaced?

**2.** How will the regulation be applied at combined Civil/Military ATS units where military is providing ATM/ANS equipment to the combined civil/military ANSP?

**3.** When changes are made in interoperability specifications (ASTERIX format for example) how shall updates then be identified? Is it a DPO task or an ANSP task, and how fast is adaptation required?

**4.** In what way can ANSPs assume what responsibility is moved to DPOs, and what contractual matters between ANSPs and DPOs can be removed/reduced due to attestations from the Agency?

**5.** There are no exemptions due to various service locations. A very small ATS unit might be forced to accept a very expensive ATM/ANS equipment from a large DPO since a small DPO might not be able to meet all requirements for attestation. This will have the effect that it will be very costly for small ATS/Airports.

response *Noted*

Following the order of the comments:

- Please refer to topic 'DPO approval discontinuation'.
- Air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military, should be excluded from the scope of this Regulation. However, Member States should ensure that when such ATM/ANS serve air traffic to which Regulation (EC) No 549/2004 applies, they offer a level of safety and



interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for ATM/ANS set out in this Regulation.

- Please refer to topic ‘ATM/ANS equipment change management’. However, it should be noted that there will be no need for a change to the ATM/ANS equipment with each amendment of the detailed specifications.
- Please refer to topic ‘Roles and responsibilities of the different actors’.
- The commenter is kindly invited to note that the new framework proposes different methods of conformity assessment considering the nature and the risk of the operation or functionality enabled by the particular equipment. For further details, please refer to topics ‘Categorisation of ATM/ANS equipment subject to conformity assessment’ and ‘Access to the market’.

comment 504

comment by: *Juan L. Diz*

I understand that detailed specifications and the AMC/ GM will be developed later, first quarter 2023. It is highly recommended that those should be based in industry international standards and also it should be beneficial to call for feedback to industry manufacturers (DPO) to identify the best way to identify suitable detailed specifications and the AMC/GM.

response *Noted*

Please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

In addition, as stated in Opinion No 01/2023, during the committee procedure for the adoption of the proposed implementing and delegated acts, EASA will continue the work preparing the issue of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specifications (DSs), which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DSs will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

Furthermore, EASA also shares the view regarding the need for inclusiveness of the ATM stakeholder community in large.

comment 519

comment by: *EUROCAE*

EUROCAE is the European leader in the development of worldwide recognised industry standards for aviation. We take an active role in coordinating European and global standardisation activities and develop high-quality standards that build upon the state of the

art expertise of its members, are fit for purpose to be adopted internationally, support the operational, development and regulatory processes, and address emerging global aviation challenges.

EUROCAE currently has over 400 members, including industry, service providers, regulators, research institutes and international organizations. EUROCAE is recognized by the World Trade Organisation as a European Standards Developing Organisation, fulfilling and respecting WTO's best practices on developing standards in order to support the principles and the foundation of the multilateral trading system, without discrimination.

We look back at a successful track record of collaboration with EASA and other authorities in developing standards, recognized as acceptable means of compliance to the regulatory framework.

Industry standards, developed following a consensus-based, open, transparent and inclusive process, are a powerful tool for regulators and industry to enable an efficient process of compliance demonstration and facilitate the introduction and deployment of innovative technologies.

EUROCAE would like to confirm our readiness to support EASA with the development of relevant standards in support of the future regulatory framework. This will build on the expertise and competencies of our members, the European and international aviation community. This work will of course be done in close collaboration with our relevant partner organisations, and any standardisation initiative will have to be carried by our members, who will be consulted in the development of the work programme, to validate the proposed deliverables and priorities, via open calls for participation to affirm their support and nominate experts. A work programme should hence be developed in cooperation between EASA and EUROCAE to determine which standards are needed, their scope and related timeframes, to be initiated in line with the relevant EUROCAE procedures.

Please clarify the wording of 'harmonised standards' (several instances within the NPA document): Does this formulation refer to harmonized standards in the sense of the single market / new legislative framework as laid down in REGULATION (EU) No 1025/2012 on European standardisation, or does it simply refer to 'technological harmonisation'?

response

*Noted*

The Agency is very pleased to receive the positive comments and support as expressed by EUROCAE. One of the main objectives of the proposed conformity assessment framework is to pave the way for the technological evolution in the European ATM system. The role of and close cooperation with EUROCAE towards this objective is essential, as it was already in the implementation of the now repealed SES Interoperability scheme too. A good recent example of such mutual cooperation between EUROCAE and EASA is the swift development of necessary standards for VTOL aircraft.

In addition, it could be confirmed that the notion of 'harmonised standards' in the proposal indeed refers to validated industry standards used as a means to demonstrate compliance with the requirements.

comment

783

comment by: AESA

The content of the link referenced in the footnote 4 (Community specifications (europa.eu)) has to be updated: Essential Requirements are established in Basic Regulation.

response *Accepted*

comment

1138

comment by: *EUMETNET*

Attachment [#1](#)

**Comments from MET Air Navigation Service Provider as coordinated by EUMETNET EIG replying to public consultation (7 October, 2022 / Version 0.7)**

**Note the attached PDF contains an Annex that complimenets the Comments noted below**

The Notice of Proposed Amendment 2022-09 aims at establishing a regulatory framework on the conformity assessment of ATM/ANS equipment to provide an implementing and delegated act to comply with the Essential Requirements of the Basic Regulation. Thus, it will eventually replace the Articles of the Interoperability Regulation (EU) 552/2004 that are still applicable by the time a new legal act enters into force or by 12 September 2023 at the latest. Having noted the document 'Application of Conformity Assessment to EATMN systems for the use of meteorological information' presented by the SES Framework Unit on the occasion of the 18th meeting of the Conformity Assessment Task Force (CATF#18) in March 2011, it is somewhat surprising that the amendments proposed therein to clarify and specify the applicable regulations seem to have been hardly or not at all taken into account in the preparation of the present proposal.

The interconnections between MET services and systems in the ATM/ANS environment, which were already pointed out in the report, were not taken into account. On the contrary, the formulations, which were already identified as too vague at that time and clarification was proposed and provided, were softened even further and therefore offer even more scope for different interpretations and inhomogeneous implementations.

Throughout the NPA, it is repeatedly emphasised that the proposed requirements for the various levels of system attestations (from the statement of conformity to certification) are intended to serve an equal market environment (*ref. 2.1; 2.2; 2.3; 2.4; 4.1; 4.5; 4.6*). From the point of view of MET Service Providers, however, it should be noted that the MET systems used are often not available on the market and must therefore either be adapted externally or even developed internally. In these cases, it must be taken into account that neither small system providers nor MET service providers have the necessary financial or manpower resources to initiate potentially necessary attestation processes. This would not lead to a 'level playing field' but on the contrary to a market distortion to devastate small and medium-sized enterprises and all those MET service providers developing and producing their own, cost-efficient systems providing fully compliant MET services for aviation.

There is a feeling that the proposed regulation might be used by some systems providers to exert a dominant position in the market. From the point of view of MET Service Providers, it must be noted and emphasised that many of the prescribed services could no longer be provided under such market conditions for the manufacturers, as often no such systems are

offered on the market and the MET market itself is rather small and unable to cope with the expenses that would become necessary under the proposed regulation. In all the explanations and specifically in the provided Impact Assessment in NPA chapter 4, there is no reference to the risk that certain services could no longer be provided at all due to a complete and utter lack of available certified and declared systems (equipment and/or constituents).

The fact that any kind of technical attestation - no matter which tier - will become applicable on top of the already existing certification requirements for service providers will have an impact on cost is also not addressed sufficiently. Even if EASA claims, that the certification and declaration processes are cost neutral from their perspective it would be naïve to believe the cost generated by such attestation requirements would not be cost recovered in one way or another and inevitably would lead to such systems being more expensive and therefore end up with increased costs of service provision. The issue of either establishing or refining the existing cost recovery system should be further discussed.

Noting at the same time that the added value for such certification or declaration for MET service provision is unclear, the proposed applicability also to MET Service Providers is seen not to reflect SES principles of proportionality and cost-efficiency.

The NPA repeatedly refers to 'safety relevance' in the explanatory text and to equipment used in the EATMN (*ref. 2.3.1.2; 2.3.1.3; 2.3.3; 4.3 ...*). This clear limitation cannot be found in the text of the different draft regulations (*ref. NPA Appendix 1 Article 2 Definitions; NPA Appendix 2 Article 4, 5 and 6; NPA Appendix 3 Article 1*). In this respect, it should be noted that MET systems and equipment are used to supply services – among others – to the EATMN and according to existing GM2 ATM/ANS.OR.B.005 these are more broadly associated with the quality of the service rather than the safety of the service. What is used in the EATMN from a MET perspective are MET services (data and information), but not equipment or systems.

The Basic Regulation (EU) 2018/1139 also states in Annex VIII chapter 3.1 that ATM/ANS systems and ATM/ANS constituents, including automatic or semi-automatic MET constituents providing by means of displays as part of a client-server system architecture information to ATCOs for activating ATS procedures (e.g. LVP procedures and AWO procedures), providing related information to and from the aircraft and on the ground are in the scope of the regulation. The key point here is that 'meteorological services' (*ref. CIR (EU) 2018/1139 Annex VIII – 3.1 (h)*) are not the provision of systems and constituents, but the provision of information and data. In this regard, the parlance used in CIR (EU) 552/2004 was clearer and left less room for interpretation.

With regard to the exchange of MET data and information, it has already been ensured for decades via internationally valid exchange mechanisms that the worldwide use of these services is guaranteed. Currently, the well-established exchange of OPMET data and services is being further developed through an internationally applicable exchange model (IWXXM) developed by ICAO together with WMO, and the replacement of the OPMET system is being prepared. Within the EU footprint, this transition has already been initialised with the publication of CIR (EU) 2021/116 and the development of SWIM services.

Due to the certification requirement concerning all ATM/ANS service providers already established by the EU - and here systems/equipment used are already subject to supervision by the national competent authority (CA) via the implementation of the Functional System - a

further level of attestation is to be classified as superfluous and will most probably only result in additional workload and unjustifiable additional costs without any demonstrable positive influence on flight safety.

Based on the accompanying text and the explanations contained therein, it seems quite obvious that from the perspective of the MET service provision and with regard to the statement above, only the lowest level of attestation requirements – if any – would be applicable. However, this supposed clarity is no longer to be found in the text and paragraphs of the proposed regulations in chapter 8 – Appendices of the NPA. The current text opens the gates for different interpretations and therefore inevitably will result in non-homogeneous transposition and thus contradicts the fundamental principles of the European legislature. From a MET Service Providers perspective, instead of waiting for an envisaged publication of AMC and GM it should be preferable a clear declaration based on the examples already presented in the explanations (*ref. 2.3.1.2 and 4.3 Table 2 Option 1*) is required.

response

*Accepted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

Indeed, the draft framework 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. In this context, the MET equipment is proposed to be subject to the SoC; thus, no reorganisation of the MET equipment market is anticipated.

For further details, please refer to topics ‘Categorisation of ATM/ANS equipment subject to conformity assessment’ and ‘Roles and responsibilities of the different actors’.

comment

1189

comment by: IAA ANSP

**What contingency arrangements (if any) will be put in place should demand exceed supply as a result of a more limited number of suppliers in the market?**

response

*Noted*

In order to complement the general CRD topic on ‘Market access’, EASA wishes to add that it is seen very unlikely that the new framework would create a market development in which the ATM equipment demand would exceed the supply capacity. In case of very specific, possibly unique tailored ATM solution, the Basic Regulation framework provides certain flexibility provisions which could be used; for example, in a situation in which the DPO

responsibilities (in case of lack of an approved supplier) must be fulfilled by an exemption solution.

### 1.3. The next steps

p. 5

comment

147

comment by: COULON FR SAA

As general comment and questions :

- is the purpose to position EASA as the certification authority for military services/systems?

- if not, military entities must be identified and legally recognised as certification authorities.

- military services and systems shall not necessarily abide by civil ATM guides for the design and production of ATM/ATS equipments, thus a certification and demonstration compliance to civil authorities will be impossible

- much sensitive matters about confidentiality of military equipments and the audit of the industrials suggested by this paper

- not the purpose of this 1st subtask, but the framework strongly suggest a new repartition of the responsibilities between EU and national level, this, as usual, put legitimate concerns on the table.

response

*Noted*

The commented proposal put forward a framework in a form of delegated and implemented acts established on the principle of the EASA Basic Regulation (EU) 2018/1139, i.e. it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military.

In addition, in accordance with Article 1(2) of the framework Regulation (EC) No 549/2004, the regulatory framework for the creation of the single European sky does not cover State aircraft (including military, customs and police aircraft) during operations and training.

Furthermore, air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military, should be excluded from the scope of this Regulation. However, Member States should ensure when opened to the public, and such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 applies, they offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for ATM/ANS.

comment

155

comment by: DSNA

*for the purpose of certification and demonstration of compliance in terms of safety, interoperability , and performance.*

Comment: Security is not mentioned.

Proposal: In addition to the respective national laws, it would be relevant to have a basic set of common requirements to address the security challenge, in particular in the environment of ATM centralized architectures, virtual centers and air/sol communications.

response

*Accepted*

EASA shares this concern and can confirm that the Part-IS regulation, establishing the requirements for aviation organisations in terms of information security, will be applicable to both ANSPs and DPOs.

Also, in this sense EASA has proposed that cybersecurity elements will also be included in the detailed specifications at the level of product requirements. For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

205

comment by: CANSO

For the purpose of certification and demonstration of compliance in terms of safety, interoperability, and performance.

Comment: Security is not mentioned.

Proposal: In addition to the respective national laws, it would be relevant to have a basic set of common requirements to address the security challenge, in particular in the environment of ATM centralized architectures, virtual centers and air/sol communications.

response

*Accepted*

EASA shares this concern and can confirm that the Part-IS regulation, establishing the requirements for aviation organisations in terms of information security, will be applicable to both ANSPs and DPOs.

Also, in this sense EASA has proposed that cybersecurity elements will also be included in the detailed specifications at the level of product requirements.

For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

234

comment by: *Indra Navia*

It is difficult to address the NPA as it is on a generic level, whilst all AMC and GM is still missing. Will there also be a hearing on AMC and GM? There needs to be a defined duration of transitional period also after the AMC and GM has been issued. If the AMC and GM for a particular type of equipment is issued towards the end of the five year period, there is not a reasonable period available for the industry to adapt and apply.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, as stated in Opinion No 01/2023, during the committee procedure for the adoption of the proposed implementing and delegated acts, EASA will continue the work preparing the issue of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specifications (DSs), which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DSs will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

Furthermore, EASA also shares the view regarding the need for inclusiveness of the ATM stakeholder community in large.

In this context,

- the answer is affirmative as regards the hearing on AMC and GM.
- The answer is affirmative, that a defined duration of transitional period for the AMC/GM/DS could be also considered.

comment

837

comment by: *ENAV*

For the purpose of certification and demonstration of compliance in terms of safety, interoperability, and performance.

Comment: Security is not mentioned.

Proposal: In addition to the respective national laws, it would be relevant to have a basic set of common requirements to address the security challenge, in particular in the environment of ATM centralized architectures, virtual centers and air/sol communications.

response

*Accepted*



EASA shares this concern and can confirm that the Part-IS regulation, establishing the requirements for aviation organisations in terms of information security, will be applicable to both ANSPs and DPOs.

Also, in this sense EASA has proposed that cybersecurity elements will also be included in the detailed specifications at the level of product requirements.

For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

907

comment by: AESA

The third paragraph in page 5 states: "[...] 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. [...]".

In page 15 it is stated: "Where certification or declaration is required, this will be based on the demonstration of compliance with the relevant detailed certification/declaration specifications [...]".

Is there going to be something similar to CSs/DSs for equipment subject to SoC?

response

*Noted.*

The answer is affirmative that detailed specifications will be available for all three attestation methods including the Statement of Compliance.

## 2. In summary - why and what

p. 6

comment

152

comment by: COULON FR SAA

- who will decide the criticality level and benefits for military equipments? the missions and the objectives are not at all the same as civils.

response

*Noted*

The commented proposal put forward a framework in a form of delegated and implemented acts established on the principle of the EASA Basic Regulation (EU) 2018/1139, i.e. it does not

apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military.

In addition, in accordance with Article 1(2) of the framework Regulation (EC) No 549/2004, the regulatory framework for the creation of the single European sky does not cover State aircraft (including military, customs and police aircraft) during operations and training.

Furthermore, air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military, should be excluded from the scope of this Regulation. However, Member States should ensure when opened to the public, and such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 applies, they offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for ATM/ANS.

comment 245

comment by: *Indra Navia*

Clarification regarding new/innovative types of functions and equipment types for which AMC and GM will not be developed. Will it be possible to issue DoC/DSU for new types of equipment, even if they can affect safety? The way the NPA is formed, it seems that there will be a higher threshold for entering into the market with new types of equipment, as the NPA can be interpreted to say that EASA must develop AMC and GM for all types of safety-related equipment, and equipment that could have some type of interoperability impact, before an application/declaration can be issued. This may make it more difficult to enter into the market with new and innovative concepts.

response *Noted*

In addition to the topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability', please refer also to topic 'Market access'.

Please acknowledge also that the proposal contemplates ways of addressing specifically new types of equipment for which the available specifications would not be adequate; see ATM/ANS.EQMT.AR.C.005 Special conditions.

comment 258

comment by: *CANSO*

In this section and in section 4.5.1 it is stated that attestation should be based on (or is at least related to) safety criticality, but in section 8.1 – 8.3 (appendices with draft regulation) there are no requirements describing how safety criticality should be addressed. Where will safety criticality be produced, and by whom? How should safety criticality be used in relation to attestation? As a criteria to select Design and Production Organisations (DPOs) or systems to attest? As input to producing specific requirements in specifications?

response

*Noted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

comment

310

comment by: *Nils PALMQVIST*

In this section and in section 4.5.1 it is stated that attestation should be based on (or is at least related to) safety criticality, but in section 8.1 – 8.3 (appendices with draft regulation) there are no requirements describing how safety criticality should be addressed. Where will safety criticality be produced, and by whom? How should safety criticality be used in relation to attestation? As a criteria to select Design and Production Organisations (DPOs) or systems to attest? As input to producing specific requirements in specifications?

response

*Noted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

comment

536

comment by: *Copenhagen Airports*

What is the definition of "airborne". Does that mean "during flight" or does it mean "in the airplane"?

Phrase "excluding airborne constituents" is used, but what about other "mobiles" such as VLT/vehicles?

response

*Noted*

According to Article 3(7) of Regulation (EU) 2018/1139, 'ATM/ANS system' means the aggregation of airborne and ground-based constituents, as well as space-based equipment, that provides support for air navigation services for all phases of flight.

In this context, airborne constituents are excluded from the scope of the proposal.

comment 569

comment by: NATS

Paragraph 5

If ANSPs are expected to rely on these certifications, is EASA and/or the manufacturer taking on any liability for the safety of the service / incidents where a certified system contributed?

response *Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment 838

comment by: ENAV

In this section and in section 4.5.1 it is stated that attestation should be based on (or is at least related to) safety criticality, but in section 8.1 – 8.3 (appendices with draft regulation) there are no requirements describing how safety criticality should be addressed. Where will safety criticality be produced, and by whom? How should safety criticality be used in relation to attestation? As a criteria to select Design and Production Organisations (DPOs) or systems to attest? As input to producing specific requirements in specifications?

response *Noted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

comment 1115

comment by: DSNA

*The 2019 Report of the Wise Persons Group on the Future of the Single European Sky<sup>8</sup> 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)".*

comment: Service providers of satellite-based augmentation systems are considered as CNS providers within the scope of Regulation (EU) 2017/373, hence are duly certified. For EGNOS, the service provider has been certified and is overseen by EASA (cf. GM1 ATS.OR.525(b)). By generalization, Pan-european CNS services provide an efficient way to harmonize and avoid scattering of systems around EU. Nothing in the NPA par2 consider these specific services (and equipment) in particular.

proposal: Contribution of EGNOS or other pan-EU CNS services to interoperability & cost-efficiency for SES should be identified clearly in the NPA and draft regulation.

response *Noted*

The Agency agrees with the comment. CNS services are indeed within the scope of the proposed framework, regardless of whether they are based on traditional ground-based equipment or they are satellite-based services and hence of pan-European nature and subject to EASA's oversight.

The comment is considered in the Opinion, including when it comes to the specific nature of the EGNOS-based services.

comment *1147*

comment by: *EUMETNET*

Throughout the NPA, it is repeatedly emphasised that the proposed requirements for the various levels of system attestations (from the statement of conformity to certification) are intended to serve an equal market environment (*ref. 2.1; 2.2; 2.3; 2.4; 4.1; 4.5; 4.6*). From the point of view of MET Service Providers, however, it should be noted that the MET systems used are often not available on the market and must therefore either be adapted externally or even developed internally. In these cases, it must be taken into account that neither small system providers nor MET service providers have the necessary financial or manpower resources to initiate potentially necessary attestation processes. This would not lead to a 'level playing field' but on the contrary to a market distortion to devastate small and medium-sized enterprises and all those MET service providers developing and producing their own, cost-efficient systems providing fully compliant MET services for aviation.

response *Accepted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

**IATA Response on EASA NPA 2022-09 regulatory framework on the conformity assessment of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment)****General Comments**

IATA Welcomes the opportunity to comment on this NPA. Although not directly affected, airspace users are concerned by the indirect consequences this NPA could produce and may impact on the wider development and implementation of ATM/ANS equipment in Europe.

- In terms of scope, the systems and constituents subject to certification should be defined in a more prescriptive manner.
- The objective and intended benefit of this NPA/Regulation should be focused on increasing flexibility and interoperability by introducing certified standards. To that end, it should also promote a significant level of cost efficiency within the ATM equipment market. We note that the Economic impact assessment is not sufficiently justified with numerical examples. The fact that stakeholders are encouraged to provide data for quantification reveals the evaluation presented is not sufficiently supported by data.
- As airlines may be impacted by OEM/ANSP's passing these costs to Airspace users through ATC Charges. IATA request that further evidence and financial impacts are provided to understand the true scale and to assess if the potential costs associated are balanced with similarly with the potential benefits. We are also concerned for the potential impact that the regulation could have on the existing investment plans of the ANSPs: more expensive systems, and more effort from ANSPs, which could decide to involve a significant increase number of FTEs to adapt to the new regulatory situation, with the consequent increases of ANS determined unit costs and ANS charges.
- On associated transition periods it is not clear why ANSPs should become a certification authority in the interim, especially for systems or elements that require certificates or acceptance of declarations (whose criticality is higher and therefore they should not be addressed by statements of compliance). Should not this role be performed by NSAs during transition? Similarly, what if an ANSP has previously developed and implemented their own system and or their own software? How would this be covered under the certification, attestation process?
- We also identify as a potential concern that not putting the appropriate measures limiting for a transition phase this new regulation, could bring a slowdown of new ATM modernization solutions, impacting the effective deployment of ATM digitalization solutions mandated in CP1, as well as other initiatives from the Airspace Architecture Study.
- This NPA should not hinder continuous modernization or development of existing systems and shall continue to allow for focused and agile development. Elements associated with other EU Single European Sky regulations (E.G CP1, PBNIR) should be prioritized. Impeding the development cycle or impacting the time to market would be a significant consequence and must be avoided. The criteria on

which a system or constituent requires certification/declaration/statement of compliance are not entirely clear. Further detailed information is requested

- Interoperability and synchronization with ICAO developments and other regions must be prioritized and standards associated must be developed accordingly. To enable a competitive market the Certification needs to be limited to pan-European systems and the definition must be sufficiently clear as to avoid any ambiguity. Equally many systems utilize components manufactured outside Europe ( E.G, Microchips, Processors) it is unclear how this NPA/Regulation would affect these aspects. Further clarification is required
- With regard to market competition and global interoperability: the regulation should establish in a clearer manner whether non-EU manufacturers of systems and constituents. ANSPs systems and constituents connected to EATMN frequently depend on non-EU suppliers as SW developers. The regulation should be more explicit in the sense that what will be required for those overseas suppliers. The new regulation should not prevent the entry of non-EU technologies. Airlines need the best, the safest, the most secured, the most competitive technological solutions, globally interoperable, and regardless of the country of origin.
- The NPA appears to indicate that routine maintenance is traditionally carried out by ANSPs themselves. This in fact could be outsourced, or subject to contractual obligations with manufacturers through Service level agreements. Consideration should be given to competition and potential costs reductions by delivering attestations to contractors for maintenance purposes
- Clarification is requested on the following statement *“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.”* IATA understand the intention of the NPA/Regulation is that certification and declarations would come from EASA, precisely to avoid a national approach with respect to certification and declaration. However, the statement appears to indicate the opposite.
- Regarding the new certification and oversight scheme to be put into practice in Europe, more definition should be provided about how the certification and continuing oversight coordination mechanisms and the working interfaces between EASA will be and NSAs, especially when technologies of one EU State are deployed in another EU State. Who is overseeing what and when, should be defined clearer? Hence, oversight processes should be optimized in the new framework, therefore the new regulation should not bring additional complexities to the existing interfaces.

response

*Noted*

Following the order of the comments:

- Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.
- Please refer to topic ‘Impact assessment’, especially ‘Certification costs and impacts on the market’.

- Please refer to topic ‘Impact assessment’, especially ‘Level playing field and benefits’ and ‘Certification costs and impacts on the market’.
- It should be noted that the competent authority responsible for the oversight of the statements of compliance issued by an ATM/ANS provider 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, i.e. during the transition period the competent authority responsible for the certification and oversight of the ATM/ANS provider would be the responsible authority. For further details, please refer to topic ‘Transitional provisions’.
- The comment is noted. The commenter is kindly invited to consider providing further details and justification on the statement.
- The Agency concurs with the comment and considers that the proposal provides flexibility to achieve the objectives mentioned. For further details, please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.
- Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.
- Taking into account the comment, the text of the delegated act is amended; please refer to Article 7. For further details, please refer to topic ‘Access to the market’.
- The proposed framework would not change this set-up; point ATM/ANS.OR.B.015 of Regulation (EU) 2017/373 would continue to apply.
- Please refer to topics ‘Roles and responsibilities of the different actors’ and ‘Access to the market’.
- The comment is duly considered.

comment

1182

comment by: *Deutscher Wetterdienst*

See 2018/1139 Art. 35 and Annex VII (1.3) - whereas it is still to be clarified whether or not MET equipment might be considered safety-related aerodrome equipment in that context. Also (EU) 139/2014. Since safety-critical equipment is subject to certification rather than declaration it should be further defined by specs and reqs.

response

*Noted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU)



2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1193

comment by: *FerroNATS*

Inconsistency with EU.2017/373 in terms of "safety criticality"

response

*Noted*

The categorisation of the equipment is based on the nature and risk of the activities supported/enabled by such equipment. This is not exclusively based on safety criticality. The text of the Opinion will be made more consistent, avoiding references to safety criticality, which might be imprecise.

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

p. 7

comment

154

comment by: *COULON FR SAA*

Procurements of equipment for french military abide by the procurement legal framework CAC Armement/les marchés de la défense, so not completely to the EU procurements. FR MOD can not abide by a procurement legal framework external to the FR MOD.

response

*Noted*

comment

156

comment by: *COULON FR SAA*

this means that military ATM equipments will abide (or not) by the IR certif ATM/ATS at the same level as for the IOP and Basic Regulation

response

*Noted*

The proposal establishes the framework on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e. it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military. In addition, in accordance with Article 1(2) of the framework Regulation (EC) No 549/2004,

the regulatory framework for the creation of the single European sky does not cover State aircraft (including military, customs and police aircraft) during operations and training.

However, Member States should ensure, in accordance with their national law, that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 applies, they offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements.

comment

199

comment by: *CANSO*

2.1. Why we need to propose new implementing and delegated acts — issue/rationale - page 7

How to mitigate the risk of monopoly positions and/or business cartel by the manufacturers which could cause systems quality decay and possible increase in costs?

response

*Noted*

Please refer to topic 'Impact assessment', especially topic 'Level playing field and benefits'.

comment

235

comment by: *Indra Navia*

Regarding the paragraph "It shall be noted that the implementation of Article 4 'Certification of ATM/ANS equipment' and Article 5 'Declaration of ATM/ANS equipment' ...". It is our understanding that also AMC and GM for approvals of DPOs will be issued. Please confirm.

response

*Noted*

The answer is affirmative.

comment

249

comment by: *Romanian CAA*

RO would appreciate further clarification with respect to the reasons and criteria that were envisaged by EASA when determining the need for an Implementing or a Delegated Act, more specifically what were the criteria that were used in determining the need for a delegated act to lay 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.

In our view, the provisions laid down in the proposed draft delegated act are of the nature of an implementing act as they refer to specific elements of R 1139 which are essential for the safety of civil aviation and have the purpose to further detail the contents of art. 46 of R 1139

in order to ensure a uniform implementation. Also, we can refer in our analysis to the legal nature of R 552/2004, which is in essence replaced by the proposed regulation and maintain the equivalent level of the act.

Furthermore, we appreciate that such an act should have the nature of an implementing act and be subject the comitology process, even though this could slower the adoption process of the act.

response *Noted*

For ATM/ANS systems and ATM/ANS constituents, the Commission is empowered under Article 47(1) of Regulation (EU) 2018/1139 to adopt delegated acts, in accordance with Article 128 of the same Regulation, laying down detailed rules with regard to:

- the conditions for establishing and notifying to an applicant the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents for the purposes of certification in accordance with Article 45(2) of the same Regulation;
- the conditions for issuing, maintaining, amending, limiting, suspending or revoking the certificates referred to in Article 45(2) of Regulation (EU) 2018/1139, and for the situations in which, with a view to achieving the objectives set out in Article 1 and while taking account of the nature and risk of the particular activity concerned, such certificates are to be required or declarations are to be permitted, as applicable;
- the privileges and responsibilities of the holders of certificates referred to in Article 45(2) of Regulation (EU) 2018/1139;
- the privileges and responsibilities of the organisations issuing declarations in accordance with Article 45(1) and (2) of Regulation (EU) 2018/1139;
- the conditions and procedures for the declaration by ATM/ANS providers, in accordance with Article 45(1) of Regulation (EU) 2018/1139, and for the situations in which, with a view to achieving the objectives set out in Article 1 and while taking account of the nature and risk of the particular activity concerned such declarations are to be required; and
- the conditions for establishing the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents which are subject to a declaration in accordance with Article 45(1) and (2) of Regulation (EU) 2018/1139.

comment 508

comment by: *Deutscher Wetterdienst*

It should be noted that the MET systems used are often not available on the market and must therefore either be adapted externally or even developed internally.

In these cases, it must be considered that neither small system providers nor MET service providers have the necessary financial or human resources to initiate proposed necessary certification processes. This would not lead to a 'level playing field' but on the contrary to a market distortion to devastate small and medium-sized enterprises and all those MET service providers developing and producing their own, cost-efficient systems providing fully compliant MET services for aviation.

response

*Accepted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

Indeed, the draft framework 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. In this context, the MET equipment is proposed to be subject to the SoC; thus, no reorganisation of the MET equipment market is anticipated.

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment', 'Roles and responsibilities of the different actors' and 'Access to the market'.

comment

522

comment by: *NATS*

Paragraph 4

What specifications are being referred to here? Each ANSP would typically have requirements which go beyond the available technical specifications, which are considered essential for a product to work within the ANSP's wider system context; having a product certified won't change/reduce this.

We can see how developing one system for all ANSPs would make manufacturers' life easier, but conversely, trying to force ANSPs to use COTS equipment with no customisation for their environment would potentially slow down the integration and deployment of systems... although this could lead to an end state where all ANSPs have the "same" system this is not currently where the industry is at, and trying to force it could be expensive.

response

*Noted*

The proposal would not impact the procurement by the ANSP of a 'tailor-made' product.

An ATM/ANS provider (or consortium) could develop the user requirements/specifications. The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of regulation (EU) 2017/1139) and contractual requirements (user requirements).

For further detail, please refer to topic 'Roles and responsibilities of the different actors'.

comment

537

comment by: *Copenhagen Airports*

Will it be possible to adapt a standardized/Type-certified system/constituent to fit requirements currently implemented in non-certified systems? How much will it be possible to adapt to individual needs?

response

*Noted*

The proposal would not impact the procurement of a 'tailor-made' product on the basis of user requirements/specifications.

The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of regulation (EU) 2017/1139) and contractual requirements (user requirements).

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

538

comment by: *Copenhagen Airports*

Will standardization and certification include "enabling technologies/components" such as Network components and Computing platforms (cloud, virtualization etc.)? If so (or not), please specify why, as this is a recurring discussion for us as an ANSP and should be clarified in the regulation, as it could have benefits to harmonize these areas.

response

*Noted*

It is acknowledged that when developing detailed specifications, the description of ATM/ANS equipment should remain as far as possible at the functional level without 'overprescribing' the technical solution.

In this regard, when developing the DSs, a differentiation should be made between different type of elements (which might be present in the different types of technical systems and constituents), e.g.: sensors (HW+SW); Network (Physical+Service); Hosting Infrastructure (Physical+Service); Data Processing (SW Application); HMI.

Some of these elements are understood to be more approachable in terms of requirements for certification or declaration (i.e. sensors, data processing SW applications, HMI), while others (i.e. network elements and hosting infrastructure) might be partially detached from the design of the system/constituent, and open to different approaches (e.g. physical HW or external service).

comment

539

comment by: *Copenhagen Airports*

Will standardization/certification handle HMI constituents such as computermonitors, keyboards, KVM-switches and other COTS components?

response

*Noted*

The comment is noted.

When the DSs are developed, it is expected that an architecture design, comprising software and hardware, is regarded in so far as it supports the required ATM-related functions, but that typical common IT services equipment is not considered within the scope.

comment

744

comment by: *POL CAA LOZ-4*

According to POL CAA/LOŽ-1, the responsibility for ensuring compliance with all requirements was equally shared between the manufacturer and the implementer, and now the burden is perhaps to be shifted to EASA/CAA in the sense that in addition to certifying ATM/ANS design organizations, there will still be an obligation to approve sf changes involving the implementation of new ATM/ANS systems/component.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

839

comment by: *ENAV*

2.1. Why we need to propose new implementing anddelegated acts — issue/rationale - page 7

How to mitigate the risk of monopoly positions and/or business cartel by the manufacturers which could causesystems quality decay and possible increase in costs?

response

*Noted*

Please refer to topic 'Impact assessment', especially topic 'Level playing field and benefits'.

comment

1120

comment by: *DSNA*

*"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."*

comment: For pan-european CNS services such as EGNOS, EASA only is in charge of certification of the service, and thus of the equipment, setting a very clear and unambiguous oversight framework.

Proposal: consider adding a note to exclude pan-EU space CNS services such as EGNOS or future ones that might be created in the frame of the Union Secure Connectivity proposed by DG DEFIS, given the explicit EASA role in certification of the service.

response

*Noted*

The Agency has assessed the specific nature of the EGNOS-based aviation CNS services, provided in the frame of the EU Space Programme. It has been concluded that the conformity assessment of the EGNOS system might require specific arrangements that would include coordination between the Agency and the European Agency for Space Programmes (EUSPA).

No specific provisions have been reflected in Opinion No 01/2023, but the work will continue during the committee procedure to reflect these particularities in the regulatory package.

## 2.2. What we want to achieve - objectives

p. 8

comment

259

comment by: *CANSO*

In both sections 2.2 and 2.3.1 it is stated that one purpose of the NPA is to ensure or contribute to safety. When it comes to creating safety in practical terms CANSO are very content with the governance provided in EU 2017/373, which is (and should be) a complete regulation when it comes to all issues like Safety Management Systems, occurrence reporting, Safety Assessment of changes etc. It seems like NPA 2022-09 does not contain any regulation which would fit better in EU 2017/373, which is a good thing. Please make sure that NPA 2022-09 does not introduce regulation regarding safety which could come in conflict with, or be redundant to EU 2017/373. The current requirements related to safety in for instance DPO.OR.A.035, ATM/ANS.EQMT.AR.A.025, ATM/ANS.EQMT.AR.A.030 and ATM/ANS.EQMT.AR.A.045 seem to address safety in a good way (reacting to safety issues of different sorts) which is not conflicting with EU 2017/373.

response

*Accepted*

The comment is duly considered in the Opinion.

comment

260

comment by: *CANSO*

Regarding ensuring and contributing to safety it is of course necessary to "create" safety in ATS equipment through safety requirements in accordance with a Safety Assessment process compliant with EU 2017/373. But how will such safety requirements be developed when the Agency are responsible for the detailed specification?

An ANSP can only accept safety which has been "created" in accordance with EU 2017/373, but how will the Agency address the Safety Assessment part? The NPA lacks details on how the Agency should interact with primarily ANSPs in order to get information on what ANSPs identifies as hazards, safety criticality and safety requirements. There is also no information how the Agency should work in order to comply with EU 2017/373, or facilitate ANSPs' compliance, regarding either Safety Assessment or Safety Support Assessment

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

261

comment by: *CANSO*

This is a general comment focusing on economic aspects. In the bullet list several objectives are listed, but the main objective is of course the reduction of costs. The purpose of all the other objectives is really to support reducing costs. This is a fine and much needed objective, but as an ANSP must question how realistic this objective is for different types of systems. ANSPs will readily admit that it is possible to reduce costs with the approach presented in the NPA, but maybe not for all ATM/ANS equipment intended. For systems like ARTAS and SDDS (Surveillance Data Distribution System) costs are probably reduced thanks to the centralised approach, where EUROCONTROL are responsible for managing the development. However, in general there are several factors which can increase costs instead.

**1.** For systems and functions with a high level of interaction between the users (mainly ATCOs) and the equipment it will be very difficult for a "third party" organisation like the Agency to develop a specification. For systems and functions like Flight Plan Processing, MTCD, sequencing etc. specification development is already difficult for a single ANSP, even more complex for a collaboration with several ANSPs, like COOPANS, and when a specification shall satisfy many ANSPs all over Europe it is difficult to see that a specification can be good enough. Also, every ANSP has their specific needs due to cultural differences in the work place, national regulations and prerequisites, other equipment to be harmonized with and more. There will be a high probability that ANSPs will need further development before ATM/ANS equipment can be put into operation.



**2.** Considering the difficulties in centralising the development of specifications it is also likely the time before new or upgraded ATM/ANS equipment can be taken into operation will increase dramatically. A lengthier development process will in itself increase the costs due to more coordination, reviews, rework etc. But there is also an increase in cost due to ANSPs having to wait longer for new functions, if improvements which aim to reduce costs with an ANSP cannot be implemented as planned.

**3.** Apart from complexity of specification, development and verification and validation the time to operation can increase due to difficulties for the Agency to find and keep the needed competent staff. It is not easy to build up such an ambitious organisation as is indicated in the intended regulation, but it is also a matter of keeping the staff over time. As ANSPs we will be dependent on an external organisation for much of the development of key equipment. A problem with staffing at the Agency will affect many ANSPs.

**4.** ATM/ANS equipment, especially highly specialised systems which have very dynamic interactions with operational staff, would be very difficult to verify and validate in a relevant way by a central organisation like the Agency. In order to take a new or upgraded system into operation it is very likely that an ANSP will still have to perform their own verification and validation the same way as today, which can be quite extensive. If the verification and validation activities by the Agency cannot replace verification and validation by ANSPs it will drive up costs.

**5.** In case ANSPs are already content with the quality and pricing of a certain ATM/ANS equipment a choice of the Agency to certify such a system will increase the costs related to this equipment. It takes time and resources to reorganise the development process, and all these costs will be put on the customers in the end.

**6.** A simplified summary of the attestation (apart from statements of compliance) is basically that the Agency certifies DPOs, the Agency produces a specification for an ATM/ANS equipment, the Agency issues an ATM/ANS equipment certificate if the DPOs fulfil the specification, and the DPOs issues a declaration of design compliance. This is quite different from the customer supplier relationship which is an essential component in creating economic efficiency in an economy based on competition in free markets. If there is too little involvement of real customers (ANSPs) in the development of these ATM/ANS equipment there is a high risk that these equipment cannot be used operationally without further development, which in turn will drive up costs. Unless it is ensured that real users are involved, the economic benefits and necessary quality of certified systems will most likely not be achieved.

**7.** It is most likely that DPOs will use the added activities with attestation as an excuse to increase prices.

**8.** If an organisation approval is required for DPOs to be involved in the design and/or production of ATM/ANS equipment there is a risk that the number of companies in the market will be reduced. Attestation can be an obstacle for new or small DPOs to compete for contracts, and the large DPOs will control the market even more. The larger DPOs might also limit the development to keep the number down of certificates they need to hold and renew.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that the most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Impact assessment’, in particular ‘Certification costs and impacts on the market’.
- ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’;
- ‘Access to the market’.

In case CANSO sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between CANSO and the Agency, or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

311

comment by: *Nils PALMQVIST*

In both sections 2.2 and 2.3.1 it is stated that one purpose of the NPA is to ensure or contribute to safety. When it comes to creating safety in practical terms LFV are very content with the governance provided in EU 2017/373, which is (and should be) a complete regulation when it comes to all issues like Safety Management Systems, occurrence reporting, Safety Assessment of changes etc. It seems like NPA 2022-09 does not contain any regulation which would fit better in EU 2017/373, which is a good thing. Please make sure that NPA 2022-09 does not introduce regulation regarding safety which could come in conflict with, or be redundant to EU 2017/373. The current requirements related to safety in for instance DPO.OR.A.035, ATM/ANS.EQMT.AR.A.025, ATM/ANS.EQMT.AR.A.030 and ATM/ANS.EQMT.AR.A.045 seem to address safety in a good way (reacting to safety issues of different sorts) which is not conflicting with EU 2017/373.

response

*Accepted*

The comment is duly considered in the Opinion.

comment

312

comment by: *Nils PALMQVIST*

Regarding ensuring and contributing to safety it is of course necessary to “create” safety in ATS equipment through safety requirements in accordance with a Safety Assessment process compliant with EU 2017/373. But how will such safety requirements be developed when the Agency are responsible for the detailed specification? As an ANSP LFV can only accept safety which has been “created” in accordance with EU 2017/373, but how will the Agency address the Safety Assessment part? The NPA lacks details on how the Agency should interact with primarily ANSPs in order to get information on what ANSPs identifies as for instance hazards,

safety criticality and safety requirements. There is also no information how the Agency should work in order to comply with EU 2017/373, or facilitate ANSPs' compliance, regarding either Safety Assessment or Safety Support Assessment.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

313

comment by: *Nils PALMQVIST*

This is a general comment focusing on economic aspects. In the bullet list several objectives are listed, but the main objective is of course the reduction of costs. The purpose of all the other objectives is really to support reducing costs. This is a fine and much needed objective, but as an ANSP LFV must question how realistic this objective is for different types of systems. LFV will readily admit that it is possible to reduce costs with the approach presented in the NPA, but maybe not for all ATM/ANS equipment intended. For systems like ARTAS and SDDS (Surveillance Data Distribution System) costs are probably reduced thanks to the centralised approach, where EUROCONTROL are responsible for managing the development. However, in general there are several factors which can increase costs instead.

**1.** For systems and functions with a high level of interaction between the users (mainly ATCOs) and the equipment it will be very difficult for a "third party" organisation like the Agency to develop a specification. For systems and functions like Flight Plan Processing, MTCD, sequencing etc. specification development is already difficult for a single ANSP, even more complex for a collaboration with several ANSPs, like COOPANS, and when a specification shall satisfy many ANSPs all over Europe it is difficult to see that a specification can be good enough. Also, every ANSP has their specific needs due to cultural differences in the work place, national regulations and prerequisites, other equipment to be harmonized with and more. There will be a high probability that ANSPs will need further development before ATM/ANS equipment can be put into operation.

**2.** Considering the difficulties in centralising the development of specifications it is also likely the time before new or upgraded ATM/ANS equipment can be take into operation will increase dramatically. A lengthier development process will in itself increase the costs due to more coordination, reviews, rework etc. But there is also an increase in cost due to ANSPs having to wait longer for new functions, if improvements which aim to reduce costs with an ANSP cannot be implemented as planned.

**3.** Apart from complexity of specification, development and verification and validation the time to operation can increase due to difficulties for the Agency to find and keep the needed competent staff. It is not easy to build up such an ambitious organisation as is indicated in the intended regulation, but it is also a matter of keeping the staff over time. As ANSPs we will be

dependent on an external organisation for much of the development of key equipment. A problem with staffing at the Agency will affect many ANSPs.

**4.** ATM/ANS equipment, especially highly specialised systems which have very dynamic interactions with operational staff, would be very difficult to verify and validate in a relevant way by a central organisation like the Agency. In order to take a new or upgraded system into operation it is very likely that an ANSP will still have to perform their own verification and validation the same way as today, which can be quite extensive. If the verification and validation activities by the Agency cannot replace verification and validation by ANSPs it will drive up costs.

**5.** In case ANSPs are already content with the quality and pricing of a certain ATM/ANS equipment a choice of the Agency to certify such a system will increase the costs related to this equipment. It takes time and resources to reorganise the development process, and all these costs will be put on the customers in the end.

**6.** A simplified summary of the attestation (apart from statements of compliance) is basically that the Agency certifies DPOs, the Agency produces a specification for an ATM/ANS equipment, the Agency issues an ATM/ANS equipment certificate if the DPOs fulfil the specification, and the DPOs issues a declaration of design compliance. This is quite different from the customer supplier relationship which is an essential component in creating economic efficiency in an economy based on competition in free markets. If there is too little involvement of real customers (ANSPs) in the development of these ATM/ANS equipment there is a high risk that these equipment cannot be used operationally without further development, which in turn will drive up costs. Unless it is ensured that real users are involved, the economic benefits and necessary quality of certified systems will most likely not be achieved.

**7.** It is most likely that DPOs will use the added activities with attestation as an excuse to increase prices.

**8.** If an organisation approval is required for DPOs to be involved in the design and/or production of ATM/ANS equipment there is a risk that the number of companies in the market will be reduced. Attestation can be an obstacle for new or small DPOs to compete for contracts, and the large DPOs will control the market even more. The larger DPOs might also limit the development to keep down the number of certificates they need to hold and renew.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that the most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Impact assessment’, in particular ‘Certification costs and impacts on the market’.
- ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’;

— 'Access to the market'.

In case CANSO sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

433

comment by: *Tern Systems*

**Fair competition is harmed and innovation hindered**

The NPA favours DPOs that can distribute the cost for approval and attestation over many customers and larger competitors that are already more experienced in regulated domains. As a result, the market will change (less DPOs overall) and competition will be reduced. This will likely hinder innovation and create monopolies in the future.

The assumption that EASA detailed specifications and guidance from EASA will in the long-term reduce design and production cost so much that these reductions cover the additional cost of attestation is not sufficiently demonstrated. Quite in contrast, considering how much equipment is adapted for different customers, we fear that we might have to obtain a certificate/ issue a declaration for each variant of the equipment delivered, that means, basically for each deployment - very much as the current EC-declaration approach - just way more expensive.

response

*Noted*

The comment is duly considered in the Opinion.

The concerns are addressed in topic 'Impact assessment', in particular topic 'Level playing field and benefits' and 'Proportionality'.

In response to the second comment, the proposal put forward a framework that certain ATM/ANS equipment should be subject of conformity assessment, establishing three different attestation instruments considering the nature and the risk of the operation or functionality enabled by the particular equipment. For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, a DPO approval is required in order for an organisation to be able to apply for the certification or to declare the design compliance of ATM/ANS equipment. This will be required only for a subset of functionalities supporting the provision of ATM/ANS services, and the organisation taking responsibility for the design and production compliance will need to be approved as DPO. Suppliers of a DPO will not need to be approved, but the integration/use of the subcontracted products and/or services to produce the ATM/ANS equipment will be under the control/management system of the approved DPO. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment 441

comment by: Tern Systems

**Claim of reduction of cost is not proven**

When justifying the cost of approval and certification for the DPO in this NPA, guidance from EASA to DPOs is promised. Also, EASA detailed specifications are named several times as a cost-reducing factor. However, it remains unclear what the guidance would entail and how detailed the EASA detailed specifications can be expected to be. With the currently available information it is hard to predict the long-term effect this has on development costs. It is unclear if the availability of detailed specifications counterweights the additional regularly reappearing approval and attestation costs that are likely higher than the current costs for declarations of constituent conformity or suitability for use. It is likely that equipment cost will increase permanently - relatively more for DPOs with fewer customers. In the end, this cost will be carried by the service providers (in the end the travellers).

For ATM/ANS providers, reduced testing and equipment verification activities are promised. But the service provider is and stays accountable for the service offered. Additionally, issues usually surface during the integration with equipment from other DPOs and the operational environment. ATM/ANS providers will still test the equipment to gain trust and experience with the equipment in its operational environment and to ensure the quality and safety of services provided. It is doubtful that those efforts will be reduced considerably.

response *Noted*

The comment is duly considered in the Opinion.

Please refer to topic 'Impact assessment', in particular 'Certification costs and impacts on the market' as well as 'Roles and responsibilities of the different actors'.

comment 443

comment by: Tern Systems

**Costs for service providers that are also DPOs increase**

Many ATM/ANS providers are DPOs themselves. Adding attestation costs to their costs will not decrease their costs as promised.

response *Noted*

The comment is duly considered in the Opinion.

Please refer to topic 'Impact assessment', in particular 'Certification costs and impacts on the market' as well as 'Roles and responsibilities of the different actors'.

comment 453

comment by: NAV Portugal E.P.E

Regarding the economic aspects, although there are several objectives listed, the main objective is cost reduction; the purpose of all the other listed objectives is, in fact, to support this cost reduction. Even though we generally support this objective, several other factors raise some questions on the ability to achieve cost reduction from the ANSPs perspective. Like many other ANSPs, NAV Portugal may also admit that it is possible to have some cost reduction with EASA's approach presented in the NPA, but maybe not for all ATM/ANS equipment intended. For systems like ARTAS and SDDS (Surveillance Data Distribution System), costs are probably reduced thanks to the centralised approach, where EUROCONTROL is responsible for managing the development. However, in general, there are several factors that can increase costs instead.

For systems and functions with a high level of interaction between the users (mainly ATCOs) and the equipment, it will be very difficult for a "third party" organisation like the Agency to develop a single specification. For systems and functions like Flight Plan Processing, MTCD, sequencing etc., specification development is already difficult for a single ANSP, even more complex with several ANSPs, like COOPANS, and when a specification has to satisfy more than one ANSP all over Europe it is difficult to see how a specification can fulfil everything. In addition, every ANSP has their specific needs (operational, cultural, and procedural) in the workplace, national regulations and prerequisites or other equipment to be harmonized. In conclusion, there will be a high probability that ANSPs will need further development before ATM/ANS equipment can be put into operation.

Considering all the difficulties in centralising the development of specifications, it is also likely that the time before new or upgraded ATM/ANS equipment can be take into operation will increase dramatically. A lengthier development process will in itself increase the costs. Additionally, there is also an increase in cost due to the fact that ANSPs will have to wait longer for new features, if improvements which aim to reduce costs with an ANSP cannot be implemented as planned.

response

*Noted*

The comment is duly considered in the Opinion.

Please refer to topic 'Impact assessment', in particular 'Certification costs and impacts on the market' as well as 'Roles and responsibilities of the different actors'.

comment

523

comment by: NATS

Most of the ERs are not about equipment; compliance can only be demonstrated by the ANSP, and the manufacturer contributes to this by complying with / implementing relevant standards (and declaring that these had been met).

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors' as well as to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment 524

comment by: *NATS*

2.2 Paragraph 2

We are not convinced it will ensure the relevant objectives are met ; this is currently done through the ANSP's Technical File, noting that the manufacturer cannot fully meet most of the ERs, and the ERs have a wider scope than the safety assessment required under EU 2017/373

response *Noted*

As the statement is not justified, the commenter is kindly invited to provide further details on the issue.

comment 543

comment by: *FOCA Switzerland*

Our experts are of the opinion that the efficiency benefits that are put forward in this chapter need to be further justified as it clearly seems that the certification (of the organisation and the systems) with the related fees to be paid will increase the cost for the manufacturers compared to the current system. The efficiency gains will depend of the number of systems that are certified and the number of their customers. If the number of systems are too high or/and the number of customers too low, we may then face a large increase of costs for ANSPs, contradicting the performance objectives mentioned in the different performance plans.

response *Noted*

Please refer to topic 'Impact assessment', especially 'Certification costs and impacts on the market'.

comment 570

comment by: *NATS*

Section 2.2

Bullet Point 2 - we see a risk that this proposal could reduce the number of suppliers.

response *Noted*

The proposed transitional period (5 years) caters initially for that risk.



The evolution of the market then should be observed in the frame of the monitoring of the effectiveness of the new framework.

The commenter is invited to further clarify why the new framework would negatively impact availability of alternative suppliers of equipment in the market, compared to the current framework.

comment

840

comment by: ENAV

In both sections 2.2 and 2.3.1 it is stated that one purpose of the NPA is to ensure or contribute to safety. When it comes to creating safety in practical terms ENAV is very content with the governance provided in EU 2017/373, which is (and should be) a complete regulation when it comes to all issues like Safety Management Systems, occurrence reporting, Safety Assessment of changes etc. It seems like NPA 2022-09 does not contain any regulation which would fit better in EU 2017/373, which is a good thing. Please make sure that NPA 2022-09 does not introduce regulation regarding safety which could come in conflict with, or be redundant to EU 2017/373. The current requirements related to safety in for instance DPO.OR.A.035, ATM/ANS.EQMT.AR.A.025, ATM/ANS.EQMT.AR.A.030 and ATM/ANS.EQMT.AR.A.045 seem to address safety in a good way (reacting to safety issues of different sorts) which is not conflicting with EU 2017/373.

response

*Accepted.*

The comment is well received and duly considered in the Opinion.

The regulatory text is amended to ensure consistency and avoid overlaps with other EU regulations.

comment

841

comment by: ENAV

Regarding ensuring and contributing to safety it is of course necessary to "create" safety in ATS equipment through safety requirements in accordance with a Safety Assessment process compliant with EU 2017/373. But how will such safety requirements be developed when the Agency are responsible for the detailed specification?

An ANSP can only accept safety which has been "created" in accordance with EU 2017/373, but how will the Agency address the Safety Assessment part? The NPA lacks details on how the Agency should interact with primarily ANSPs in order to get information on what ANSPs identifies as hazards, safety criticality and safety requirements. There is also no information how the Agency should work in order to comply with EU 2017/373, or facilitate ANSPs' compliance, regarding either Safety Assessment or Safety Support Assessment

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 842

comment by: ENAV

This is a general comment focusing on economic aspects. In the bullet list several objectives are listed, but the main objective is of course the reduction of costs. The purpose of all the other objectives is really to support reducing costs. This is a fine and much needed objective, but as an ANSP must question how realistic this objective is for different types of systems. ANSPs will readily admit that it is possible to reduce costs with the approach presented in the NPA, but maybe not for all ATM/ANS equipment intended. For systems like ARTAS and SDDS (Surveillance Data Distribution System) costs are probably reduced thanks to the centralised approach, where EUROCONTROL are responsible for managing the development. However, in general there are several factors which can increase costs instead.

**1.** For systems and functions with a high level of interaction between the users (mainly ATCOs) and the equipment it will be very difficult for a "third party" organisation like the Agency to develop a specification. For systems and functions like Flight Plan Processing, MTCO, sequencing etc. specification development is already difficult for a single ANSP, even more complex for a collaboration with several ANSPs, like COOPANS, and when a specification shall satisfy many ANSPs all over Europe it is difficult to see that a specification can be good enough. Also, every ANSP has their specific needs due to cultural differences in the work place, national regulations and prerequisites, other equipment to be harmonized with and more. There will be a high probability that ANSPs will need further development before ATM/ANS equipment can be put into operation.

Considering the difficulties in centralising the development of specifications it is also likely the time before new or upgraded ATM/ANS equipment can be taken into operation will increase dramatically. A lengthier development process will in itself increase the costs due to more coordination, reviews, rework etc. But there is also an increase in cost due to ANSPs having to wait longer for new functions, if improvements which aim to reduce costs with an ANSP cannot be implemented as planned.

Apart from complexity of specification, development and verification and validation the time to operation can increase due to difficulties for the Agency to find and keep the needed competent staff. It is not easy to build up such an ambitious organisation as is indicated in the intended regulation, but it is also a matter of keeping the staff over time. As ANSPs we will be dependent on an external organisation for much of the development of key equipment. A problem with staffing at the Agency will affect many ANSPs.

ATM/ANS equipment, especially highly specialised systems which have very dynamic interactions with operational staff, would be very difficult to verify and validate in a relevant

way by a central organisation like the Agency. In order to take a new or upgraded system into operation it is very likely that an ANSP will still have to perform their own verification and validation the same way as today, which can be quite extensive. If the verification and validation activities by the Agency cannot replace verification and validation by ANSPs it will drive up costs.

5. In case ANSPs are already content with the quality and pricing of a certain ATM/ANS equipment a choice of the Agency to certify such a system will increase the costs related to this equipment. It takes time and resources to reorganise the development process, and all these costs will be put on the customers in the end.

6. A simplified summary of the attestation (apart from statements of compliance) is basically that the Agency certifies DPOs, the Agency produces a specification for an ATM/ANS equipment, the Agency issues an ATM/ANS equipment certificate if the DPOs fulfil the specification, and the DPOs issues a declaration of design compliance. This is quite different from the customer supplier relationship which is an essential component in creating economic efficiency in an economy based on competition in free markets. If there is too little involvement of real customers (ANSPs) in the development of these ATM/ANS equipment there is a high risk that these equipment cannot be used operationally without further development, which in turn will drive up costs. Unless it is ensured that real users are involved, the economic benefits and necessary quality of certified systems will most likely not be achieved.

It is most likely that DPOs will use the added activities with attestation as an excuse to increase prices.

8. If an organisation approval is required for DPOs to be involved in the design and/or production of ATM/ANS equipment there is a risk that the number of companies in the market will be reduced. Attestation can be an obstacle for new or small DPOs to compete for contracts, and the large DPOs will control the market even more. The larger DPOs might also limit the development to keep the number down of certificates they need to hold and renew.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that the most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- 'Impact assessment', in particular 'Certification costs and impacts on the market'.
- 'Detailed certification/declaration/SoC (technical) specifications and their development/availability';
- 'Access to the market'.

In case the commentator sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

1192

comment by: *Juan L. Diz*

One of the objectives is to 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;

- For DPOs it is often necessary to make changes all the way up to after installation, close to the customer's go-live date. If this needs to certify the system after all documents have been closed and the configuration record has been issued, but before the go-live date, it will delay customers' go-live dates significantly and impact ANSP and DPO contracts.

response

*Noted*

The comment is well received and will be duly considered during the activities of RMT.0161 Subtask 3.

comment

1195

comment by: *FerroNATS*

Fair competition: The cost and effort on administrative and bureaucratic aspects will remove some actors from the competition.

response

*Noted*

The proposed transitional period (5 years) caters initially for that risk.

The evolution of the market then should be observed in the frame of the monitoring of the effectiveness of the new framework.

For further details, please refer to topic 'Access to the market'.

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

p. 9

comment

158

comment by: *COULON FR SAA*

the evidence required for civil ATM certification process should not be the same as per military equipments as the missions, safety objectives and organisational RRM are not the same.

response

*Noted*

The comment is duly considered in the Opinion.

comment 242

comment by: *Indra Navia*

Generic question on process:

Is there a possibility for early involvement by EASA along the development process when a new product, due for certification, is being developed? E.g., should EASA receive the Plan for Software/Hardware Aspects of Certification early in the development process? If so, will EASA have capacity to provide feedback within a few weeks so that the feedback can be taken into account and provide added value in the project?

response *Noted*

Taking into account the proposal, in particular ATM/ANS.EQMT.AR.C.010 on Level of involvement and data to be provided with the application as required in accordance with ATM/ANS.EQMT.CERT.015 of the proposed delegated act, the intent is confirmed.

comment 371

comment by: *Civil Aviation Authority the Netherlands*

MoD The Netherlands is of the opinion that the Basic Regulation (EU)2018/1139 Articles 2.3 and 2.5 are applicable and the essential requirements in annex VII and VIII are applicable requirements to provide safety and operability at an equivalent level. The competent authority in the Netherlands has communicated by a formal letter to EASA that the military in The Netherlands fully comply to the BR Articles 2.3 and 2.5 by the Military Aviation Requirements.

response *Noted*

comment 745

comment by: *POL CAA LOZ-4*

I do not agree that there was a lack of supervision in the design or production phase of ATM/ANS equipment. And why then did (were supposed to serve?) all those HAL, PAL, SWAL?

response *Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

The commenter is invited to further justify the statement.

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

p. 10

comment

35

comment by: *German NSA (BAF)*

page 11

The detailed internal architectural design for equipment described on page 11 deems not necessary as input/output and functions of equipment is already covered by technical standards. ATM/ANS equipment has to fulfil technical and functional requirements. Therefore, a provision on how a manufacturer has to design the equipment is not necessary.

This ensures more entrepreneurial freedom and less administrative burden.

response

*Noted*

The comment is considered in the Opinion.

The proposal address the capability and not the means which the organisation should use to perform its activities.

comment

36

comment by: *German NSA (BAF)*

page 13

The BAF's legal understanding of Article 80 1 (c) Regulation 2018/1139 concerning responsibilities of EASA and NSA is as follows:

EASA shall be responsible, in accordance with Article 80(1)(c) of Regulation (EU) 2018/1139, for the certificates for and the declarations made by the organisations referred to in Article 42, where those organisations are involved in the design, production or maintenance of ATM/ANS systems and ATM/ANS constituents, including where they contribute to Single European Sky ATM Research (SESAR) implementation, used in the provision of the services referred to in point (b) of this paragraph

It cannot be concluded from the regulation that all ATM/ANS systems and components contributing to the implementation of the SESAR project should be considered pan-European. Article 80 (1)(c) only regulates the competence of the EASA when these systems and constituents are used for the provision of pan-European services. The insertion of the text "including where they contribute to Single European Sky ATM Research (SESAR) implementation" expresses that these ATS/ATM (pan-European) systems and constituents can also contribute to implement SESAR.

Accordingly, **EASA is only competent for those organisations within the meaning of Art. 42(1) which are involved in the design, manufacture or maintenance of ATM/ANS systems and constituents (contributing (as appropriate) to the implementation of SESAR) used for pan-European ATM/ANS services.**

**Unless the ATM/ANS systems and constituents (which may contribute to the implementation of SESAR) that the organisation is involved in designing/manufacturing/maintaining are used for pan-European ATM/ANS services, according to Article 42 (4)(6) the national authority of the Member State is responsible in which the organisation applying for the certificate or making the declaration has its principal place of business or is resident/established.**

Legal understanding of pan-European service

The regulation (EU) 2018/1139 leaves it open when a pan-European service is to be assumed. Only recital 54 of the regulation mentions the EGNOS service provider as an example of an organisation that offers ATM/ANS throughout Europe. However, the term "pan-European services" is defined by the Implementing Regulation (EU) 2017/373, which was still based on the terminology from Article 22a of Regulation (EC) No. 216/2008. This is understood to mean activities that are designed and set up for users in most or all Member States and may also extend beyond the airspace of the territory to which the Treaty applies.

In the absence of provisions to the contrary, from a general linguistic point of view, "most" would mean more than 50%. However, as can be seen from the EASA Opinion 02/2010 (page 5) (which, among other things, dealt with the regulation text of the later implementing regulations (EU) no. 1035/2011, which defined the term "pan-European air navigation service" with substantially identical wording), the use of the term "most" was intended to cover cases "where the air navigation service, although intended to be pan-European, may not be available to users in all Member States (e.g. where a satellite constellation does not cover all Member States)". This seems to suggest that in principle all Member States should be affected and only in (comparable) exceptional cases also less than 100 % (but at least 51 %) of the Member States are affected.

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

37

comment by: *German NSA (BAF)*

page 13:

*"Before the ATM/ANS equipment is designed or produced,..." and  
„As regards the framework, ...“*

Taking into account that pan-European services are services like EGNOS (see comment No 36), it is irrelevant in how many Member States an ATM/ANS system is used. Therefore the argument in this paragraph is not effective.

Europe-wide validity of the approval of a DPO after approval by an NSA is seen in the same way as of the certification of ANSPs. If a DPO gets an approval of an NSA the approval should be valid within EU. No national limitation is seen.

EASA is the competent authority for the oversight over certifications/declarations of ATM/ANS systems constituents.

response *Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment 58

comment by: *ENAIRE*

**Original text:**

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.

**Proposed amended text:**

Installation, **transfer into operation (entry into service)** 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.

**Comment/Rationale:**

Transfer into operation (entry into service) shall be considered as a part of the critical processes responsible of the ANSP.

response *Noted*

Please refer to topic 'Roles and responsibility of different actors'.

In addition, taking into account the comment, the text was amended to emphasise this principle.

Furthermore, the development of the associated AMC/GM is under consideration.



comment

153

comment by: DSNA

**#1** -reference :*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;*
- *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.*

comment: \_\_\_\_\_ data are missing  
ATM systems do require a lot of parameters and data for configuration to particular ANSP environments.

It is unclear for product certification which dataset will be used (standard one to specified ?) and how to avoid a re-certification when a new dataset will be necessary for different ANSP environments

proposal: EASA to clarify certification process with regard to data.

**#2** - Comment: Will equipment for overseas territories (outside EATMN) be concerned by certification or declaration?

response

*Noted*

Following the order of the comments:

- the development of the associated AMC/GM is under consideration;
- the proposed framework should apply where the Treaty on the Functioning of the European Union applies.

comment

159

comment by: COULON FR SAA

*ATM/ANS providers.../...  
they will be relieved of the responsibility*

it can not be the case for military service providers.

response

*Accepted*

The comment is duly considered in the Opinion.

The commented proposed framework is DA/IA to EASA Basic Regulation; thus, air traffic management and air navigation services ('ATM/ANS') that are provided or made available by the military, should be excluded from the scope of this Regulation. However, Member States should ensure that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 applies, they offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

comment 160

comment by: COULON FR SAA

*EASA to act as the competent authority*

mil organisations are not included in the area of authority of EASA. how will they be approved? delegation from the national approval authorities? other?

response *Noted*

The proposal establishes the framework on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military.

The commented proposed framework is DA/IA on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e. it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military; However, Member States should ensure that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 of the European Parliament and of the Council applies, they offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

comment 206

comment by: CANSO

Reference :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;
- 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.  
comment: data are missing  
ATM systems do require a lot of parameters and data for configuration to particular ANSP environments.  
It is unclear for product certification which dataset will be used (standard one to specified ?) and how to avoid a recertification when a new dataset will be necessary for different ANSP environments  
proposal: EASA to clarify certification process with regard to data.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 207

comment by: *CANSO*

Comment: Will equipment for overseas territories (outside EATMN) be concerned by certification or declaration?

response *Noted*

The proposed framework should apply where the Treaty on the Functioning of the European Union applies and will be implemented within the single European sky airspace.

comment 251

comment by: *Romanian CAA*

Regarding the proposal for EASA to act as the competent authority for the approval of organisations involved in the design and/or production of ATM/ANS equipment, there is no detail on how EASA will ensure the adequate number of personnel involved in this activity, the training required for the personnel as well as details related to how EASA plans to budget this activity and what is the impact on the EASA budget. Regulation on charges and tariffs is impacted or not?

response *Noted.*

Please refer to topic 'EASA action as competent authority for all DPOs'.

Taking into account the comment, the explanatory note of the Opinion considers the subject.

In reference to the question raised by the commentator, the answer is affirmative, the respective 'Fees & charges' Regulation should be amended.

comment

252

comment by: *Romanian CAA*

Regarding the production of ATM/ANS equipment exclusively for the provision of ATM/ANS at national level, we believe that provisions should clarify this situation as well, either in the form of a statement of compliance or a derogation from the general requirements.

response

*Noted*

The categorisation of the equipment is based on the nature and risk of the activities supported/enabled by such equipment. This is not exclusively based on safety criticality. In this context, the text of the Opinion is made more consistent, avoiding references to safety criticality, which might be imprecise.

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

comment

262

comment by: *CANSO*

The proposed organisation approval and the certification/declaration could possibly hinder research and development projects by limiting the number of DPOs to cooperate with. Companies that are in other markets than ATM/ANS could bring positive effects into the market of ATM/ANS if they are able to compete without too many obstacles such as a lengthy and costly attestation process via a centralized body. The ATM/ANS sector can benefit from for example tech companies competing for research contracts to widen the scope and increase the knowledge in our industry.

response

*Noted*

The proposed transitional period (5 years) caters initially for that risk.

The evolution of the market then should be observed in the frame of the monitoring of the effectiveness of the new framework.

The commenter is invited to further clarify why the new framework would negatively impact the DPO market in the context of research and development, compared to the current framework.

On the contrary, the prevalence of national technical specifications used in procurement has led to the fragmentation of the ATM/ANS ground equipment market and has not facilitated

industry cooperation at European Union level. As a result, the manufacturing industry is negatively affected since it often needs to adapt its products to various national markets, i.e. to ATM/ANS service providers across the Union. These practices render the development and the implementation of new technologies unnecessarily difficult and, in turn, slow down the introduction of new operational concepts that are required to increase the capacity of the ATM system and to improve its performance.

To address those deficiencies, the new regulatory framework for ATM/ANS equipment aims to facilitate the establishment of a controlled mechanism for the coordinated development and implementation of new, agreed and validated ATM/ANS concepts of operation and/or technologies.

comment

275

comment by: *CANSO*

Proposed amended text

Installation, **transfer into operation (entry into service)** 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 close 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.

Comment/Rationale

Transfer into operation (entry into service) shall be considered as a part of the critical processes responsible of the ANSP.

response

*Noted*

Please refer to topic 'Roles and responsibility of different actors'.

In addition, taking into account the comment, the text was amended to emphasise this principle.

Furthermore, the development of the associated AMC/GM is under consideration.

comment

314

comment by: *Nils PALMQVIST*

The proposed organisation approval and the certification/declaration could possibly hinder research and development projects by limiting the number of DPOs to cooperate with. Companies that are in other markets than ATM/ANS could bring positive effects into the market of ATM/ANS if they are able to compete without too many obstacles such as a lengthy and costly attestation process via a centralized body. The ATM/ANS sector can benefit from

for example tech companies competing for research contracts to widen the scope and increase the knowledge in our industry.

response

*Noted*

The proposed transitional period (5 years) caters initially for that risk.

The evolution of the market then should be observed in the frame of the monitoring of the effectiveness of the new framework.

The commenter is invited to further clarify why the new framework would negatively impact the DPO market in the context of research and development, compared to the current framework.

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

To address those deficiencies, the new regulatory framework for ATM/ANS equipment aims to facilitate the establishment of a controlled mechanism for the coordinated development and implementation of new, agreed and validated ATM/ANS concepts of operation and/or technologies.

comment

355

comment by: CAA - Norway

It is proposed that "*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*". The same follows from the proposed article 4 (on page 43), by use of the word "shall".

It is somewhat difficult to see how this relates to the voluntary possibility to apply for a certificate, in the proposed DPO.OR.A.005 (on page 45), by use of the word "may".

Could it possibly be explained better what the relation is between the voluntary possibility to apply for a certificate, and the compulsory requirement to demonstrate the capability to carry out their activities, for organisations that are involved in the design and/or production of ATM/ANS equipment?

response

*Noted*

Please refer to topic 'Roles and responsibility of the different actors'.

The categorisation of the equipment is based on the nature and risk of the activities supported/enabled by such equipment. The addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported.

In this context, in order for an applicant to apply for ATM/ANS equipment certificate or be eligible to declare design compliance, the DPO should be an approved organisation in the process of approval.

comment

372

comment by: *Civil Aviation Authority the Netherlands*

2.3.1.1, first bullet

“identification of the functional requirements for ATM/ANS equipment;”

As functional requirements are usually determined by ANSPs, does this mean that all ANSPs require a DPO certificate?

response

*Noted*

The comment is duly considered.

Please refer to topic ‘Roles and responsibilities of the different actors’.

The answer to the question is negative; there is no need for DPO approval in order to define ATM/ANS equipment functional requirements.

comment

382

comment by: *Tern Systems*

**Single competent authority is a risk for overall safety, innovation and a business risk for DPOs**

The NPA proposes EASA as the single competent authority for all DPOs and the provided equipment: This creates a single point of failure and bottleneck in the production of future ATM/ANS equipment.

If the EASA infrastructure is not sufficient, this will delay delivery of equipment. This can influence safety of operations and can hinder DPOs to fulfil their contracts with ANSPs. Neither Appendix 1 or 2 of the NPA define any restrictions for the duration of the process of obtaining approval for a DPO or certification and declaration of compliance for equipment.

ATM/ANS.EQMT.CERT.015 Application for an ATM/ANS equipment certificate (d): “An application for the issue of an ATM/ANS equipment certificate shall be valid for 5 years” could indicate processing times of several years. For a software DPO, development cycles of several years are unrealistic and not supportive of innovation.

Were other options considered to achieve consistent regulation of ATM/ANS equipment throughout Europe by the national regulators? Guidance by EASA to the national regulators for example? Using the existing infrastructure of national regulators allows for distributing the load of approval/certification/ ... Could the competence issue be solved by better knowledge distribution and sharing of EASA expertise? These questions have to be addressed also internally at EASA to ensure consistent evaluation of all DPOs and equipment.

response *Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs', in addition to topic 'Impact assessment' with special attention to 'Option chosen'.

comment

451

comment by: NAV Portugal E.P.E

**About DPOs:**

- The proposal doesn't present a clear indication of what will happen to a concerned equipment "CERT" or "DEC" if a DPO loses its approval or ceases its activity (including during the transition periods); in these cases, would the CERT or DEC lose their prerogatives too and the ANSPs be subjected to removing the concerned equipment from operations? (ref to new ATM/ANS.OR.A.045(g) and (h) that are part of this NPA)

On the other hand, what happens if the equipment suppliers are not based in the EU? What are the alternative means of compliance if those suppliers are not complying with this future regulation? If they do not, will they be excluded? What will be the impact on the competition and the prices? The example (E.g.) proposed in question (8.1#1) may undermine the ability of an ANSP to provide their services if this "equivalent system" takes a longer period to be approved by EASA. At the end of the day, there are no guarantees that a Non- EU manufacturer could accept these provisions.

response *Noted*

Please refer to topic 'DPO approval discontinuation'.

Taking into account the feedback received, the text of the delegated act is amended; please refer to Article 7. For further details, please refer to topic 'Access to the market'.

comment

507

comment by: Juan L. Diz

*· The transition phase should be set up to ensure a smooth implementation of the new requirements taking into consideration contractual obligations;*

*There should be balance iduring transition phase to put in plance the new regulation and meantime to do not jeopardise the already commitment in the operation contracts.*

*T*



response

*Noted*

Please refer to topic 'Transitional provisions'.

comment

540

comment by: *Copenhagen Airports*

If an ANSP is engaged in designing and producing custom software for bespoke ATM/ANS-systems, will the ANSP have to be certified DPO, or can such software be implemented under Article 6?

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

572

comment by: *NATS*

Page 11

Does this suggest that e.g. installation is an activity performed under the ANSP's 373 certification (and thus if a certified DPO is also contracted to install the equipment, this would not be covered by their certificate, and would become a contracted activity under 373, requiring full oversight)?

There seems to be a misunderstanding on the scope and scale of engineering work performed by ANSPs to create a fit-for-purpose System; they are not comparable to airline operators, who can maintain and operate aircraft without needing to be involved in the engineering of the aircraft.

Looking at the list of activities above, most ANSPs will need to certify as DPOs... and ANSPs could even end up in the situation where they contract a certified DPO to supply a system, but the supplier then needs to provide oversight of the ANSP, to ensure the ANSP is competent to determine the requirements for their system!

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

573

comment by: *NATS*

Page 11

Paragraph 2

This would mean that a (demonstrably) perfectly good piece of equipment e.g. in-use elsewhere in the world couldn't be certified for use in the EU without first certifying the manufacturer. It is also unclear how this would work for existing equipment, as a supplier would presumably need to be certified based on current process, even though they may have developed it decades ago?

response

*Noted*

Please refer to topics 'Roles and responsibilities of the different actors' and 'Transitional provisions'.

comment

580

comment by: NATS

Page 12  
paragraph 1

Such attestation would only be in the context of their test environment, which may be entirely different to the operational environment, noting the increasing use of data centres etc. as ANSPs move towards procuring "software-only" products.

The DoV currently produced by the ANSP attest the compliance of the overall system, based on evidence showing how conditions of use have been met, performance and interfaces have been tested and in a representative environment, etc. and this is the level at which compliance with most ERs must be demonstrated.

response

*Noted*

The comment is duly considered in the Opinion.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration, in particular regarding ATM/ANS.OR.A.045(g)(5).

comment

581

comment by: NATS

Page 12  
Paragraph 1 *focus will be on the operational integration of ATM/ANS equipment*

This sounds reasonable in theory, but note that a manufacturer's claim of compliance is largely irrelevant until verified by the ANSP in an operationally-representative environment, and again this is the only level at which ER compliance can truly be confirmed; the ANSP's

engineering and integration activities to support ER compliance need documenting through a TF, and should form the basis for NSA audit and approval of System change.

response

*Noted*

The comment is well received.

Taking into account the comment, the development of the associated AMC/GM is under considerations.

comment

582

comment by: NATS

Page 12

Bulletpoint 3 - sub bulletpoint 1

It is not clear what set of requirements is considered in scope, e.g. would H&S legislation be in scope of such a requirement, or just the applicable requirements from the legislation which uses the term?

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under development.

comment

584

comment by: NATS

Page 13

Bulletpoint 2 sub bulletpoint 2

Although the "checking function" may be independent, the verification platform is not independent, i.e. if a manufacturer misinterprets a specification, that same error can creep into both their product and their test bed.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under development.

comment

585

comment by: NATS

Main Paragraph 1

The rationale for only EASA being able to certify DPOs seems weak (other than it being a requirement of 1139), given that NSAs are certifying the ANSPs (and that EASA's role is to perform standardisation audits of the NSAs), and noting that it creates a potential bottleneck and a new monopoly (as DPOs can only pay EASA for certification, unlike the current 552 mechanism which allows any organisation to seek approval as a Notified Body).

response *Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

586

comment by: NATS

Page 13

Paragraph 3 Bulletpoint 1

This is not the usual intent of a pan-european service, e.g. network management functions.

By this definition almost every EU ANSPs should be certified by EASA because there will likely be some amount of delegated airspace, we are not sure this is the real intention.

response *Noted*

comment

746

comment by: POL CAA LOZ-4

These are tasks that CAA already performs anyway in the process of overseeing the implementation of changes in sf ATM.

response *Noted*

comment

747

comment by: POL CAA LOZ-4

Isn't the implementation of these elements already ensured by at least QMS and ISO certification in this area anyway ?

response *Noted*

If the question is if an ISO Certificate could be considered as a means of compliance with regard to the management systems requirements of a DPO, the subject could be considered during the AM/GM development.

comment 843

comment by: ENAV

Reference :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/ANSequipment;
- definition of the technical requirements;
- detailed architectural design;
- definition of the processes and methods for manufactureand assembly;
- manufacture in accordance with design documentation;
- preparation and update of complete technicaldocumentation and records; and
- preparation and update of all required manuals to beprovided with the equipment

comment: data are missing

ATM systems do require a lot of parameters and data forconfiguration to particular ANSP environments.

It is unclear for product certification which dataset will be used(standard one to specified ?) and how to avoid a recertificationwhen a new dataset will be nessary for differents ANSP environments

proposal: EASA to clarify certification process with regard todata

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 844

comment by: ENAV

Comment: Will equipment for overseas territories (outside EATMN) be concerned by certification or declaration?

response *Noted*

The proposed framework should apply where the Treaty on the Functioning of the European Union applies.

comment

845

comment by: ENAV

The proposed organisation approval and the certification/declaration could possibly hinder research and development projects by limiting the number of DPOs to cooperate with. Companies that are in other markets than ATM/ANS could bring positive effects into the market of ATM/ANS if they are able to compete without too many obstacles such as a lengthy and costly attestation process via a centralized body. The ATM/ANS sector can benefit from for example tech companies competing for research contracts to widen the scope and increase the knowledge in our industry.

response

*Noted*

The proposed transitional period (5 years) caters initially for that risk.

The evolution of the market then should be observed in the frame of the monitoring of the effectiveness of the new framework.

The commenter is invited to further clarify why the new framework would negatively impact the DPO market in the context of research and development, compared to the current framework.

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

To address those deficiencies, the new regulatory framework for ATM/ANS equipment aims to facilitate the establishment of a controlled mechanism for the coordinated development and implementation of new, agreed and validated ATM/ANS concepts of operation and/or technologies.

comment

846

comment by: ENAV

Proposed amended text

Installation, **transfer into operation (entry into service)** 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.

Comment/Rationale

Transfer into operation (entry into service) shall be considered as a part of the critical processes responsible of the ANSP.

response

*Noted*

Please refer to topic 'Roles and responsibility of different actors'.

In addition, taking into account the comment, the text was amended to emphasise this principle.

Furthermore, the development of the associated AMC/GM is under consideration.

comment

908

comment by: AESA

In page 11, Figure 2 is not complete. It's necessary to include "recurrent maintenance" (as it is named in page 11, 2.3.1.1) / "routine maintenance" (as it is named in page 21, 2.3.2) and withdrawal from service, by ATM/ANS providers; and "evolutive maintenance" (as it is named in page 11, 2.3.1.1) / "equipment upgrade" (as it is named in page 21, 2.3.2) by manufacturer.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

909

comment by: AESA

In page 11, in relation to the following: "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"

Is an organisation approval required for the "evolutive maintenance" / "equipment upgrade" carried out by a manufacturer for an ATM/ANS equipment that is not subject to certification/declaration (it's subject to a statement of compliance (SoC))?

Will a manufacturer that it's not a DPO be able to carry out "evolutive maintenance" / "equipment upgrade" of an ATM/ANS equipment that is not subject to certification/declaration (it's subject to a statement of compliance (SoC))?

Which kind of "evolutive maintenance" / "equipment upgrade" would imply the elaboration of a new statement of compliance?

response

*Noted*

The statement of compliance (SoC) is made either by the ATM/ANS provider certified in accordance with Regulation (EU) 2017/373 or by an approved organisation involved in the design and/or production of ATM/ANS equipment for other ATM/ANS equipment, confirming that the equipment complies with the technical standards listed in DSs (**Article 6**); this

approach is similar to the current EU declaration of conformity scheme based on the SES interoperability Regulation as the ATM/ANS providers should verify that certain ATM/ANS equipment complies with the technical standards established by recognised standardisation bodies and listed in DSs (i.e. for that ATM/ANS equipment, which is neither subject to certification by EASA nor to declaration by organisations involved in its design and/or production). The novelty is the inclusion of the possibility for an approved organisation involved in the design and/or production of ATM/ANS equipment to issue a SoC, which provides flexibility and is beneficial for the ATM/ANS providers.

In conclusion, the SoC should be issued by regulated party – either the ATM/ANS provider or the approved DPO.

comment

910

comment by: AESA

In page 12, although it is stated: "[...] 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.[...]", this is not explicitly included in the proposals (neither Appendix 1 nor Appendix 2).  
For example, what about CP1/AF5 (SWIM)?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

911

comment by: AESA

In page 12, regarding: "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." It is not clear in what cases and how is it measured that "Added Value"

response

*Noted*

The comment is well received and considering it, the statement is removed.

comment

912

comment by: AESA

In relation to page 13 and 14, some concerns arise regarding the definition of 'pan-European ATM/ANS' that should need to be further clarified taking in mind a legal assessment of what



it's stated in Article 80 of Reg. (EU) 2018/1139 vs Article 2(4) of Implementing Regulation (EU) 2017/373.

response *Noted*

The subject could be considered, but would require a deeper discussion, analysis and evaluation. Therefore, the commenter is kindly invited also to consider whether a more detailed rulemaking proposal on the issue would be possible.

comment *1092* comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

The identification of functional requirements for ATM/ANS equipment is often done by the ATSP/ANSP or at least in collaboration with it. Please clarify whether an ATSP/ANSP involved in the identification of functional requirements for ATM/ANS equipment requires a DPO certificate.

response *Noted*

The comment is duly considered.

Please refer to topic 'Roles and responsibilities of the different actors'.

The answer to the question is negative; there is no need for DPO approval in order to define ATM/ANS equipment functional requirements.

comment *1134* comment by: *Romanian CAA*

Regarding the maintenance of the equipment (page 12), we consider that it is needed to clarify what happens with equipment in operation if the supplier organisation fails to maintain its certificate and (evolutive) maintenance is still demanded for safe operation.

response *Noted*

Please refer to topic 'DPO approval discontinuation'.

comment *1141* comment by: *Romanian CAA*

Regarding EASA as competent authority (page 13), the NPA clearly states that EASA will be responsible for certification/approval of manufacturers. This seems to be in contradiction to article 80 (1) (b / c) of Reg. (EU) 2018/1139. This article requires that EASA shall only be responsible for the certification of organisations involved in the design, production or maintenance of ATM/ANS systems and ATM/ANS constituents, that are used by providers of

ATM/ANS who offer pan-European services. Although it is expected manufactures to be interested to offer products at pan-European level the manufacturing activity should be at pan-European level (production facilities across EU Member States).

response *Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment 1175

comment by: *Deutscher Wetterdienst*

All equipment can potentially be used for international market & distribution, thus EASA should be responsible for oversight. Organisations exclusively working at a national level are not considered representative and therefore not considered within the proposals. This excludes the current practice of ANSPs developing their own constituents for exclusive use within the organization (e.g. MET ANSP). However, it is still not defined whether or not (and which) systems and constituents operated by ANSPs e.g. for distribution of MET data & information are considered to be part of EATMN and thus are covered by IOP regulations. Clarification needed.

response *Noted*

Please refer to topics:

- 'EASA acting as competent authority for all DPOs'; and
- 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 1184

comment by: *Deutscher Wetterdienst*

"Some of these phases are usually performed by the ATM/ANS provider...":

'Usually' is not-conclusive and provisions should be clarified for cases that do not fall under this assumption (might be within the AMC, better yet within the IA itself)

response *Noted*

Taking into account the comment, the regulatory text has been amended and the development associated AMC/GM is under consideration.

comment 1185

comment by: *Deutscher Wetterdienst*

"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."

This statement does not appropriately take note of ANSPs activities in developing constituents and systems for internal use only.

response

*Noted*

Please refer to topics:

- 'Access to the market'; and
- 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, the proposed transitional period (5 years) caters initially for that risk.

The evolution of the market then should be observed in the frame of the monitoring of the effectiveness of the new framework.

The commenter is invited to further clarify why the new framework would negatively impact the development of ATM/ANS equipment for internal use only, compared to the current framework.

### 2.3.1. Proposals

p. 10

comment

359

comment by: *LEONARDO*

Corrective/evolutive maintainance and (re)certification: It is not clear if, after a corrective/evolutive maintenance, just the modified part or the whole modified component is going to be certified again

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

571

comment by: *NATS*

2.3.1.1

There appears to be no option for a supplier to develop ATM/ANS equipment without organisational certification, but this presents a significant barrier to entry for SMEs, and potentially for the use of equipment produced by non-EU DPOs.

A more pragmatic approach could be to use Organisational certification to enable the production of self-declarations of compliance, while non-certified organisations could instead opt for product certification.

response

*Not accepted*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'; consequently, ATM/ANS equipment subject to SoC could be manufactured by non-approved DPOs, as the ATM/ANS provider will take the responsibility for the conformity assessment of that equipment. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, the aspect on non-EU manufacturers is addressed in the new Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the draft Delegated Regulation.

comment

610

comment by: *Austro Control*

**Comment:**

"identification of functional requirements for ATM/ANS equipment" is often done by the ATSP/ANSP or at least in collaboration with.

**Proposed Change:**

Please clarify whether an ATSP/ANSP involved in the identification of functional requirements for ATM/ANS equipment requires a DPO certificate

**Classification:**

Major/conceptual

response

*Noted*

The comment is duly considered.

Please refer to topic 'Roles and responsibilities of the different actors'.

The answer to the question is negative; there is no need for DPO approval in order to define ATM/ANS equipment functional requirements.

comment

705

comment by: *Safety and Quality Directorate ROMATSA*

**Reduction of cost:**

this claim is not supported by evidence; no cost benefit analysis is presented specifically in the domain of the cost of the approval of the DPOs; the certification and declaration of design compliance processes of the concerned ATM/ANS equipment and cost of the associated oversight

Reduction of cost shall be supported by evidence for all compliance processes not only for DPOs but also for SPs.

**“One size fits all”:**

Equipment in the domain of ATM/ANS are highly adapted to their context and local reality; different data sets in 2 ATSU of the same ANSP would trigger different needs for demonstrations of compliance. Even in the context of COOPANS, the local realities require specific modules for the different ATSPs. Development of new functionalities are triggered by different local realities and contexts, the content of this NPA would impair the associated innovations and competitions

**Unavailability of what is inconsistently refer to as “EASA measures”, “Design Specifications”, “Certification Specifications”, “AMC”, “GM”.**

Without those, this NPA represents a framework proposing a solution that is at best immature and that is equivalent to a “blank cheque”.

**Fair competition:**

The cost and effort on administrative and bureaucratic aspects will remove some actors from the competition.

Many if not all SPs will have to become DPOs as they are designing or developing parts of their own ATM/ANS equipment. The ones not willing to follow that path will have to depend on the industry at higher costs.

The competition will only be fair for the ones (SPs or equipment providers) that get the DPO approval; the other will disappear from the scene; prices will go higher.

**About DPOs:**

No consideration provided on what happens to the concerned equipment CERT or DEC when the DPO loses its approval or disappears (including during the transition periods); the CERT or DEC would become invalid and the SPs will have to remove the concerned equipment from operations (ref to new ATM/ANS.OR.A.045(g) and (h) that are part of this NPA); and then... Would there be a opportunity for demonstrating that the risk on underperformance or on safety would be better controlled with the equipment in operation?

What happens if the equipment suppliers are not based in the EU? Are we expecting that those comply with the regulation? If they don't, will they be excluded? What will be the impact on the competition and the prices?

**About design specification**

What if the design specifications (or other wording used in an inconsistent way through the NPA) are not demanding enough?

What would happen if there were an event where the CERT or DEC equipment is identified as being the root cause for a major incident or even an accident? Who will bear the responsibility? EASA?

In accordance with EU.2017/373, SPs are responsible for the service they provide. Are all actors ready to believe the statement of the CERT or DEC?

Once this framework will be in place, DPOs will limit themselves on the demonstration of the design specifications (or other wording used in an inconsistent way through the NPA). Changing DPO will not provide better evidence to the SPs.

**Responsibilities of the SPs,**

SPs remain accountable for the service they provide through their Compliance Monitoring and compliance with ATM/ANS.OR.B.015 (contracted activities). All the processes for demonstration of compliance with requirements (regulatory, technical, functional, non-functional, SW...) on the procured equipment will need to remain.

**Cost for SPs**

The evaluation of the cost for SPs for procuring “certified” or “subject to Declaration of Compliance” ATM/ANS equipment is not provided

- To avoid subjective evaluation, the demonstration process for a manufacturer to be validated as "certified" should be defined. Capability demonstration should be based on real and objective criteria. The certification could depend on the product. Small manufacturers and also ATM/ANS service providers could produce reliable software for certain functionalities and their capabilities should be correctly evaluated.

- The differences and benefits for the ANSPs between current ANSP responsibilities and future ANSP responsibilities are not evident and should be detailed.

response

*Noted*

Following the order of the comments:

- Please refer to topic ‘Impact assessment’.
- Please refer to topic ‘Roles and responsibilities of the different actors’.
- EASA is working on the development of the associated draft acceptable means of compliance (AMC) and guidance material (GM) and the 1st set of detailed specifications, which will be publicly consulted with EASA stakeholders. These draft AMC and GM will be aligned with the final text of the subject EU regulation and will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.
- Please refer to topic ‘Access to the market’.
- Please refer to topic ‘DPO approval discontinuation’.
- Please acknowledge also that the proposal anticipates ways of addressing specifically new types of equipment for which the available specifications would not be adequate; see ATM/ANS.EQMT.AR.C.005 Special conditions.
- Please refer to topic ‘Roles and responsibilities of the different actors’.
- The proposal does not anticipate amendments to ATM/ANS.OR.B.015 of Regulation (EU) 2017/373.
- Please refer to topic ‘Impact assessment’, in particular ‘Costs and impact on the market’.
- The comment is considered in the Opinion.

— The changes of the requirements as regards the new conformity assessment are limited and proposed in ATM/ANS.OR.A.045 (g) and (h).

comment 1042

comment by: FOCA Switzerland

We wonder if the draft rules would also apply to constituents and system used for meteorological services. An indication on this point in the regulation would be useful to avoid any misunderstanding.

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 1150

comment by: FOCA Switzerland

The NPA indicates that it covers ATM/ANS equipment but in the explanations and the draft regulations only ATS, C, N, S and ATFM is addressed. That could lead to confusion between the stakeholder. It is necessary to know exactly which ATS/ATM-Services/Functions are covered. This would avoid discussions e.g. between ANSP and NSA concerning equipments that are concerned by the draft regulation or not.

In this context, we recommend that the COM/NAV/SUR equipments, having already setup appropriate standards among the ATM/ANS equipment, need a certification or DPO declaration. These systems are mainly covered by ICAO SARPS and can be integrated into an ATM/ANS system much more easily and without major dependencies.

response *Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 1183

comment by: Deutscher Wetterdienst

"a new implementing act (IA) laying down requirements on the approval of organisations involved in the design and/or production of ATM/ANS equipment":

Clarify whether or not this includes provisions for ATM/ANS Providers involved in design & production; do those need a separate approval or is this included in the general certificate for services?

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

The answer to the question is affirmative if the ATM/ANS provider is involved in the design and/or production of ATM/ANS equipment subject to certification (in accordance with Article 4) or declaration (Article 5);

The answer to the question is negative if the ATM/ANS provider deploys ATM/ANS equipment, subject to statement of compliance.

comment

1194

comment by: *FerroNATS*

Unavailability of what is inconsistently refer to as "EASA measures", "Design Specifications", "Certification Specifications", "AMC", "GM".

response

*Noted*

It should be noted that the implementing measures (EASA Measures) refer to soft law i.e AMC/GM/Detailed specifications.

Taking into the account, the development of the associated GM is under consideration.

comment

1199

comment by: *Safety and Quality Directorate ROMATSA*

**Reduction of cost:**

This claim should be supported by evidence. No cost-benefit analysis is presented specifically in the domain of the cost of the approval of the DPOs. The cost for certification and declaration of design compliance processes of the concerned ATM/ANS equipment and cost of the associated oversight should be presented.

Reduction of cost shall be supported by evidence for all compliance processes not only for DPOs but also for SPs and all actors involved in the process.

**"One size fits all":**

Equipment in the domain of ATM/ANS are highly adapted to their context and local reality; different data sets in 2 ATSU of the same ANSP would trigger different needs for demonstrations of compliance. Development of new functionalities are triggered by different local realities and contexts, the content of this NPA would impair the associated innovations and competitions.

Restricting the equipment too much could lead to higher costs (either due to monopole situations or due to usage of inappropriate equipment).

**Unavailability of EASA measures/specification:**

Some general terms should be detailed to be more specific: "EASA measures", "Design Specifications", "Certification Specifications", "AMC", "GM".



Without those clarifications, this NPA represents a framework proposing a solution that is equivalent to a “blank cheque” so it would not be trusted as an efficient and cost effective solution.

**Uniformity of terms:**

A introductory chapter explaining a list of acronyms and terms will be welcome. The same terms should be used uniformly through the document. Using the same acronyms, terms and expressions through entire document will lead to clarity and will make the document more readable.

**Fair competition:**

The cost and effort on administrative and bureaucratic aspects will remove some actors from the competition.

Many SPs will have to become DPOs as they are designing or developing parts of their own ATM/ANS equipment. The ones not willing or not able to follow that costing path will have to depend on the industry at higher costs.

The competition will only be fair for the ones (SPs or equipment providers) that get the DPO approval; the other will disappear from the scene; prices will go higher.

**Lose/Lack of certification:**

No consideration provided on what happens to the concerned equipment CERT or DEC when the DPO loses its approval or disappears (including during the transition periods). The CERT or DEC would become invalid and the SPs will have to remove the concerned equipment from operations (ref to new ATM/ANS.OR.A.045(g) and (h) that are part of this NPA). In addition, after that what is the way to go?

What happens if the equipment suppliers are not based in the EU? Are we expecting that those comply with the regulation? If they do not, will they be excluded? What will be the impact on the competition and the prices?

**Responsibility vs design specification:**

What if the design specifications are not enough?

What would happen if there were an event where the CERT or DEC equipment is identified as being the root cause for a major incident or even an accident? Who will bear the responsibility? EASA? National CAA? DPO? SP?

In accordance with EU.2017/373, SPs are responsible for the service they provide.

**Demonstration of compliance:**

SPs remain accountable for the service they provide through their Compliance Monitoring and compliance with ATM/ANS.OR.B.015 (contracted activities). All the processes for demonstration of compliance with requirements (regulatory, technical, functional, non-functional, SW...) on the procured equipment will need to remain. Therefore, the human/time resources used by SP for validating equipment may not be decreased.

**Cost for SPs**

The evaluation of the cost for SPs for procuring “certified” or “subject to Declaration of Compliance” ATM/ANS equipment is not provided.

**Evaluation criteria for certifying DPO**

To avoid subjective evaluation, the demonstration process for a manufacturer to be validated as "certified" should be more concretely defined. Capability demonstration should be based on real and objective criteria.

Moreover, the certification could depend on the product. Small manufacturers and also ATM/ANS service providers could produce reliable software for certain functionalities. Their capabilities should be correctly evaluated.

### Differences and benefits

The differences and benefits for the ANSPs between current ANSP responsibilities and future ANSP responsibilities are not evident and they should be detailed.

### "On the shelf" general usage products

There should be clarified if the manufacturer of some general usage equipment as a computer (hardware) should be certified in order for the product to be approved for operational usage. Will there be mandatory the certification of the manufacturer for "on the shelf" products (as computers) not produced only for aviation?

In our opinion, for general usage products the products characteristics are more important and product compliance with declared characteristics is certified by other processes not involving Aviation Authorities.

response

*Noted*

Following the order of the comments:

- Please refer to topic 'Impact assessment'.
- Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.
- It should be noted that the implementing measures (EASA Measures) refer to soft law i.e. AMC/GM/Detailed specifications.
- Please refer to topic 'Access to the market'.
- Please refer to topic 'DPO approval discontinuation'.
- In addition to topic 'Roles and responsibilities of the different actors', it should be acknowledged also that the proposal anticipates ways of addressing specifically new types of equipment for which the available specifications would not be adequate; see ATM/ANS.EQMT.AR.C.005 Special conditions.
- The proposal does not anticipate amendments to ATM/ANS.OR.B.015 of Regulation (EU) 2017/373.
- Please refer to topic 'Certification costs and impacts on the market'.
- The comment is considered in the Opinion; in addition, the commenter is invited to consider a more detailed rulemaking proposal.
- The comment is considered in the Opinion. The changes of the requirements as regards the new conformity assessment are limited and proposed in ATM/ANS.OR.A.045 (g) and (h).
- Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

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

p. 14

comment

38

comment by: *German NSA (BAF)*

- *"Furthermore, as described in Section 2.3.1.2"*

Regulation (EU) 2018/1139 does not state any necessity to approve DPO and to certify ATM/ANS equipment by the same authority. It lays down tasks and responsibilities of EASA and the NSA's. Certification and oversight of DPO, certification of ATM/ANS equipment as well as oversight over ATM/ANS equipment's certificates/declarations should be performed by that authority that Regulation (EU) 2018/1139 stipulates.

response

*Noted*

The comment is duly considered in the Opinion.

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

39

comment by: *German NSA (BAF)*

page 15:

-*"certification by EASA of certain safety-critical ATM/ANS"*

There should be a transparent process to determine safety critical ATM/ANS equipment. The process of this determination could not be found and should be added.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

40

comment by: *German NSA (BAF)*

page 15:

*"In this context, it should..."*

Due to the fact, that detailed specifications for certification and declaration of ATM/ANS equipment stipulate also the covered equipment the rules how the detailed specifications will be developed are very important. Therefore, a transparent process including the participation of relevant stakeholder (EASA, NSA, DPO, ANSP) should be implemented.

In NPA 2022-09 several draft provisions refer to Article 76 (3) of Regulation (EU) 2018/1139 . This article refers to Article 115 which leads at the end to the EASA Management Board Decision 01-2022.

This decision does not cover how the working group(s) for detailed certification specification is/are composed. It should be ensured that members of ANSP, manufacturer and NSA can participate. It is deemed necessary to adapt the Management Board Decision.

response

*Noted*

Please refer to ToR for RMT.0161 and the Group Composition for the referenced RMT.

comment

41

comment by: *German NSA (BAF)*

page 15:  
"Article 3 defines..."

Concerning responsibility of EASA as regards approval of DPO see comment 36.

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

42

comment by: *German NSA (BAF)*

page 16:  
"The forecast evolution..."

See comment 40.

response

*Noted*

comment

151

comment by: *DSNA*

**#1-** *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.*

Comments: The processes to produce harmonized common detailed (certification or declaration) specifications is not described and is not clear. How EASA will guarantee that all stakeholders are involved in the process of producing these common detailed (certification or declaration) specifications, in order to satisfy to different operating environment. Will SWAL be defined in certification specifications?

Proposal: The process to produce harmonized common detailed (certification or declaration) specifications should be described. These process should involve all stakeholders. Detailed specifications should include SWAL.

**#2 - 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).

Comment: There is no HMI in the examples. Will HMI be covered by detailed specifications?

Proposal: Detailed certification HMI specifications, if existing, should remain at right level, and allow the HMI to be tailored to its operating context

**#3 - 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.**

Comment: ATM/ANS equipment concerned by certification or declaration are not clearly defined, creating ambiguity and difficulties for organizations for becoming DPO or not.

Proposal: The list of ATM/ANS equipment for certification and declaration should be defined.

**#4 - 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.**

Comment: In a worse case scenario, an ANSP may have to replace all or most of its ATM equipment if EASA decides so, which would be economically prohibitive.

Proposal: A real grandfathering process shall be in place in order to avoid unacceptable costs for ANSP whereas current operational systems do meet the applicable essential requirements of the Basic Regulation and the corresponding delegated and implementing acts.

**#5: “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.

**Comment:** Declaration by an approved organisation (art.5) is proposed as main solution for CNS local equipment to rationalize the design & certification burden. Pan EU CNS space services is an alternative way to avoid scattering of various CNS systems in EU.

**Proposal:** consider adding a note to make an exclusion for pan-EU space CNS services such as EGNOS or future ones that might be created in the frame of the Union Secure Connectivity proposed by DG DEFIS, given the unicity of service provider and manufacturer.

#6 “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).”

**Comment:** EGNOS, as Pan EU CNS service, fits into current DoV method. This situation provides an efficient way to harmonize and centralize the certification of the service – as mentioned by GM1 ATS.OR.525(b).

**Proposal:** consider adding a mention to pan-EU space CNS services in article 6 explanation. EGNOS could be considered as a valid example of Article 6 when EASA is already the certification body for a unique service provider.

response

*Noted*

Following the order of the comments:

- In addition to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’, the commenter is kindly invited to refer to Management Board Decision No 01-2022 of 2 May 2022 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’) as referred to in Article 76(1) and (3) of the Basic Regulation. This procedure aims at transparency to the Member States, to other affected and interested parties, to the EASA Advisory Bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation, and to the public on how EASA develops regulatory material.
- Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’. In this regard, equipment supporting the provision of ATS, and in particular HMI, is within the scope of certification. The comment about the detailed specifications is supported and will be duly considered during the activities of RMT.0161 Subtask 3.
- Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.
- Please refer to topic ‘Transitional provisions’. In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.
- Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’. In addition, the Agency has assessed the specific nature of the EGNOS-based aviation CNS services, provided in the frame of the EU Space Programme. It has been concluded that the conformity assessment of the EGNOS system might require specific arrangements that would include coordination between the Agency and the European Agency for Space Programmes (EUSPA). No specific provisions have been reflected in Opinion No 01/2023, but the work will continue during the committee procedure to reflect these particularities in the regulatory package.
- Please refer to the response above.

comment

161

comment by: COULON FR SAA

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

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

a particular level of applicability must be identified for military equipments of these 2 categories.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, it should be noted that according to Article 2(3), the referenced ATM/ANS systems and ATM/ANS constituents are out of the scope of EASA Basic Regulation and its implementing/delegating acts. However, Member States should ensure that the ATM/ANS referred to in Article 2(3)(c) of Regulation (EU) 2018/1139 that are provided to air traffic to which Regulation (EC) No 549/2004 applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements set out in Annexes VII and VIII to Regulation (EU) 2018/1139.

comment

162

comment by: COULON FR SAA

*Furthermore, these ATM/ANS equipment manufacturers shall submit the referenced ATM/ANS equipment declarations to EASA as*

*except military CNS equipments*

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, it should be noted that according to Article 2(3), the referenced ATM/ANS systems and ATM/ANS constituents are out of the scope of EASA Basic Regulation and its implementing/delegating acts. However, Member States should ensure that the ATM/ANS referred to in Article 2(3)(c) of regulation (EU) 2018/1139 that are provided to air traffic to which Regulation (EC) No 549/2004 applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements set out in Annexes VII and VIII to Regulation (EU) 2018/1139.

comment

163

comment by: COULON FR SAA

*how compliance of the currently deployed ATM/ANS equipment that will be subjected to certification or declaration under the new scheme will be ensured.*

*including MIL ATM equipments??*

response

*Noted*

Please refer to topic 'Transitional provisions'.



In addition, it should be noted that according to Article 2(3), the referenced ATM/ANS systems and ATM/ANS constituents are out of the scope of EASA Basic Regulation and its implementing/delegating acts. However, Member States should ensure that the ATM/ANS referred to in Article 2(3)(c) of regulation (EU) 2018/1139 that are provided to air traffic to which Regulation (EC) No 549/2004 applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements set out in Annexes VII and VIII to Regulation (EU) 2018/1139.

comment 208

comment by: *CANSO*

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.

Comments:

The processes to produce harmonized common detailed (certification or declaration) specifications is not described and is not clear. How EASA will guarantee that all stakeholders are involved in the process of producing these common detailed (certification or declaration) specifications, in order to satisfy users needs?

Will SWAL be defined in certification specifications?

Proposal: The process to produce harmonized common detailed (certification or declaration) specifications should be described. These process should involve all stakeholders. Detailed specifications should include SWAL.

response *Noted*

The commenter is kindly invited to refer to Management Board Decision No 01-2022 of 2 May 2022 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') as referred to in Article 76(1) and (3) of the Basic Regulation.

This procedure aims at transparency to the Member States, to other affected and interested parties, to the EASA Advisory Bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation, and to the public on how EASA develops regulatory material.

comment 209

comment by: *CANSO*

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).

Comment:

There is no HMI in the examples. Will HMI be covered by detailed specifications?

Proposal:

Detailed certification HMI specifications, if existing, should remain at right level, and allow ANSPs to tailor HMI to their users' needs.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'. In this regard, equipment supporting the provision of ATS, and in particular HMI, is within the scope of certification.

The comment about the detailed specifications is supported and will be duly considered during the activities of RMT.0161 Subtask 3.

comment

210

comment by: *CANSO*

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.

Comment: ATM/CNS equipment concerned by certification or declaration are not clearly defined, creating ambiguity and difficulties for organizations for becoming DPO or not.

Proposal: The list of ATM/CNS equipment for certification and declaration should be defined.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS subject to conformity assessment'.

comment

211

comment by: *CANSO*

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 .

Comment: In a worse case scenario, an ANSP may have to replace all or most of its ATM equipment if EASA decides so, which would be economically prohibitive.

Proposal: A real grandfathering process shall be in place in order to avoid unacceptable costs for ANSP whereas current operational systems do meet the applicable essential requirements of the Basic Regulation and the corresponding delegated and implementing acts.

response *Noted*

Please refer to topic 'Transitional provisions'. In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 237

comment by: *Indra Navia*

Article 7, transitional provisions, 4<sup>th</sup> paragraph "For equipment that holds an EC declaration of Verification (DoV)...": According to this paragraph, the competent authorities to which the DoV has been issued, are required to submit the DoV and the technical file.

It should be noted that there is equipment 15-20 years old (and probably older) still operating. This equipment was built under previous, or non-existing rules, and it can therefore not be expected that the owners will pay for producing evidence for that equipment against any regulations. Any questions or findings from the competent authorities or EASA on discontinued product lines and obsolete products still in operation, or deliverables delivered in already closed contracts, cannot be expected to be addressed by manufacturers free of charge, and it may also be very difficult also if cost is not an issue.

response *Noted*

Please refer to topic 'Transitional provisions'.

comment 239

comment by: *Indra Navia*

In article 7, '**Transitional provisions**', **two apparently contradictory statements appear:**

**1:** "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."

**2:**" 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."

It is our interpretation that existing DSUs and DoCs are considered valid for five years after the regulation enters into force, and that DSUs and DoCs can be issued for new versions of existing equipment being deployed during the five year period starting 13 September 2023. For new equipment entering into service after 13 September 2023, for which new DSUs or

DoCs are required, these can be issued against existing regulations (primarily (EU) 2018/1139) during the transition period. Please clarify.

response

*Noted*

DSUs and DoCs are instruments regulated under Regulation (EC) No 552/2004, which is repealed, and the articles referring to the issuance of these declarations cease to apply on 12 September 2023, as prescribed by Regulation EU 2018/1139. Therefore, DSUs and DoCs could not be considered as a means for demonstrating compliance after 12 September 2023.

During the transitional period, ANSPs will be required to issue SoC for all the equipment they introduce into operation that does not hold a certificate or declaration by an approved DPO. The manner in which ANSPs will produce the SoC will be further detailed in AMC/GM and complemented by the content of the relevant detailed specifications.

comment

241

comment by: *Indra Navia*

[Article 7 transitional provisions](#), defines two categories:

“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 a particular part number which is in series production, that have a pre-existing DoV, will equipment manufactured and put into operation after September 2023, but in accordance with the pre-existing DoV, fall in the first or the latter category? Please clarify.

response

*Noted*

The DoVs are issued by the ANSP for a particular integration of equipment in their functional system; thus, it is not valid for different instantiations of the same equipment produced in series.

DoVs can only be issued until 12 September 2023, as the provisional application of Articles from Regulation (EC) No 552/2004 cease on that day. Therefore, the equipment referred to in the question would fall in the ‘equipment manufactured or put into operations after 12 September 2023’.

comment

243

comment by: *Indra Navia*

Regarding the difference between the “Certification” category and the “Declaration category”, our understanding is that the level of scrutiny from EASAs side is the same, but the difference is a timing lag in terms of when it will be possible to enter into operation with the equipment. Please confirm.

response

*Noted*

The answer is affirmative provided that the approved organisation having the privileges to issue declaration of design compliance remains in compliance with the applicable requirements.

comment

253

comment by: *Romanian CAA*

Transitional provisions consider that the date of 12 September 2023 splits ATM/ANS equipment into two categories: either operational or not yet manufactured / put into service at that date. For the latter, new legislation theoretically shall apply, needing certified organisations and certificates / declarations for ATM/ANS equipment. However, equipment may already be under development as foreseen in a given contract on 12 September 2023, that is not yet manufactured or put into service, but under way. What should be the approach in this case? The rules may change during the game for some actors.

Also, what should ATM/ANS providers do while EASA evaluates equipment subject to certification/declaration and also during the time it takes for organisations to get a certificate (3-5 years)?

Note: Transitional provisions presented may need more clarifications and could be a good point for discussions. The first 3-5 years envisaged after 12 September 2023 to be the timeframe needed for EASA to perform evaluations and also for organisations to get certified for the design/production of ATM/ANS equipment (and for issuing corresponding certificates and declarations) leaves a gap that needs to be clearly understood by ATM/ANS providers and NSAs.

response

*Noted*

The transitional provisions cater for the equipment under development, which will be subject to SoC by the ANSP until the proposed end of the period [2028].

The detailed specifications will further clarify how the demonstration of compliance for specific equipment is to be built. It is important to highlight that the essential requirements for ATM/ANS equipment are those contained in Regulation (EU) 2018/1139, and therefore, all ongoing developments should already have planned/performed conformity assessment activities in line with these essential requirements.

comment

315

comment by: *Nils PALMQVIST*

Regarding "CNS Advisory Group" where are the official papers with such recommendations, and who or which organisation has approved them?

response

*Noted*

The CNS Advisory Group is composed of experts from DG MOVE, EASA, EUROCONTROL, SESAR Joint Undertaking, SESAR Deployment Manager, European Defence Agency and EUROCAE. It has been enlarged with representatives from stakeholders (from CANSO, IATA/EBAA representing airspace users, ACI, chair team of the Expert Group of the Human Dimension of SES, and chair team of Industry Consultation Body). The expanded group has been working to update the draft CNS report and to prepare a preliminary CNS action plan considering the feedback received from the first workshop held in May 2021, and the outcome of consultation with stakeholders held in late 2021.

comment 349

comment by: DAC-LU

***"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."***

The correct functioning of surveillance sensors is essential to ensure the systems using this information are safe and stable (e.g. SDPS, Safety nets), as well as to avoid overall loss of detection due to issues such as over-interrogation. ANSPs all all sizes depend on the support of DPOs for compliance verifications. It would be logic to place this verification with the DPO.

The rationale why essential constituents of the surveillance chain like PSR/SSR radars, ADS-B receivers or MLAT equipment should be excluded from the certification performed by EASA, when other surveillance components are subject to EASA certification cannot be easily identified.

***"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."***

More clarification on the means to make this information available to the Agency is needed. At national level, a sharepoint with the local ANSP is set up to store such files. Access could be granted to the Agency.

response

*Noted*

Please refer to topics:

- ‘Categorisation of ATM/ANS equipment subject to conformity assessment’;
- ‘Transitional provisions’.

comment

373

comment by: *Civil Aviation Authority the Netherlands*

Page 16, last bullet list on page

“Examples of ATM/ANS equipment that would be subject to certification”

In our opinion, it should be completely clear which ATM/ANS equipment is liable for certification. Otherwise, States do not know to which package they are supposed to agree.

For this reason, the details of this should in our opinion not be elaborated on at a later stage by an AMC (as set by the EASA-ED), but should be set right away (possibly by way of an annex to the proposed regulation) at IR-level.

Could EASA indicate if it could agree to this line of thinking (and if not, why not)?

response

*Accepted.*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment

374

comment by: *Civil Aviation Authority the Netherlands*

Page 16, last bullet on page

“certain integration of these systems (e.g. remote tower system).”

It might be that the integration of systems as subject of certification restrict the flexibility which systems are used and restrict the market. We therefore wonder if this is a sound example.

response

*Noted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment

382 ❖

comment by: *Tern Systems*

**Single competent authority is a risk for overall safety, innovation and a business risk for DPOs**

The NPA proposes EASA as the single competent authority for all DPOs and the provided equipment: This creates a single point of failure and bottleneck in the production of future ATM/ANS equipment.

If the EASA infrastructure is not sufficient, this will delay delivery of equipment. This can influence safety of operations and can hinder DPOs to fulfil their contracts with ANSPs. Neither Appendix 1 or 2 of the NPA define any restrictions for the duration of the process of obtaining approval for a DPO or certification and declaration of compliance for equipment.

ATM/ANS.EQMT.CERT.015 Application for an ATM/ANS equipment certificate (d): "An application for the issue of an ATM/ANS equipment certificate shall be valid for 5 years" could indicate processing times of several years. For a software DPO, development cycles of several years are unrealistic and not supportive of innovation.

Were other options considered to achieve consistent regulation of ATM/ANS equipment throughout Europe by the national regulators? Guidance by EASA to the national regulators for example? Using the existing infrastructure of national regulators allows for distributing the load of approval/certification/ ... Could the competence issue be solved by better knowledge distribution and sharing of EASA expertise? These questions have to be addressed also internally at EASA to ensure consistent evaluation of all DPOs and equipment.

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

In addition, the subject is duly addressed in Opinion No 01/2023 and its explanatory note.

comment

412

comment by: *Tern Systems*

**Rushed implementation & Detailed specifications, AMC, GM ... unavailable**

How fast can EASA build the necessary infrastructure up, especially, find/educate enough competent personnel

- for executing consistent and high-quality approval of DPOs and certification of equipment etc.,
- for providing the detailed specifications that are key to the success of the proposed changes, design specifications, certification specifications?

Given the timeframe of 5 to 6 years, we have our doubts this can be implemented timely and with sufficient quality. DPOs will likely be faced with complying to an underspecified and unclear regulatory framework and to ensure their products comply to technical specifications that lack in quality as well.

Within the same timeframe of 5 to 6 years DPOs need to adapt their processes to address approval, certification and, likely, declaration of compliance, ensure appropriate resources are available to execute those processes, and demonstrate compliance of the DPO and the



products to EASA, possibly adapt products to newly issued EASA detailed specifications. However, these adaptations and the demonstration of compliance depend on EASA having provided more details than the discussed NPA first. DPOs cannot be expected to fulfil a moving target of which the details remain unclear.

Has it been considered to introduce the proposed changes in steps over a longer time? Focus first on the detailed specifications.

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

In addition, the subject is duly addressed in Opinion No 01/2023 and its explanatory note.

comment

438

comment by: *Tern Systems*

**Detailed specifications applicable for all operations contexts?**

The NPA assumes that it is possible to create EASA detailed specifications covering all ATM/ANS equipment needs throughout Europe. DPOs have to demonstrate compliance to EASA detailed specifications. What will happen if the SP (Service Provider), the DPO's customer, and EASA disagree on the needs for the equipment? This will hinder cooperation between SPs and DPOs. DPOs will have to comply with EASA specifications - even if they contradict their customer's needs. However, nowadays, SP-to-DPO cooperation drives innovation because it facilitates direct input of operational needs to DPOs. Due to that even small European DPOs stay competitive on the world market. Adding a man-in-the-middle (EASA) will harm this.

How will it be ensured that the needs of all SPs with varying needs are covered by the detailed specifications? How will those specifications be developed? Who will contribute? How is it supposed to be achieved within the proposed time frame? How will we ensure innovation in the future? How will adaptation to the needs of different service providers be supported? Will DPOs have to obtain certificates for different variants of the same equipment? ATM/ANS equipment is often software centric and very adaptable. This is different to the airborne industry.

response

*Noted*

Following the general response under this topic, EASA wishes also to clarify that the proposal aims to achieve a reasonable balance between the need to ensure the necessary interoperability and safety of critical ATM/ANS equipment with the flexibility to drive innovation and effective deployment of new technologies/functionalities.

The commenter is invited to note also that the specifications will be prepared by EASA in close cooperation with all interested stakeholders, in particular the relevant industry, then followed by an EASA Decision adopting and issuing the respective set of the detailed

(certification/declaration/SoC) specifications. Such specifications will provide via a single process the common requirements for the purpose of demonstration of compliance in terms of safety, functionality, interoperability, security and performance as necessary for the European aviation market. Before the publication of such an ED Decision, the proposed specifications will be publicly consulted through a dedicated EASA NPA.

EASA will aim at performance- and objective-based specifications and will refer to widely recognised standards published by industry, developed through standards development organisations (SDOs), as far as possible, but obviously this is without prejudicing the outcomes of the public consultation.

comment 541

comment by: *Copenhagen Airports*

There is a need for a very detailed specification of the criteria that defines the systems and constituents as "ATM/ANS". Where does the need for certification/declaration end? How far down the line will the regulations apply? COTS-products, network, non ATM/ANS-systems that feed non-safety-related data to ATM/ANS-systems. The criteria for systems and constituents being in-scope/out-of-scope for certification are important to clarify, not just for design and production, but also for operational deployment and integration.

response *Noted*

The proposal aims to achieve a reasonable balance between the need to ensure the necessary interoperability and safety of critical ATM/ANS equipment with the flexibility to drive innovation and effective deployment of new technologies/functionality.

For further details, please refer to the following topics:

- 'Categorisation of ATM/ANS equipment subject to conformity assessment';
- 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment 553

comment by: *MeteoSwiss*

The examples described in this section, together with their explanations, give a MET Service Provider the supposed confidence of being excluded from most of these requirements. Only in exceptional cases does a DSU for MET equipment already exist and therefore only the presented Article 6 would apply, if at all. Unfortunately, this supposed clarity cannot be found in the corresponding wording of the proposed regulation texts in Annex 8.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'. In this context, the ATM/ANS equipment required to support MET services functions and services is proposed to be subject to SoC.

In addition, EASA is working on the development of the associated draft acceptable means of compliance (AMC) and guidance material (GM) and the 1st set of detailed specifications. These draft AMC and GM will be aligned with the final text of the subject EU regulation and will be published by EASA following the publication of the aforementioned EU regulations by the European Commission.

comment

559

comment by: *FOCA Switzerland*

The draft article 3 proposes that EASA is responsible for certification / approval of manufacturers (called DPO). That being said, according to our current understanding of Article 80 (1) (c) of Regulation 2018/1139, the competence of EASA is limited to those systems and constituents that are only used for the provision of pan-European services which does not include system and constituent used for national or crossborder services. In our opinion, the draft article 3 is not aligned with the current regulation.

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

587

comment by: *NATS*

Page 15  
Bulletpoint 1

How will "legacy" implementations of safety critical systems be certified (e.g. an FDP system which needs to implement an older version of OLDI for a particular interface)?

It isn't as simple as saying equipment X is safety critical and equipment Y is not; an air traffic service is safety critical, and we use lots of equipment (including e.g. CNS equipment) to deliver a safe service (and ideally we ensure that no single failure should cause a safety incident).

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

588

comment by: NATS

Page 15

Bullet 3

The supplier takes on responsibility for the equipment under 552 when signing a DoC/DSU (although full compliance with the ERs/IRs/CSs can normally only be demonstrated by the ANSP through our TF & DoV); this proposal seems to shift full responsibility for the product to the ANSP.

**Declarations of Conformity / Suitability of Use could still be issued for such equipment (without the need for DPO approval), but ANSPs should still need to show that the System is compliant (which includes ensuring each product works in the operational environment).**

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

589

comment by: NATS

Page 16

Para 2

Exact meaning is unclear, but a valid certificate doesn't mean a product will work in our environment, and there is an assumption that the specifications are perfect with no ambiguity (which is very rarely the case)!

response

*Noted*

Please refer to the following topics:

- 'Roles and responsibilities of the different actors'; and
- 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

590

comment by: NATS

Page 16  
Paragraph 3

Bulletpoint 2

Whether the equipment will work and meet the requirements in practice requires specialised knowledge of the integrated system, which again is why the overall attestation should be by the ANSP via the TF / DoV

response *Noted*

Responsibilities in relation with the installation, operational integration and recurrent maintenance (following the instructions/manuals provided by the design and production organisation) of the equipment are in the sphere of the ATM/ANS provider.

These activities are already covered by the provisions of Regulation (EU) 2017/373 and are not affected by the proposal.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

591

comment by: *NATS*

Page 16  
Paragraph 4

Bulletpoint 3

This would obviously need to include comms systems, and probably many more. It gets interesting when considering HMIs, as these are undeniably very important, but it would be incredibly difficult to create specifications for / validate and certify these, and would an ANSP be expected to use an HMI on the basis that it is certified without further evaluation?

response

*Noted*

Please refer to topics:

- 'Categorisation of ATM/ANS equipment subject to conformity assessment';
- 'Roles and responsibilities of the different actors'.

comment

592

comment by: *NATS*

Page 17

Paragraph 8

This is a key problem with the proposal: it attempts to shift responsibility to manufacturers, but in most cases, compliance with the ERs can only be demonstrated by the ANSP at the "System" level.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

593

comment by: *NATS*

Page 18  
Paragraph 2  
Bulletpoint2

The DoV is for the System, which is understood to be the overall set of equipment supporting a service (e.g. a MET Service is supported by a MET System, which may have multiple Constituents... which are the products purchased from manufacturers and integrated by the ANSP). This is another key misunderstanding of this proposal.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM, in particular to ATM/ANS.OR.A.045(g), is under consideration.

comment

594

comment by: *NATS*

Page 18 Paragraph 4

Does this suggests that EASA will be reviewing and approving all TFs and/or DoCs/DSUs, and the evidence referenced by these TFs and declarations, for all EU ANSPs, to re-confirm compliance with the existing ERs and IRs, or will it be retrospectively confirmed that they comply with the new requirements (and would this include organisational competence... and if it doesn't, wouldn't this support the idea that equipment compliance can be confirmed without the need for supplier certification?)... either way this sounds like a big task, and it is not clear what benefit this would bring compared to just exempting in-service equipment?

response

*Noted*

Please refer to topic 'Transitional provisions'.

comment

611

comment by: *Austro Control*

**Comment: Page 16**

"collision avoidance" is a term normally not used in ATS provision

**Proposed Change:**

	Rephrase to "Conflict avoidance"
	<b>Classification:</b> Minor
response	<i>Noted</i>

comment	612 <span style="float: right;">comment by: <i>Austro Control</i></span>
	<b>Comment: Page 16</b> "The interoperability and safety criticality of the functions with regard to processing and delivering data for operations will become more reliable" This sentence makes no sense, safety criticality cannot become more reliable.
	<b>Proposed Change:</b> "The safety of the functions with regard to processing and delivering data for operations and their interoperability will improve"
	<b>Classification:</b> Editorial
response	<i>Noted</i>  The comment is considered in the Opinion.

comment	614 <span style="float: right;">comment by: <i>Austro Control</i></span>
	<b>Comment: Page 16</b> "Examples of ATM/ANS equipment that would be subject to certification are the following: [...] certain integration of these systems" If the integration is subject to certification; the freedom of choice of systems is severely limited. In essence e.g. the entire remote tower would be one system in this case and must be bought from one manufacturer. This restricts the market and competition and is not proportional.
	<b>Proposed Change:</b> Remove the bullet on "Certain integration of these systems [...]"
	<b>Classification:</b> Major/conceptual
response	<i>Accepted</i>  The comment is considered in the Opinion.

comment 847

comment by: ENAV

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.

Comments:

The processes to produce harmonized common detailed (certification or declaration) specifications is not described and is not clear. How EASA will guarantee that all stakeholders are involved in the process of producing these common detailed (certification or declaration) specifications, in order to satisfy users needs?

Will SWAL be defined in certification specifications? Proposal: The process to produce harmonized common detailed (certification or declaration) specifications should be described. These process should involve all stakeholders.

Detailed specifications should include SWAL

response *Noted*

The commenter is kindly invited to refer to Management Board Decision No 01-2022 of 2 May 2022 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') as referred to in Article 76(1) and (3) of the Basic Regulation.

This procedure aims at transparency to the Member States, to other affected and interested parties, to the EASA Advisory Bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation, and to the public on how EASA develops regulatory material.

comment 848

comment by: ENAV

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).

Comment:

There is no HMI in the examples. Will HMI be covered by detailed specifications?



Proposal:  
Detailed certification HMI specifications, if existing, should remain at right level, and allow ANSPs to tailor HMI to their users' needs.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'. In this regard, equipment supporting the provision of ATS, and in particular HMI, is within the scope of certification.

The comment about the detailed specifications is supported and will be duly considered during the activities of RMT.0161 Subtask 3.

comment

849

comment by: ENAV

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.

Comment: ATM/CNS equipment concerned by certification or declaration are not clearly defined, creating ambiguity and difficulties for organizations for becoming DPO or not.

Proposal: The list of ATM/CNS equipment for certification and declaration should be defined

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

850

comment by: ENAV

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.

Comment: In a worse case scenario, an ANSP may have to replace all or most of its ATM equipment if EASA decides so, which would be economically prohibitive.

Proposal: A real grandfathering process shall be in place in order to avoid unacceptable costs for ANSP whereas current operational systems do meet the applicable essential requirements of the Basic Regulation and the corresponding delegated and implementing acts.

response

*Noted*

Please refer to topic 'Transitional provisions'.

Furthermore, following the consultation outcome' the development of the associated AMC/GM is under consideration.

comment

913

comment by: AESA

In page 16, regarding examples of ATM/ANS equipment that would be subject to certification:  
1. Would it be necessary to define what system changes imply a change of the certificate? Which system changes will not require a change of the certificate? Will it be specified by AMC/GM?

2. In the case of FDP systems, how will the certification specifications be defined so that they apply homogeneously to all systems in every operational environment?

3. For communications equipment it could be "easy" to standardize certification specifications, but for systems with developed SW or specific SW of the ATM/ANS provider, such as ATC systems, how would it be defined the certification specifications?

response

*Noted*

Following the order of the comments:

- The answer is affirmative; further details on the concept 'major/minor' changes' will be provided at AMC/GM level. For further details, please refer to topic 'ATM/ANS equipment change management'.
- Management Board Decision No 01-2022 of 2 May 2022 addresses 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') as referred to in Article 76(1) and (3) of the Basic Regulation. This procedure aims at transparency to the Member States, to other affected and interested parties, to the EASA Advisory Bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation, and to the public on how EASA develops regulatory material, including the working methods, e.g. rulemaking group establishment.
- Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

914

comment by: AESA

In pages 16 and 17, which equipments are supposed to be subject to a certification, a declaration, or a statement of compliance (SoC)? When the approval process of the NPA is finished, will there be an unequivocal list?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

915

comment by: AESA

In page 1 and the first paragraph of page 16, it is only mentioned the ATM "ground" equipment and in the examples of ATM/ANS equipment for which declaration is proposed, it is mentioned "GBAS". Does it mean that any other ATM "air" equipment such as SBAS or ABAS (GNSS) are not involved in the NPA?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

916

comment by: AESA

Regarding article 5 of Appendix 2 and related to Question 8.2#1 (page 55): Due to its importance to monitor and provide adequate separation to a/c, SUR sensors should be part of the equipment subject to certification

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1053

comment by: DGAC (French CAA)

Page 18,

Reference: Article 7 'Transitional provisions' and expected role of the Authority in charge of certification of the ANS/ATM provider

Comment: The proposal of EASA is not supported. Authority in charge of certification of ATM/ANS provider will not be involved in certification and declaration of equipment and DPOA. As EASA will be in charge of granting the certification and DPO approval, relevant

documentation should be directly collected from the equipment supplier/designer or designer candidate to DPOA.

response

*Noted*

The transitional provision mentioned refers exclusively to equipment introduced into operations before the entry into force of the new framework for conformity assessment. For these systems, the conformity assessment was performed on the basis of Regulation (EC) No 552/2004, and a Declaration of Verification (DoV) was submitted by the ANSP to the NSA. The provision has been introduced to ensure that all those legacy files are transferred to EASA. All further interaction will be managed by EASA with the DPO (when the organisation that produced the equipment becomes an approved DPO) or with the ANSP and the relevant competent authority (if a DPO is not present at the end of the transitional period).

For further details, please refer to 'Transitional provisions'.

comment

1093

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Integrations of systems must not be subject to certification, but only modules and constituents. If the integration is subject to certification, the freedom of choice of systems is severely limited. In essence e.g. the entire remote tower would be one system in this case and must be bought from one manufacturer. This restricts the market and competition and is not proportional.

Please remove the bullet on p.16 accordingly.

response

*Noted*

The proposal does not prevent the integration of different modules/products by the ANSP. When such modules/products contain functionalities subject to certification or declaration, they must have been designed and produced under the responsibility of an approved DPO. Such DPOs can place freely their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and their business cases. Additionally, it is important to highlight that any ANSP could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

1094

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

P.17, Art. 6: A SoC by the ATSP/ANSP iaw Art. 6 would be required even for already certified equipment, since the configuration of a system and its integration into a specific environment

have an influence on its behaviour. It is impossible to certify all possible configurations of an equipment upfront.  
Please clarify, what the added value of certification in this context is.

response

*Noted*

The proposal does not prevent the integration of different modules/products by the ANSP. When such modules/products contain functionalities subject to certification or declaration, they must have been designed and produced under the responsibility of an approved DPO. Such DPOs can place freely their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and their business cases. Additionally, it is important to highlight that any ANSP could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

1095

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

P.18, Art. 7: This is a major burden for CAs. Furthermore, CAs can only provide the information they have received pursuant to Reg. (EC) 552/2004. It is doubtful whether this would be sufficient to certify a system retro-actively.

P.18, Art. 7: Equipment that holds an EC DoV: It is very unlikely that legacy equipment will be able to fulfil newly drawn-up requirements. What would happen in the case a system is not considered compliant by EASA? What if the manufacturer does not exist any more? Please also clarify what EASA considers an appropriate action in case a non-compliance is identified.

If equipment must be depreciated prematurely due to this regulation, this will produce sunk costs on the hand and major investments for new equipment on the other hand, both with negative effects on the unit rate. Furthermore, as the assessment by EASA will take place amidst RP4, these issues cannot be reflected in the Performance Plan for RP4, which has to be submitted in 2024 already!

response

*Noted*

Please refer to topic 'Transitional provisions'.

In addition, taking into account the consultation feedback, the development of the associated AMC/GM is under consideration.

comment

1176

comment by: *Deutscher Wetterdienst*

The provisional lists and examples do not include any reference to MET related equipment.

It would be a good approach to consider for the MET part recommendations from the MET Expert Advisory Group which is in contact with the EASA MET expert.

All other equipment (not listed) will then be considered subject to Statement of Conformity or not at all as considered outside the scope of the IOP regulations (e.g. equipment (i.e. sensors and/or systems/software) operated by MET ANSPs for measurement and distribution of MET data).

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

On this specific case, the MET equipment is proposed to be subject to a statement of compliance issued by the ATM/ANS provider.

comment

1186

comment by: *Deutscher Wetterdienst*

"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."

Still needs to be clarified exactly which equipment falls under the IOP provisions (e.g. for systems for the distribution of MET data and information). Does not appropriately take into account the repeal of EATMN definition. Without further specifications systems outside the scope of the old IOP-regulation 552/2004 should be considered to not fall under the new IOP regulation.

The new framework does not sufficiently support NSA and ANSPs with regard to MET systems.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

On this specific case, the MET equipment is proposed to be subject to a statement of compliance issued by the ATM/ANS provider.

In addition, taking into account the comment, the definition of EATMN is included into the framework.

comment

238

comment by: *Indra Navia*

It is understood that a transitional period of 1 to 3 years is foreseen for EASA to grant approval of the organisations involved in the design and/or production of ATM/ANS equipment following the adoption of the new regulatory framework. It is unclear what the deadline is for submission of applications for approval of organisations involved in the design and/or production of ATM/ANS Equipment, assuming that, at some point, non-approved organisations will be excluded from the European market. At which point is this foreseen?

response

*Noted*

Once the new framework is in place, organisations may apply for a DPO approval anytime. Only approved DPOs have the privilege to issue declarations or to be ATM/ANS equipment certificate holders.

For further details, please refer to 'Transitional provisions' and 'Roles and responsibilities of the different actors'.

comment

505

comment by: *Juan L. Diz*

It is stated the following "Declaration will be the method mandated for an intermediate layer in terms of criticality."

Which are the ATM/ANS equipment that will require a certification method?

Which are the ATM/ANS equipment that will require a declaration method?

Is there going to be a list indicating which ATM/ANS equipment will require a certification method? AND those for the declaration?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

515

comment by: *Deutscher Wetterdienst*

Why is in Figure 3 the Functional System called ATM/ANS Functional System?

What is the difference and the purpose behind it?

This term is new, not defined and not used in the (EU) 2017/373 at all.

Same as for the components of a Functional System. (EU) 2017/373 states it means a combination of procedures, human resources and equipment, including hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions;

It must be noted that the definition and distinction of the terms 'function' and 'service' have also been mixed up and forgotten within the mentioned regulations of the proposal.

response *Noted*

The comment is duly considered in the Opinion and the final proposal.

comment 558

comment by: *MeteoSwiss*

It is not only in this section that 'safety relevance' is used as an argument for assignment to a level of attestation (ref. also 2.3.1.2, 2.3.3, 4.3 etc.). In this respect, it should be noted that MET systems and equipment are used to supply services – among others – to the EATMN and according to existing GM2 ATM/ANS.OR.B.005 these are more broadly associated with the quality of the service rather than the safety of the service. What is used in the EATMN from a MET perspective are MET services (data and information), but not equipment or systems.

The Basic Regulation (EU) 2018/1139 also states in Annex VIII chapter 3.1 that ATM/ANS systems and ATM/ANS constituents providing related information to and from the aircraft and on the ground are in the scope of the regulation. The distinction made here between systems and constituents excludes MET systems as a matter of principle, since as a rule there is no such connection between the corresponding systems and constituents. The key point here is that 'meteorological services' (ref. CIR (EU) 2018/1139 Annex VIII – 3.1 (h)) are not the provision of systems and constituents, but the provision of information and data. In this regard, the parlance used in CIR (EU) 552/2004 was clearer and left less room for interpretation.

With regard to the exchange of MET data and information, it has already been ensured for decades via internationally valid exchange mechanisms that the worldwide use of these services is guaranteed. Currently, the well-established exchange of OPMET data and services is being further developed through an internationally applicable exchange model (IWXXM) developed by ICAO together with WMO, and the replacement of the OPMET system is being prepared. Within the EU footprint, this transition has already been initialised with the publication of CIR (EU) 2021/116 and the development of SWIM services.

response *Noted*

It should be acknowledged that Regulation (EC) No 552/2004 is repealed by Regulation (EU) 2018/1139, which contains currently the interoperability objectives.

In response to the comment, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 595

comment by: *NATS*



Paragraph 1

Page 19

*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.*

The implications of this statement need further assessment and clarification

response

*Noted*

The comment is considered in the Opinion.

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

596

comment by: NATS

Paragraph 2

Page 19

It is not clear if/how NSA oversight would actually change as a result of EASA certification of equipment.

The ANSP needs to understand product behaviour, deficiencies, etc. which requires detailed information on the product, and getting this information from EASA (or worse, hiding it from ANSPs behind a certificate) doesn't seem to offer sufficient benefits compared to the close relationships ANSPs currently develop with their suppliers; we would still need to verify that the product worked in the intended environment, and whether or not a product has a certificate/declaration would likely at best save ANSPs some effort in determining the competence of the supplier.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actor'.

comment

597

comment by: NATS

Paragraph 6

Page 19

Very few of the existing detailed specifications are at the level of individual pieces of equipment; the requirements often go beyond the bounds of a single piece of equipment and the required functionality can be distributed across multiple Constituents (potentially with very different splits between System implementations)... many specifications (and pretty much every ER) are only demonstrable at the System level, and the ANSP needs to guide the supplier in what their product must implement to ensure the overall System is compliant.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

917

comment by: AESA

Regarding the equipment would be subject to certification, the certification process will include all the HW&SW needed to perform their services?

response

*Noted*

When the specifications are developed, it is expected that an architecture design, comprising software and hardware, is regarded in so far as it supports the required ATM-related functions.

In this regard, when developing the specifications differentiation must be made between different type of elements (which might be present in the different types of technical systems and constituents), e.g.: sensors (HW+SW); Network (Physical+Service); Hosting Infrastructure (Physical+Service); Data Processing (SW Application); HMI.

Some of these elements are understood to be more approachable in terms of requirements for certification or declaration (i.e. sensors, data processing SW applications, HMI), while others (i.e. network elements and hosting infrastructure) might be partially detached from the design of the system/constituent, and open to different approaches (e.g. physical HW or external service).

comment

1054

comment by: DGAC (French CAA)

Reference: §2.3.1.3 – level of 'equipment, including hardware and software'

Comment: The actual scope of the certification/declaration activities is not clear. Most ATM/ANS systems/components are constituted by multiple pieces of equipment and can only perform the final ATM function once all pieces are integrated together. Will the certification/declaration address every single piece of equipment, or will it consider the

system in its entirety? For example, A-SMGCS which already has community specifications specifying high level functions and performances usually (not to say always) on a lot of individual components. What could be the strategy for certifying such kind of system “equipment”.

On the opposite, some ATM systems are released as software only systems. The integration of this software on the operational platform (physical, virtual or cloud-based platform) is currently done by the ATM/ANS provider. Could the certification/declaration address only the piece of software knowing that hardware/software compatibility is of high interest for safety?

Proposal: Clarify the actual scope of a certification/declaration specifically for highly complex systems and software-only components.

response

*Noted*

In addition to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’, it should be highlighted that the proposal does not prevent the integration of different modules/products by the ATM/ANS providers. When such modules/products contain functionalities subject to certification or declaration, they should be designed and produced by approved DPOs in order they place free their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and the business cases. Additionally, it is important to highlight that any ATM/ANS provider could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topic ‘Roles and responsibilities of the different actors’.

### 2.3.2. Maintenance activities

p. 21

comment

150

comment by: DSNA

**#1** - *Equipment upgrade is normally ...these activities are to be carried out under the responsibility of the approved ATM/ANS equipment manufacturer .*

Comment: For maintenance activities, the initial equipment manufacturer may not exist anymore, or ANSP may be obliged to open again the competition for maintenance contracts. In that case, this responsibility will need to be transferred to another maintenance organization than the one of the initial DPO. How will this situation be handled ?

Proposal: It is of the utmost importance that ANSPs still keep the capability to transfer maintenance activities to an another organization. EASA should describe the conditions which allow to do so.

**#2** - 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.

Comment: These conditions should be applicable only to equipment deployed during the transitional period and not to equipment already deployed.

Proposal: As described in article 7, replace "all equipment will be subjected " by "all equipment deployed during the transitional period will be subjected "

response

*Noted*

Following the order of the comments:

- Please refer to topic ‘Roles and responsibilities of the different actors’. In addition, taking into account the comment, the development of the associated AMC/GM is under consideration. Moreover, it should be noted that no amendments to the contracted activities provision laid down in ATM/ANS.OR.B.015 of Regulation (EU) 2017/373 are anticipated.
- The intention in the Explanatory Note of NPA 2022-09 was to refer to equipment deployed during the transitional period, as it can be observed from the fact that the transitional provisions also include that the Declarations of Verification issued before September 2023 will be considered equivalent to the instrument issued under the new framework. The comment is well considered. For further details, please refer to topic ‘Transitional provisions’.

comment

200

comment by: CANSO

#### 2.3.2. Maintenance activities - Figure 4

Clarity is required on the intended scope of integration activities, as this activity may be variously split between the ANSP and DPOs, and would usually require DPO involvement.

Addition of word “operational” does not solve the issue, as it might be wrongly interpreted by different actors (ANSP, DPO and NSA). If your objective was to underline the ANSP accountability for the usage of the entire system, then a different expression might be beneficial (e.g. Operational Acceptance, Validation, Transfer into operations, etc.).

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

212

comment by: *CANSO*

Equipment upgrade is normally ...these activities are to be carried out under the responsibility of the approved ATM/ANS equipment manufacturer.

Comment: For maintenance activities, the initial equipment manufacturer may not exist anymore, or ANSP may be obliged to open again the competition for maintenance contracts. In that case, this responsibility will need to be transferred to another maintenance organization than the one of the initial DPO. How will this situation be handled?

Proposal: It is of the utmost importance that ANSPs still keep the capability to transfer maintenance activities to an another organization. EASA should describe the conditions which allow to do so.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

Moreover, it should be noted that no amendments to the contracted activities provision laid down in ATM/ANS.OR.B.015 of Regulation (EU) 2017/373 are anticipated.

comment

213

comment by: *CANSO*

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.

Comment: These conditions should be applicable only to equipment deployed during the transitional period and not to equipment already deployed.

Proposal: As described in article 7, replace "all equipment will be subjected " by "all equipment deployed during the transitional period will be subjected "

response

*Partially accepted*

The intention in the Explanatory Note of NPA 2022-09 was to refer to equipment deployed during the transitional period, as it can be observed from the fact that the transitional provisions also include that the Declarations of Verification issued before September 2023 will be considered equivalent to the instrument issued under the new framework. The comment is well considered. For further details, please refer to topic 'Transitional provisions'.

comment

250

comment by: *Romanian CAA*

Regarding the maintenance of certified equipment, we believe that this approach affects the way in which ATM/ANS providers settle their business with design and/or production organisations, as it implies that contracts need to continue for as long as the integrated equipment is operational, thus relating the lifecycle of the ATM/ANS equipment with the contractual agreement, whereas in practice a warranty period is usually the maximum timeframe foreseen. Also, some organisations may not be on the market for as long as their equipment operates and there could be a need for maintenance even after they exit the market.

response

*Noted*

It should be highlighted that the continuous operation of ATM/ANS equipment (subject to certification or declaration by a DPO) requires an organisation assuming the responsibility for the design and production of such equipment, in particular ensuring that the equipment remains in compliance with the Essential Requirements in Annex VIII to the Basic Regulation.

comment

263

comment by: *CANSO*

It is not clear exactly what counts as routine maintenance and when new equipment certification is required under Equipment upgrade. The distinction between these types of changes should be better defined

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

For further details, please refer to 'Roles and responsibilities of the different actors'.

comment

316

comment by: *Nils PALMQVIST*

It is not clear exactly what counts as routine maintenance and when new equipment certification is required under Equipment upgrade. The distinction between these types of changes should be better defined.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

For further details, please refer to 'Roles and responsibilities of the different actors'.

comment

598

comment by: *NATS*

Paragraph 1 Page 21

The future direction of ATM systems is to make use of common IT infrastructure, data centres, etc. which would not by themselves perform any ATM function; the ANSP would procure software products from DPOs and host them on these platforms. There is still "equipment", but it would not be in scope of the certification, and the provider would not be a DPO.

**ANSPs should retain responsibility for ER compliance of the System, demonstrated through the Technical Files.**

response

*Noted*

The comment is considered in the Opinion.

For further details, please refer to topics:

- 'Categorisation of ATM/ANS equipment subject to conformity assessment';
- 'Roles and responsibilities of the different actors'.

comment

599

comment by: *NATS*

Paragraph 1 Page 21

This seems contrary to EU 2017/373, e.g. changing the requirements is not maintenance, it is "change". If a manufacturer decides to implement a new version of an interface standard as a "maintenance" change, this could break the interfaces.

response

*Noted*

The comment is duly considered and will be addressed during the development of the associated AMC/GM under RMT.0161 Subtask 3.

comment 600

comment by: NATS

Paragraph 2  
Page 21

What these two seem to have missed is bug fixes; these "software maintenance" changes shouldn't be considered an upgrade, but potentially cannot be considered "routine maintenance" performed by the ANSP.

Some ANSPs want to retain the right to make software changes to a constituent themselves / by a third party, to prevent manufacturers exploiting their position; this proposal effectively ensures that ANSPs are at the mercy of their suppliers.

response *Noted*

The comment is duly considered and will be addressed during the development of the associated AMC/GM under RMT.0161 Subtask 3.

However, it should be noted that if there will be a change to the functionality, it should be performed by an approved DPOs in case of ATM/ANS equipment subject to certification or declaration.

Moreover, changes to an item if ATM/ANS equipment are to be done under the control of the DPO responsible for its certificate. This does not prevent that certain changes (e.g. under maintenance instruction, in the frame of configurable elements) could be implemented by the user (ANSP) but always under the conditions prescribed by the DPO in the relevant manuals.

comment 851

comment by: ENAV

2.3.2. Maintenance activities - Figure 4

Clarity is required on the intended scope of integration activities, as this activity may be variously split between the ANSP and DPOs, and would usually require DPO involvement.

Addition of word "operational" does not solve the issue, as it might be wrongly interpreted by different actors (ANSP, DPO and NSA). If your objective was to underline the ANSP accountability for the usage of the entire system, then a different expression might be beneficial (e.g. Operational Acceptance, Validation, Transfer into operations, etc.).



response

*Noted.*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

852

comment by: ENAV

Equipment upgrade is normally ...these activities are to be carried out under the responsibility of the approved ATM/ANS equipment manufacturer.

Comment: For maintenance activities, the initial equipment manufacturer may not exist anymore, or ANSP may be obliged to open again the competition for maintenance contracts. In that case, this responsibility will need to be transferred to another maintenance organization than the one of the initial DPO. How will this situation be handled?

Proposal: It is of the utmost importance that ANSPs still keep the capability to transfer maintenance activities to another organization. EASA should describe the conditions which allow to do so.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

Moreover, it should be noted that no amendments are anticipated to the contracted activities provision laid down in ATM/ANS.OR.B.015 of Regulation (EU) 2017/373.

comment

853

comment by: ENAV

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.

Comment: These conditions should be applicable only to equipment deployed during the transitional period and not to equipment already deployed.

Proposal: As described in article 7, replace "all equipment will be subjected " by "all equipment deployed during

the transitional period will be subjected "

response *Partially accepted*

The intention in the Explanatory Note of NPA 2022-09 was to refer to equipment deployed during the transitional period, as it can be observed from the fact that the transitional provisions also include that the Declarations of Verification issued before September 2023 will be considered equivalent to the instrument issued under the new framework. The comment is well considered. For further details, please refer to topic 'Transitional provisions'.

comment 854

comment by: ENAV

It is not clear exactly what counts as routine maintenance and when new equipment certification is required under Equipment upgrade. The distinction between these types of changes should be better defined

response *Noted*

Under the new framework, the DPO is responsible to specify, design, produce and certify/declare the equipment. In doing so, the DPO should also establish the maintenance requirements (procedure, periodicity, etc.). Once an item of ATM/ANS equipment is certified/declared, the user (ATM/ANS provider) must install and integrate it respecting the DPO requirements and undertake the routine maintenance required to ensure that the equipment remains functional.

In addition, please refer to topic 'Roles and responsibilities of the different actors'.

Moreover, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 918

comment by: AESA

It is stated, about routine maintenance, that "[...] 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".

Will ATM/ANS providers be able to elaborate their own manuals based on manufacturer's ones?

response *Noted*

Under the new framework, the DPO is responsible to specify, design, produce and certify/declare the equipment. In doing so, the DPO should also establish the maintenance requirements (procedure, periodicity, etc.). Once an ATM/ANS equipment is certified/declared, the user (ATM/ANS provider) must install and integrate it respecting the DPO requirements and undertake the routine maintenance required to ensure that the equipment remains functional.

In conclusion, the answer is affirmative.

In addition, please refer to topic 'Roles and responsibilities of the different actors'.

Moreover, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 919

comment by: AESA

Related to equipment upgrades, when as a result of the safety case of the functional change the ANSP establishes safety requirements on certified or declared equipment and those safety requirements are not considered in the certification specification (and therefore not covered in the certificate or declaration) clear directives on how to coordinate the processes of approval of a change to a functional system and attestation of ATM/ANS equipment are highly necessary. This is particularly important when evidences generated in attestation process are necessary in the context of the assesment and review of changes to the functional systems.

Clear requirements, AMCs and GMs on the following topics would be highly appreciate:

- coordination between the Agency, competent authorities, DPO and ANSP;
- the specific case the coordination between ANSP and DPO when the changes stem from the need to apply immediate measures.

response *Accepted*

It should be noted that an ATM/ANS provider (or consortium) could develop the user requirements/specifications during the procurement or as described by the commenter. The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of Regulation (EU) 2018/1139) and contractual requirements (user requirements).

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 920

comment by: AESA

In page 22, regarding Maintenance activities, it's stated: "[...] the ATM/ANS equipment manufacturer should establish the maintenance requirements (procedures, periodicity, etc) [...]".

- How is it going to be guaranteed that the ATM/ANS providers comply with the maintenance requirements established by the manufacturer in its certificate?

- Will there be agreements between ATM/ANS providers and DPO's to ensure that the ATM/ANS providers apply maintenance requirements in accordance with the certificate?

- How will equipment upgrades made by the DPO be coordinated with the ATM/ANS provider? Will it be specified in AMCs?

response *Noted*

Under the new framework, the DPO is responsible to specify, design, produce and certify/declare the equipment. In doing so, the DPO should also establish the maintenance requirements (procedure, periodicity, etc.). Once an ATM/ANS equipment is certified/declared, the user (ATM/ANS provider) must install and integrate it respecting the DPO requirements and undertake the routine maintenance required to ensure that the equipment remains functional.

Following the order of the questions:

- This aspect will be subject to oversight by the competent authority of the ATM/ANS provider.
- It should be established with formal arrangements.
- Please refer to topic 'Roles and responsibilities of the different actors'. Moreover, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 921

comment by: AESA

In page 22, Figure 4 doesn't include EASA's role.

When an Equipment update occurs, it may have an impact on the validity of the related certificates or declarations, so it would be necessary to clarify the role of EASA as the certifying party in this process.

response *Accepted*

The comment is considered in the Opinion and the final regulatory proposal.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 922

comment by: AESA

Assuming not all manufacturers are DPO, does the changes and equipment upgrade fall among ANSP responsibilities in the case of a equipment subject to SoC? Clarification needed

response

*Noted*

Provided that the ATM/ANS equipment is subject to SoC, the answer is affirmative.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1055

comment by: *DGAC (French CAA)*

Reference: §2.3.2 – Maintenance activities

Comment: This is not clear how corrective maintenance is managed especially for software bug corrections. This can be understood either as a routine maintenance (it allows to continue to operate correctly) but also as an equipment upgrade (it requires a complement to the initial certification and in a sense consists in a functional upgrade since the function didn't operate correctly before the correction, and so was not available, and is available after the change). This topic is already subject to discussions and to disagreements in ATM community.

Proposal: Clarify this situation and state clearly how a software correction (without additional feature) is considered.

response

*Noted*

Under the new framework, the DPO is responsible to specify, design, produce and certify/declare the equipment. In doing so, the DPO should also establish the maintenance requirements (procedure, periodicity, etc.). Once an ATM/ANS equipment is certified/declared, the user (ATM/ANS provider) must install and integrate it respecting the DPO requirements and undertake the routine maintenance required to ensure that the equipment remains functional. In addition, please refer to topic 'Roles and responsibilities of the different actors'.

Moreover, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1191

comment by: *Juan L. Diz*

· The certification maintenance requirements should be commensurate with the level of change undertaken on an ATM/ANS equipment;

- e.g Enable the management of minor changes by Design and Production Organisations, without requiring a new certificate to ensure an efficient certification maintenance process

It is understood that AMC level will address the classification of changes to ATM/ANS equipment, e.g. classification of ‘minor’ and ‘major’ changes. It would be beneficial to ask for industry collaboration or consultation before final outcomes for this issue.

response *Accepted*

The comment is well received and agreed with.

The subject and the concept of minor/major changes for the ATM/ANS equipment will be further defined at the level of AMC.

The commenter is invited to refer to Subtask 3 of RMT.0161 and it is anticipated that the established Rulemaking Group for RMT.0161 will support this development.

### 2.3.3. Transitional provisions

p. 22

comment 419

comment by: *Tern Systems*

**Unclear requirements on DPOs after 12th of September 2023 - transition period not sufficiently defined**

This even ignores the unclear situation after September 2023. It is doubtful that within less than a year from now the following that is promised can be achieved: *“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”*. Even EASA acknowledges that *“EASA will issue an opinion during 2023/Q3”*.

What is expected of DPOs that provide equipment after the 12th of September 2023 until the new regulatory ATM/ANS equipment framework is in place? DPOs need to be given time to implement the framework, to seek approval from EASA, to apply for certificates etc.. As of now, the framework is not even yet completely specified.

response *Noted*

Please refer to topic ‘Transitional provisions’.

In addition, it should be noted that the referenced NPA will propose the associated AMC/GM/DS to the proposed regulatory framework.

The new framework will be in place as from 13 September 2023 anticipating a 5-year transition period, within which the DPO should become an approved DPO if their product would be subject to certification and/or declaration.

comment 452

comment by: NAV Portugal E.P.E

A transition period of 5 years is, in our opinion, too short and, in this respect, quite unrealistic. It is acceptable that legacy systems must be adapted to the new standards over time. If this is imposed in a short period, it may lead to premature depreciation and therefore impact ANSPs costs. **Our recommendation goes for a ten years transition period.**

According to the text, 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 our opinion, these conditions should be applicable only to equipment deployed during the transitional period and not to equipment already deployed. In that sense, we propose to replace "all equipment will be subjected (...)" by "all equipment deployed during the transitional period will be subjected (...)".

response *Partially accepted*

The intention in the Explanatory Note of NPA 2022-09 was to refer to equipment deployed during the transitional period, as it can be observed from the fact that the transitional provisions also include that the Declarations of Verification issued before September 2023 will be considered equivalent to the instrument issued under the new framework. The comment is well considered. For further details, please refer to topic 'Transitional provisions'.

comment 557

comment by: FOCA Switzerland

We would like to have some clarification regarding the basis on which the ATM/ANS service providers will issue SoCs during the transition period if they do not have updated DSUs or EASA specifications at that time.

How will the ATM/ANS service providers keep their DoVs updated, if manufacturers do not update their DSUs during the transition period?

What will be the procedure during the transition period when ATM/ANS equipments manufactured before the entry into force of the draft regulation are modified by the means of various patches or releases?

We understand that, under the new proposed regulation, the manufacturer will not have anymore the obligation to update the DSUs, which is a part of the Technical file belonging to certain DoV.

response

*Noted*

Please refer to topic 'Transitional provisions'.

The detailed specifications for the demonstration of compliance of ATM/ANS equipment subject to SoC should be available with the adaption of the proposed framework. For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'. In this context, it should be noted that as from 13 September 2023, the DSU cease to apply. During that period the ATM/ANS providers would be responsible for the issue of the SoC and the change management of that ATM/ANS equipment. Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

601

comment by: *NATS*

Figure 4 Page 22

ANSPs are not like airline operators, who can purchase complete aircraft without the need to be involved in the engineering of the aircraft (although they still need to maintain and operate them in accordance with manufacturer instructions, etc.); in reality, all ANSPs are necessarily DPOs as well as service providers

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

1151

comment by: *FOCA Switzerland*

We would like to have some clarification on how to handle cases where ATM/ANS service provider will use ATM/ANS constituents or systems from a manufacturer that will not apply for a certificate and will also no longer be in possession of the regulatory approval as DPO. Is there already an envisaged procedure, what entity are responsible for what?

response

*Noted*

The answer to the question is provided in topics 'Roles and responsibilities of the different actors' and 'DPO approval discontinuation'. For further details, please refer to topic 'Access to the market'.

comment

1174

comment by: *Finnish Transport and Communications Agency*



Organisations should be provided with sufficient time for implementation of the changes, and thus the time between the applicability date and entry into force date should be thoroughly considered.

It should also be noted that organisations might require some time to implement, so possible transitional period should be considered, either be included in the regulation or by competent authority/national decision.

response *Noted*

The comment is duly considered. However, the proposal contemplates a transitional period of 5 years, allowing the different actors to prepare and be approved accordingly.

comment

1187

comment by: *Deutscher Wetterdienst*

*"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)."*

This should be stated as clear as here in the drafted regulations, reference to the IOP regulation 552/2004 is missing (or the adoption of the systems definitions)

response *Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

#### 2.3.4. Other associated deliverables

p. 23

comment

462

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

#### **2.3.4, page 24**

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. The classification of minor/major changes should also be addressed in (EU) 2017/373 to be consistent.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 542

comment by: *Copenhagen Airports*

Is there an RMT or subtask established for the future NPA that will address safety-related aerodrome equipment? If so, what is the reference number?

response *Noted*

The answer is affirmative. Please refer to Subtask 4 of RMT.0161 as it is defined in EPAS 2023-2025.

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

p. 24

comment  
t

149

comment by: *DSNA*

*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.*

Comment: Reducing fragmentation may concentrate the market providers. Therefore, this might increase the costs of individual equipment. In the end, lower costs for ANSPs system procurement will only be achieved if the global system integration and certification costs are reduced.

response

*Noted*

Please refer to topic 'Impact assessment', especially 'Certification costs and impacts on the market'.

comment

215

comment by: *CANSO*

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.

Comment: Reducing fragmentation may concentrate the market providers. Therefore, this might increase the costs of individual equipment. In the end, lower costs for ANSPs system procurement will only be achieved if the global system integration and certification costs are reduced.

response *Noted*

Please refer to topic 'Impact assessment', especially 'Certification costs and impacts on the market'.

comment 509

comment by: *Deutscher Wetterdienst*

This section sounds that the proposed regulation secures the dominant market position of a few large system manufacturers and stifles healthy competition. It entails the risk that the service providers become dependent, for better or worse.

From the point of view of MET Service Providers, it must be emphasized that the required MET systems to provide the prescribed services are not offered on the market, and the MET market itself is rather small. These specific, mostly small manufacturers could no longer provided under such market conditions and they as well as small MET Service providers itself will be unable to cope with the expenses that would become necessary as described in the proposal.

response *Noted.*

The draft framework 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. In this context, the proposal anticipates that MET equipment would be subject to the SoC; thus, no reorganisation of the MET equipment market is anticipated.

For further details, please refer to topic 'Impact assessment', especially 'Certification costs and impacts on the market'.

comment 748

comment by: *POL CAA LOZ-4*

When is this "approval" to be made? Is it during this "transitional period" (5 years)?

response *Noted*

The answer is affirmative.

comment

855

comment by: ENAV

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.

Comment: Reducing fragmentation may concentrate the market providers. Therefore, this might increase the costs of individual equipment. In the end, lower costs for ANSPs system procurement will only be achieved if the global system integration and certification costs are reduced.

response

*Noted*

Please refer to topic 'Impact assessment', especially 'Certification costs and impacts on the market'.

comment

1056

comment by: DGAC (French CAA)

Reference: §2.3.4 – Safety-related aerodrome equipment

Comment: Some types of aerodrome safety-related equipment are also operated by ATM/ANS providers. Thus, it should be clear which responsibilities are to be allocated to aerodrome provider and ATM/ANS provider and how to allocate proper requirements to both stakeholders.

Proposal: When addressing safety-related aerodrome equipment, consider also that ATM/ANS can also be in charge of a part of the operation.

response

*Noted*

The issue will be further considered under RMT.0161 Subtask 4.

comment

1096

comment by: Federal Ministry for Climate Action, Environment, Energy, Mobili

As this section lists only benefits please consider and comment the following drawbacks:

- The approach is not proportional in terms of the equipment covered.

- It could lead to a market exit of small manufacturers who can't afford the cost. This would reduce fragmentation, but in an unwanted manner.
- It could drive up cost for system procurement due to shrunk markets.
- It could be a major obstacle to innovation as for every new idea/feature a specification or an exemption by EASA is required. This could mean disclosing new ideas to competitors.

response

*Noted.*

Following the order of the comments:

- Please refer to topic 'Impact assessment', especially 'Proportionality'.
- Please refer to topic 'Access to the market'.
- The statement is not agreed. The stakeholder is invited to provide further details to justify this opinion.
- On the contrary, the proposed scheme would enable an effective and standardised oversight of ATM/ANS equipment subject to conformity assessment, while promoting and enabling the development and implementation of new technologies and allocating clear responsibilities for each of the actors involved, namely organisations involved in the design and/or production of ATM/ANS equipment, ATM/ANS providers as customers and users, as well as competent authorities (either NCAs or EASA).

**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)**

p. 25

comment

560

comment by: *MeteoSwiss*

Based on the text and explanations provided in chapter 2, it seems quite obvious that MET service provision including its systems and equipment will not be subject to the 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).

However, this supposed clarity is no longer to be found in the text and paragraphs of the proposed regulations in chapter 8 – Appendix 1. The current text opens the gates for different interpretations and therefore inevitably will result in non-homogeneous transposition and thus contradicts the fundamental principles of the European legislature. From a MET Service Providers perspective, it is not enough to wait for the publication of AMC and GM. Instead, a clear declaration on level IR (e.g. in an annex) based on the examples already presented in the explanations (ref. 2.3.1.2 and 4.3 Table 2 Option 1), stating that only ATM/ANS equipment

and constituents of the EATMN but not services used therein are affected by these regulations, is absolutely required.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'. In this context, the proposal anticipates the ATM/ANS equipment to be subject to SoC.

**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)**

p. 25

comment

561

comment by: *MeteoSwiss*

Based on the text and explanations provided in chapter 2, it seems quite obvious that MET service provision including its systems and equipment will not be subject to the 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).

However, this supposed clarity is no longer to be found in the text and paragraphs of the proposed regulations in chapter 8 – Appendix 2. The current text opens the gates for different interpretations and therefore inevitably will result in non-homogeneous transposition and thus contradicts the fundamental principles of the European legislature. From a MET Service Providers perspective, it is not enough to wait for the publication of AMC and GM. Instead, a clear declaration on level IR (e.g. in an annex) based on the examples already presented in the explanations (ref. 2.3.1.2 and 4.3 Table 2 Option 1), stating that only ATM/ANS equipment and constituents of the EATMN but not services used therein are affected by these regulations, is absolutely required.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'. In this context, the proposal anticipates the ATM/ANS equipment to be subject to SoC.

**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)**

p. 25

comment 562

comment by: *MeteoSwiss*

Based on the text and explanations provided in chapter 2, it seems quite obvious that MET service provision including its systems and equipment will at most require a statement of conformity if already today they were subject to a DSU, otherwise not attestation will be required.

However, this supposed clarity is no longer to be found in the text and paragraphs of the proposed regulations in chapter 8 – Appendix 3. The current text opens the gates for different interpretations and therefore inevitably will result in non-homogeneous transposition and thus contradicts the fundamental principles of the European legislature. From a MET Service Providers perspective, it is not enough to wait for the publication of AMC and GM. Instead, a clear declaration on level IR (e.g. in an annex) based on the examples already presented in the explanations (ref. 2.3.1.2 and 4.3 Table 2 Option 1), stating that only ATM/ANS equipment and constituents of the EATMN but not services used therein are affected by these regulations, is absolutely required.

response *Noted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’. In this context, the proposal anticipates the ATM/ANS equipment to be subject to SoC.

#### 4. Impact assessment (IA)

p. 26

comment 189

comment by: *CANSO*

Paragraph 4 – Page 26 onward

Wording used to describe the Impact Assessment IA seems not aligned to the NPA context. It is important to clarify the difference among equipment, systems, and components.

response *Noted*

The proposal puts forward a definition of ‘ATM/ANS equipment’.

The comment is considered in the Opinion.

comment 563

comment by: *MeteoSwiss*

Throughout the NPA, it is repeatedly emphasised that the proposed requirements for the various levels of system attestations (from the statement of conformity to certification) are intended to serve an equal market environment (ref. 2.1; 2.2; 2.3; 2.4; 4.1; 4.5; 4.6). From the point of view of MET Service Providers, however, it should be noted that the MET systems used are often not available on the market and must therefore either be adapted externally or even developed internally. In these cases, it must also be taken into account that neither small system providers nor MET service providers have the necessary financial or manpower resources to initiate potentially necessary attestation processes. This would not lead to a 'level playing field' but on the contrary to a market distortion to devastate small and medium-sized enterprises and all those MET service providers developing and producing their own, cost-efficient systems providing fully compliant MET services for aviation.

There is a feeling that the proposed regulation might be used by a few large system providers to secure their dominant position in the market and to stifle healthy competition, which entails the risk that the service providers become dependent, for better or worse. From the point of view of MET Service Providers, it must be noted and emphasised that many of the required services could potentially no longer be provided under such market conditions for the manufacturers, as often no such systems are offered on the market and the MET market itself is rather small and unable to cope with the expenses that would become necessary under the proposed regulation. In all the explanations and specifically in the provided Impact Assessment, no reference to the risk that certain services could no longer be provided at all due to a complete and utter lack of available certified and/or declared systems (equipment and/or constituents) is not addressed at all.

The fact that any kind of technical attestation - no matter which tier - will become applicable on top of the already existing certification requirements for service providers will have an impact on cost is also not addressed sufficiently. Even if EASA claims, that the certification and declaration processes are cost neutral from their perspective, the cost generated by such attestation requirements will be cost recovered in one way or another and inevitably will lead to such systems being more expensive and therefore end up with increased over-all costs of service provision.

Due to the certification requirement concerning all ATM/ANS service providers already established by the EU - and here systems/equipment used are already subject to supervision by the national competent authority (CA) via the implementation of the Functional System - a further level of attestation is to be classified as superfluous and will most probably only result in additional workload and unjustifiable additional costs without any demonstrable positive influence on flight safety.

Noting at the same time that the added value for such certification or declaration for MET service provision is unclear, the proposed applicability also to MET Service Providers is seen as not to reflect SES principles of proportionality and cost-efficiency.

response

*Noted*

Taking into account the comment, the addition to the delegated regulation takes the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal



consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation is accordingly adapted.

The draft framework 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. In this context, it is proposed the MET systems to be subject to the SoC; thus, no reorganisation of the MET equipment market is anticipated.

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

comment

617

comment by: *Austro Control*

**Comment:**

"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." Even EASA acknowledges that there are no safety issues, but devises a scheme based on the pure assumption that action regarding safety must be taken. There is no justification nor an explanation for this.

**Proposed Change:**

Revise the text

**Classification:**

Major/conceptual

response

*Noted*

The comment is considered in the Opinion.

comment

618

comment by: *Austro Control*

**Comment:**

"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." This statement neglects that ATM/ANS equipment is not used off-the-shelf but heavily configured and that it must interact with a variety of systems. The configuration and integration is thus a major effort in the entire development chain.

**Proposed Change:**

Please explain how responsibilities are shared between EASA, DPO, ANSP and CA in regard to system configuration and integration and who takes responsibility for the final system

**Classification:**

Major/conceptual

response

*Noted*

The proposal allows the integration of different modules/products by the ATM/ANS providers. When such modules/products contain functionalities subject to certification or declaration, they must have been designed and produced under the responsibility of an approved DPO. Such DPOs can place freely their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and their business cases. Additionally, it is important to highlight that any ATM/ANS provider could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

780

comment by: *EUROCONTROL*

EASA staffing and competence

No plan is provided on the impact this regulatory framework will have on EASA needs on staffing and competence and the associated timeline (potential delays on deployment -e.g. CP1 -).

We are concerned that with this proposal EASA would become a single point of failure in the case it cannot provide the adequate resources and competence.

What will be the competency scheme of the concerned inspectors and their capability to keep on with a fast-evolving industry?

ATM/ANS.EQMT.AR.B.001(2) only refers to "availability of personnel" and "proper completion of all related tasks": "sufficient", "proper" this is not enough.

Proposed action:

EASA should provide a trustworthy plan defining its needs and associated strategy to get the needed staff and competence. And a provisional plan for the associated costs.

response

*Noted*

The comment is considered in the Opinion.

Please refer to Section 2.5 'EASA acting as competent authority' of Opinion No 01/2023.

comment

818

comment by: *EUROCONTROL*

**Impact assessment - General comment:**

It is not clear what the problem is that this proposed regulation is trying to solve. It is also not clear what cost reduction it can have on all categories of ATM/ANS stakeholders, first estimates on EUROCONTROL indicates that there is a significant cost impact for the NM, MUAC and other activities such as tools and services and innovation.

Moreover, for ARTAS for example not only the cost, resources and delay supporting the new certification requirements will significantly increase (we estimate a factor of 4 compared to today) but, and most importantly, the additional time necessary for an emergency fix to deploy into operational. There is a clear risk that ANSPs could face a crash of their systems as the certification for the emergency fix will be late (too late).

Proposed actions:

EASA shall provide a quantified impact assessment that can demonstrate the claims and clarify the issues that this regulation intends to solve.

EASA should consider how to manage quick fixes that could hinder and potentially stop operational systems.

response

*Noted*

The comment is well received.

The Agency would welcome quantitative information to further substantiate the analysis.

The additional information would justify or reject the statements presented by commenter.

comment

821

comment by: *EUROCONTROL*

**Maintenance**

How the maintenance organisation would be affected by this proposed regulation. In particular, further clarification should be provided regarding re-certification requirements.

In the NPA impact assessment we could not find any consideration regarding maintenance costs notably regarding the DPO and SPs.

Moreover, for maintenance activities, it is not clear also what would happen if the initial equipment manufacturer does not exist or does not want to conform to the new process.

Proposed actions:

EASA should provide additional provisions on re-certification by maintenance organisations if applicable, as well as new provisions regarding DPO transfer maintenance activities to another organization.

response

*Noted*

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, this proposal should differentiate 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 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.

In conclusion, the activity between the routine maintenance and upgrades/evolution is clearly allocated between the ATM/ANS providers and the ATM/ANS equipment manufacturer.

In addition, please refer to topic 'Roles and responsibilities of the different actors'.

Moreover, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

856

comment by: ENAV

Paragraph 4 – Page 26 onward

Wording used to describe the Impact Assessment IA seems not aligned to the NPA context. It is important to clarify the difference among equipment, systems, and components

response

*Accepted.*

The comment is considered in the Opinion aiming at ensuring consistency.

comment

857

comment by: ENAV

To further delay introduction of and increase the workload for new technologies by more certification requirements and administrative workload will benefit companies and inventions outside of Europe. Companies within Europe might lose initiative by more regulation in this field. The notion of "... compromising safety, performance and the necessary confidence in solutions..." has to be weighed against possibility to make new inventions and be on the frontlines of technological advances that benefit Europe.

response

*Noted*

The intent of the 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, is not to jeopardise the development and integration of new technologies; it should be noted that the deployment of detailed specifications would not be managed through the committee procedure.

For further details, please refer to the following topics:

- ‘Impact assessment’;
- ‘Roles and responsibilities of the different actors’; and
- ‘Access to the market’.

comment

1057

comment by: DGAC (French CAA)

Reference: §4.1.2 – Who is affected – “*but [ATM/ANS providers] will not perform any more activities in relation to the conformity assessment of the most critical ATM/ANS equipment*”

Comment: ATM/ANS providers may design and produce ATM/ANS equipment by themselves or may contribute at some stage to the development and/or integration of equipment. Is it foreseen that the ATM/ANS provider should apply to a DPO approval complementary to the ATM/ANS provider certificate, or could it be considered that the ATM/ANS provider certificate grants DPO privileges? Would EASA also perform DPOA certification audits of currently certified ATM/ANS providers or could it be delegated to Member States NSA?

Proposal: Clarify the situation for ATM/ANS providers involved in equipment design and production.

response

Noted

Please refer to topic ‘Impact assessment’, in particular to topic ‘Certification costs and impacts on the market’.

#### 4.1.2. Who is affected

p. 26

comment

240

comment by: Indra Navia

How far does the scope of the definition “Organisations involved in the design and/or production of ATM/ANS Equipment” reach? Many components, that form part of ATM/ANS equipment are manufactured outside the factories of the ATM/ANS equipment suppliers. Examples:

Manufacturers of general computer platforms, Ethernet switches etc.

Manufacturers of components (microprocessors, controllers, FPGAs and all the way down to simple hardware components)

General manufacturers of circuit boards, manufacturing boards based on the ATM/ANS manufacturers detailed specifications  
 Mechanical factories (antennas, racks, masts etc) delivering mechanics based on designs specified by the ATM/ANS equipment supplier.  
 Do these organisations require an approval as “organisations involved in production of ATM/ANS equipment”? The first two categories are addressed as “Commercial-off-the-shelf” suppliers according to ED-109A/ED-80 today, and the products delivered are analyzed, integrated and tested within the ATM/ANS equipment supply chain. In the last case, it should be taken into account that very few ATM/ANS equipment manufacturers, if any, have internal manufacturing facility for circuit boards any longer. This work is typically sourced to a generic manufacturer, manufacturing based on the ATM/ANS equipment supplier’s design, that is being audited and followed up closely by the ATM/ANS equipment supplier. Please ensure that the regulation is clear in terms of limiting the scope. This scope must also be clear in all AMC and GM that will be issued later on.

response

*Noted*

The comment is considered in the Opinion.

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. In this context, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

For further details please refer to topics:

- ‘Roles and responsibilities of the different actors’; and
- ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

In conclusion, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

360 comment by: LEONARDO

It is not clear if the ANSP are considered the final responsible for system integration. The integration responsibility should be under DPO responsibility

response

*Noted*

The proposed framework stipulates that the DPO will be responsible to specify, design and produce the equipment. The equipment will need to be certified or the DPO will need declare that the equipment is compliant with the relevant essential requirements through the demonstration of compliance with the detailed specifications, depending on the type of equipment. ATM/ANS equipment will then be integrated into the functional system of an ATM/ANS provider.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

379

comment by: *Civil Aviation Authority the Netherlands*

It should be mentioned here that service providers design and produce - or adjust significantly - their ATM/ANS equipment. Therefore almost all service providers will be affected. The impact assessment does not address that service providers are also manufacturers.

response

*Noted*

The comment has been considered in the proposal.

Please refer to the following topics:

- 'Roles and responsibilities of the different actors'; and
- 'Impact assessment', in particular 'Certification costs and impacts on the market'.

comment

380

comment by: *Civil Aviation Authority the Netherlands*

4.1.2 Who is affected

"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."

The proposed regulation is a limited reduction in work, compared to the work that oversight of the integration and entry into service of the ATM/ANS equipment comprises.

response

*Noted*

Nowadays the competent authorities are responsible via the oversight of the ATM/ANS provider to oversee the complete life cycle of an ATM/ANS equipment, while the establishment of common rules for ATM/ANS equipment within the EU facilitates the efficient use of related resources at Union and national level. Indeed, national authorities will experience less burden and work reduction as all activities linked to the conformity assessment at national level will benefit from a single, mutually recognised EASA certification or declaration processes.

Once an item of ATM/ANS equipment is certified/declared, the user (ATM/ANS provider) should install and integrate it respecting the DPO requirements, and undertake the routine maintenance required to ensure that the equipment remains functional, which will be the scope of the oversight of the national competent authorities.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

602

comment by: NATS

Paragraph 3

Page 26

The ANSP currently plays a much bigger role in the development of a new product than just overseeing the manufacturer; it appears this could be lost (unless ANSP also certifies as a DPO).

response

*Noted*

The comment is considered in the Opinion.

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

603

comment by: NATS

Paragraph 5

Page 26

This creates is a potential bottleneck which the 552 framework avoided through the concept of Notified Bodies; in hindsight, ANSPs/EUROCONTROL could have fulfilled this role, offering independent test platforms against which the conformity of products could have been assessed... this independent testing would have offer other ANSPs more confidence.

response

*Noted*

The commener is invited to note that Regulation (EC) No 552/2004 is repealed with effect from 11 September 2018. However, Articles 4, 5, 6, 6a and 7 of that Regulation and Annexes III and IV thereto continue to apply until the date of application of the new framework.

In this context, Article 8 on Notified bodies does not apply since the referenced date.

comment

749

comment by: POL CAA LOZ-4

The CAA's tasks will be reduced and reduced from what level? After all, the supervision mentioned in this paragraph is already being carried out by the CAA today anyway.

response

*Noted*

For ATM/ANS equipment which will be subject to certification/declaration, the oversight by the national competent authorities will focus on the integration of the ATM/ANS equipment; while for the ATM/ANS equipment which will be subject to SoC, the commenter is right that the oversight will remain within the NSA's scope, as the current practice nowadays is.



For further details, please refer to 'Roles and responsibilities of the different actors'.

comment

923

comment by: AESA

Regarding the next paragraph from chapter 4.1.2: "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."

So, with the entry into force of this Regulation, the oversight of the integration and entry into service is considered regulated in ATM/ANS.OR.A.045 for all ATM/ANS equipments (subject of certification/declaration/statement of compliance)?

response

*Noted*

If the Agency understands correctly the question, the answer is affirmative.

comment

1098

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

"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." This statement neglects that ATM/ANS equipment is not used off-the-shelf but heavily configured and that it must interact with a variety of systems. The configuration and integration is thus a major effort in the entire development chain.

Please explain how responsibilities and liability are shared between EASA, DPO, ANSP and CA in regard to system configuration and integration and who takes responsibility/liability for the finally deployed system.

response

*Noted*

The comment is considered.

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

1188

comment by: *Deutscher Wetterdienst*

*"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."*

That's a correct statement, unclear if that is going to stay, or if that is suppose to be changed with the new IOP regulations.

response *Noted*

In response to the question, please refer to topic 'Roles and responsibilities of the different actors'.

comment *1198*

comment by: *FerroNATS*

SPs remain accountable for the service they provide through their Compliance Monitoring and compliance with ATM/ANS.OR.B.015 (contracted activities). All the processes for demonstration of compliance with requirements (regulatory, technical, functional, non-functional, SW...) on the procured equipment will need to remain.

response *Accepted*

The proposal does not anticipate any change to the referenced provisions, including ATM/ANS.OR.B.015.

#### **4.1.1. Safety risk assessment**

p. 26

comment *264*

comment by: *CANSO*

To further delay introduction of and increase the workload for new technologies by more certification requirements and administrative workload will benefit companies and inventions outside of Europe. Companies within Europe might lose initiative by more regulation in this field. The notion of "... compromising safety, performance and the necessary confidence in solutions..." has to be weighed against possibility to make new inventions and be on the frontlines of technological advances that benefit Europe.

response *Noted*

The intent of the 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, is not to jeopardise the development and integration of new technologies; it should be noted that the deployment of detailed specifications would not be managed through the committee procedure.

For further details, please refer to the following topics:

- ‘Impact assessment’;
- ‘Roles and responsibilities of the different actors’; and
- ‘Access to the market’.

comment 317

comment by: *Nils PALMQVIST*

The ability for a central body such as EASA to understand if a technology is mature enough to be used in the complex environment of a specific ATS unit for which it is specified and designed is limited. ATM/ANS need new technologies and systems to cope with increasing demands and lower costs.

response *Noted*

The intent of the 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, is not to jeopardise the development and integration of new technologies.

The proposal is considered as achieving a good balance between the need to ensure the necessary integrity, performance, and reliability of critical ATM/ANS equipment and the flexibility to drive innovation and effective deployment of new technologies/functionalities.

comment 318

comment by: *Nils PALMQVIST*

To further delay introduction of and increase the workload for new technologies by more certification requirements and administrative workload will benefit companies and inventions outside of Europe. Companies within Europe might lose initiative by more regulation in this field. The notion of “... *compromising safety, performance and the necessary confidence in solutions...*” has to be weighed against possibility to make new inventions and be on the frontlines of technological advances that benefit Europe.

response *Noted*

The intent of the 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, is not to jeopardise the development and integration of new technologies; it should be noted that the deployment of detailed specifications would not be managed through the committee procedure.

For further details, please refer to the following topics:

- ‘Impact assessment’;

- ‘Roles and responsibilities of the different actors’; and
- ‘Access to the market’.

comment 378

comment by: *Civil Aviation Authority the Netherlands*

4.1.1

“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.”

Throughout the NPA safety is used as an argument for the proposed regulation. There is no proof for this argument and based on assumptions, as is stated here and commonly acknowledged. Furthermore (EU)2017/373 already ensures safety of ATM/ANS equipment sufficiently.

In case that conformity assessment would be expanded to certification and declaration (new style) in the framework of safety, it would lead to:

- Double work, as the competent authorities will still carry out the safety reviews of safety related changes to the functional system (this includes the introduction of new/revised equipment), and
- Possibly divergent opinions between the competent authorities, carrying out a safety review and EASA, carrying out oversight in the framework of certification/declaration.

Given the above, in our opinion conformity assessment oversight should remain to be limited to issues of interoperability of equipment. A proper interoperability of systems should then be guaranteed by an elaborate and complete set of sound technical specifications. This elaborate and complete set could be developed within the framework of the current rulemaking task.

response *Accepted*

The comment is agreed and considered in the Opinion.

comment 545

comment by: *FOCA Switzerland*

We understand that the draft proposal (i.e the need for certification / declaration of systems) is not driven by current safety issues but motivated by anticipated safety risks brought by new digital technologies. Would that mean that the certification scheme should be limited to new systems implementing those new digital technologies and should not be applied to legacy

systems? The question is then about the scheme to be applied when we have an evolution of such legacy systems, which require an update of the DSU with the current legislation.

response *Noted*

In response to the question, please refer to topics 'Transitional provisions' and 'Roles and responsibilities of the different actors'.

comment 1097 comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Even EASA acknowledges that currently there are no safety issues, but devises a scheme based on the pure assumption that action regarding safety must be taken. Please add a justification or an explanation for this.

response *Noted*

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, which was not adequately achieved with the current SES IOP framework in place since 2004.

For further details, please refer to topic 'Impact assessment'.

The comment is considered in the Opinion.

#### 4.1.3. How could the issue evolve

p. 27

comment 319 comment by: *Nils PALMQVIST*

Are the markets and service provisions in Europe so unified that it will be possible for DPOs to develop products that will fit several markets? There are big differences between countries regarding for instance Civil/Military integration, handling of ENR/TMA in same ground equipment, various airspace classes etc.

response *Noted*

The proposal would not impact the procurement by the ANSP of a 'tailor-made' product.

An ATM/ANS provider (or consortium) could develop the user requirements/specifications. The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of Regulation (EU) 2018/1139) and contractual requirements (user requirements).

comment

381

comment by: *Civil Aviation Authority the Netherlands*

4.1.3 How could the issue evolve

“In the absence of appropriate, specific, and proportionate provisions on the attestation of ATM/ANS equipment...”

Introduction of new technologies above all requires sound technical detailed specifications. In our opinion, the focus of this NPA should be on this. As this is not the case in the current proposed regulatory set-up, it could be expected that the current proposed set-up will not achieve this goal.

response

*Noted*

It is agreed that having a better identification of the requirements to ensure compliance with the essential requirements, through the detailed specifications, will improve the overall performance of the conformity assessment processes.

For further details, please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

comment

387

comment by: *Civil Aviation Authority the Netherlands*

4.1.3 How could the issue evolve

“- the predominance of local (national) technical specifications [...]”

The current framework puts no limits to the level playing field. A fragmented market has a level playing field contrary to a market with a limited number of suppliers. This argument should be removed.

response

*Noted*

Please refer to topic ‘Impact assessment’, in particular ‘Level playing field and benefits’.

comment

388

comment by: *Civil Aviation Authority the Netherlands*

4.1.3 How could the issue evolve

5th paragraph: “[...] contrary to the practice followed in the other aviation domains (e.g. airworthiness).”

The ATM/ANS equipment market is compared with the market for airworthiness equipment in this NPA. Whilst in airworthiness a high level of standardisation can be achieved for aircraft that have to perform equally everywhere, ATM/ANS equipment has to be very configurable

to be able to optimise performance for different airports, operators, airspace, etc. Regulations for airworthiness therefore do not seem to be appropriate in this case and should therefore rather not form the basis for ATM/ANS equipment regulations.

response

*Noted*

The commentator is invited to note that not all ATM equipment will be subject to attestation considering the nature and the risk of the particular activity.

For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

389

comment by: *Civil Aviation Authority the Netherlands*

4.1.3

"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)."

The current framework puts no limits to the level playing field. This statement should be removed at multiple places in the NPA.

response

*Noted*

Please refer to topic 'Impact assessment', in particular 'Level playing field and benefits'.

comment

605

comment by: *NATS*

Paragraph 2

Most ANSPs do make use of the DoC/DSUs... but we normally can't rely solely on them as evidence that the product will actually do what we need it to do; the TF builds on these declarations and ensures that each constituent and the overall system meet the requirements placed on them.

Most issues are arguably the result of poor standards and the realities of integrating new components into much wider existing operational system, rather than the 552 framework.

In general, we are still a long way from ANSPs being able to deploy COTS (commercial off the shelf) products and trying to force this could create far more problems than it solves.

response

*Noted*

The comment is considered in the Opinion.

The purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and he users, such as ANSPs. As the commenter mentions, the purpose of the proposal is to replace the use of poor standards by a more robust control mechanism.

For further details, please refer to 'Roles and responsibilities of the different actors'.

comment 607

comment by: NATS

Paragraph 2

This is a good idea, but the proposal takes it too far, requiring organisational certification and oversight of all DPOs regardless of the number of "criticality" of the products they manufacturer.

**Organisational certification should be optional, to be utilised by DPOs where it makes sense for them (unless – in exceptional cases – the nature of the product makes this essential); the framework should allow for alternatives to DPO organisational approvals.**

response *Noted*

In response to the question, please refer to topic 'Roles and responsibility of the different actors' as well as to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 619

comment by: Austro Control

**Comment:**

"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" It remains unclear why is this not a level playing field. The rules are the same for everyone, which meets the definition of a level playing field

**Proposed Change:**

Remove this and all references to level playing field as the statements are simply wrong.

**Classification:**

Major/conceptual

response *Noted*



Please refer to topic 'Impact assessment', in particular 'Level playing field and benefits'.

comment 1099 comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

"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"

It remains unclear why currently there is not a level playing field. The rules are the same for everyone, which meets the definition of a level playing field.

Remove this and all references to level playing field as the statements are wrong.

response *Noted*

Please refer to topic 'Impact assessment', in particular 'Level playing field and benefits'.

## 4.2. What we want to achieve - objectives

p. 27

comment 390 comment by: *Civil Aviation Authority the Netherlands*

4.2 What we want to achieve — objectives

Compared to the Terms of Reference of this rule making task, two objectives are slightly changed and an new objective has been added in section 2.2. The consequences for the impact assessment should be mentioned clearly.

response *Noted*

The objectives have been adjusted during the rules development process.

The impact assessment reflects the objectives included in the proposal.

For further details, please refer to topic 'Impact assessment'.

## 4.3. How we want to achieve it - options

p. 28

comment 164 comment by: *COULON FR SAA*

*EASA proposes a single, harmonised and mutually recognised mechanism to attest the compliance*

mil ATM equipment should not abide by the same criterias. the performance based approach should be adapted to mil missions and objectives.

response

*Noted*

The proposal establishes the framework on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military.

In addition, having in mind that the commented proposed framework is DA/IA on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e. it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military. However, Member States should ensure that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

comment

236

comment by: *Indra Navia*

It is noted that equipment types that are generally subject to changes and adaptations for each installation/delivery, are proposed as subject to certification.

Many ATM/ANS equipment types can be subject to some bespoke development and sometimes quite comprehensive customer adaptation for each delivery. Even for certified systems, it should be possible to declare quite comprehensive changes using a declaration process, without having to wait to go operational until after EASA has addressed the declaration. Please refer to paragraph 4.5.4, page 35, where it is suggested that these types of equipment could be subject to certification.

Furthermore, customers often expect suppliers to make modifications after installation, right until shortly before the system goes operational. There is still an expectation to be able to go live shortly after the customer is satisfied with the functionality *and* associated verification and paperwork. How can a certification/change process be organized so that it does not delay the customer's go-live-date?

response

*Noted*

The proposal would not impact the deployment by the ANSP of a 'tailor-made' product.

An ATM/ANS provider (or consortium) could develop the user requirements/specifications. The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of regulation (EU) 2017/1139) and

contractual requirements (user requirements). For further detail, please refer to topic 'Roles and responsibilities of the different actors'.

In response to the question, please refer to topic 'ATM/ANS equipment change management' in case the ATM/ANS equipment in question is subject to certification/declaration.

comment 265

comment by: CANSO

It is stated "*With this approach, the essential requirements as regards safety, performance and interoperability would be met.*" Well, the same is true for option No 0. ANSPs will still have to fulfil requirements on safety, performance and interoperability if option No 0 becomes reality.

response *Noted*

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. In this context, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

For further details please refer to topic 'Roles and responsibilities of the different actors'.

In addition, please refer to topic 'Impact assessment', in particular 'Option chosen'.

comment 320

comment by: Nils PALMQVIST

It is stated "*With this approach, the essential requirements as regards safety, performance and interoperability would be met.*" Well, the same is true for option No 0. ANSPs will still have to fulfil requirements on safety, performance and interoperability if option No 0 becomes reality.

response *Noted*

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. In this context, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, please refer to topic 'Impact assessment', in particular 'Option chosen'.

comment

391

comment by: *Civil Aviation Authority the Netherlands*

4.3. How we want to achieve it — options  
Option 0

In our opinion, there should be an option inbetween 0 and 1 which would more or less be the continuation of the current situation, effectuated with a new regulation similar to (EC) 552/2004. The comparison between the Option 0 and 1 put forward in this impact assessment is therefore in our opinion incomplete.

response

*Noted*

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. In this context, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

For further details please refer to topic 'Roles and responsibilities of the different actors'.

In addition, please refer to topic 'Impact assessment', in particular 'Option chosen'.

comment

392

comment by: *Civil Aviation Authority the Netherlands*

4.3. How we want to achieve it — options  
Option 1

The proposed regulation includes much more than 'only certain safety-critical equipment' as is illustrated later in the same section under "Note to option 1". This impact assessment should have taken into account the complete scope of equipment that is used in the proposed regulation.

response

*Noted*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. In this context, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, please refer to topic 'Impact assessment', in particular 'Option chosen'.

comment

606

comment by: ERA a.s.

ERA a.s. considers Option No 0 as a scenario which has already happened. The Regulation 552/2004 ceased to exist. ERA uses Regulation 2018/1139 to declare safe interoperability. ERA has not faced any issue connected to this Regulation, therefore ERA considers Option No 0 sufficient for the future.

response

*Noted*

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. In this context, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, please refer to topic 'Impact assessment', in particular 'Option chosen'.

comment

608

comment by: NATS

#### Note to Option 1

Page 28

Disagree: the proposed framework focuses on equipment approval, while compliance with most of the applicable requirements can only be fully achieved at System level-.

Noting that almost all technical specifications contain some degree of ambiguity, the generic specifications to be produced by EASA will not ensure a product is suitable for use within any given ANSP's environment

response

*Noted*

This proposal focuses on the framework as commented, while RMT.0161 Subtask 3 is focusing on the detailed specifications. The comment will be further considered in the context of the activities of RMT.0161 Subtask 3.

For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

858

comment by: ENAV

It is stated "*With this approach, the essential requirements as regards safety, performance and interoperability would be met.*" Well, the same is true for option No 0. ANSPs will still have

to fulfil requirements on safety, performance and interoperability if option No 0 becomes reality.

response

*Noted*

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. In this context, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, please refer to topic 'Impact assessment', in particular 'Option chosen'.

comment

1100

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

The proposal presents a very limited, black-and-white view of the options. Between the do-nothing option and the proposed approach, there are several more light-weight options that have been disregarded. EASA should consider other, more light-weight approaches like certification only at module interface level and assess them as well.

response

*Noted*

Please refer to topic 'Impact assessment', in particular topic 'Option chosen'.

The proposal does not prevent the integration of different modules/products by the ATM/ANS providers. When such modules/products contain functionalities subject to certification or declaration, they must have been designed and produced under the responsibility of an approved DPO. Such DPOs can place freely their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and their business cases. Additionally, it is important to highlight that any ATM/ANS provider could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

#### 4.4.1. Methodology applied

p. 29

comment

266

comment by: *CANSO*

Regarding the text "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.” This does not give a correct and fair assessment. Either set the option 0 as the baseline (score 0) for all criteria and validate option 1 to that baseline, OR validate both option 0 and option 1 to the same criteria from the Basic Regulation. To neglect all scoring for Option 0 in regards to the base line in the Basic Regulation is not a correct way to do it.

response *Noted*

Please refer to topic ‘Impact assessment’, in particular topics ‘Methodology used and scoring proposed’ and ‘Option chosen’.

comment 321

comment by: *Nils PALMQVIST*

Regarding the text “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.” This does not give a correct and fair assessment. Either set the option 0 as the baseline (score 0) for all criteria and validate option 1 to that baseline, OR validate both option 0 and option 1 to the same criteria from the Basic Regulation. To neglect all scoring for Option 0 in regards to the base line in the Basic Regulation is not a correct way to do it.

response *Noted*

Please refer to topic ‘Impact assessment’, in particular topics ‘Methodology used and scoring proposed’ and ‘Option chosen’.

comment 859

comment by: *ENAV*

Regarding the text “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.” This does not give a correct and fair assessment. Either set the option 0 as the baseline (score 0) for all criteria and validate option 1 to that baseline, OR validate both option 0 and option 1 to the same criteria from the Basic Regulation. To neglect all scoring for Option 0 in regards to the base line in the Basic Regulation is not a correct way to do it

response *Noted*

Please refer to topic ‘Impact assessment’, in particular topics ‘Methodology used and scoring proposed’ and ‘Option chosen’.

comment 1101

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

"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."  
While the ranking of options in this approach might be correct, it distorts the absolute values of the options and creates a false impression of the relative differences. Please explain and correct!

response

*Noted*

Please refer to topic 'Impact assessment', in particular topics 'Methodology used and scoring proposed' and 'Option chosen'.

#### 4.5.1. Safety impact

p. 30

comment

148

comment by: *DSNA*

*The mandatory application of the EASA detailed specifications (as opposed to the voluntary use of Community specifications 17 ) is also expected to reduce the potential for unsafe deployment.*

Comment: True only if detailed specifications are harmonized thanks to a large consultation between all stakeholders.

response

*Accepted*

EASA could indeed confirm that the process to develop and maintain the detailed specifications will contain wide industry involvement and proper public consultation.

For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

216

comment by: *CANSO*

The mandatory application of the EASA detailed specifications (as opposed to the voluntary use of Community specifications 17 ) is also expected to reduce the potential for unsafe deployment.

Comment: True only if detailed specifications are harmonized thanks to a large consultation between all stakeholders.

response

*Accepted*



EASA could indeed confirm that the process to develop and maintain the detailed specifications will contain wide industry involvement and proper public consultation.

For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

393

comment by: *Civil Aviation Authority the Netherlands*

4.5.1 Safety impact  
"With Option 1[...]"

Following our comment on paragraph 4.1.1, there cannot be a positive safety effect for Option 1.

response

*Noted*

The comment is considered in the Opinion.

For further details, please refer to topic 'Impact assessment', in particular topic 'Methodology used and scoring proposed'.

comment

395

comment by: *Civil Aviation Authority the Netherlands*

Page 31, "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[...]"

The role of national authorities will decrease on this subject with this regulation.

response

*Noted*

The comment is agreed and considered in the Opinion.

comment

396

comment by: *Civil Aviation Authority the Netherlands*

Page 31, "- It allows the accelerated deployment of new functionalities as enabled by the EASA detailed specifications"

"Accelerated deployment of new technologies" is in general not linked to more safe operations.

response

*Noted*

The comment is agreed and considered in the Opinion.

comment

438 ❖

comment by: *Tern Systems*

**Detailed specifications applicable for all operations contexts?**

The NPA assumes that it is possible to create EASA detailed specifications covering all ATM/ANS equipment needs throughout Europe. DPOs have to demonstrate compliance to EASA detailed specifications. What will happen if the SP (Service Provider), the DPO's customer, and EASA disagree on the needs for the equipment? This will hinder cooperation between SPs and DPOs. DPOs will have to comply with EASA specifications - even if they contradict their customer's needs. However, nowadays, SP-to-DPO cooperation drives innovation because it facilitates direct input of operational needs to DPOs. Due to that even small European DPOs stay competitive on the world market. Adding a man-in-the-middle (EASA) will harm this.

How will it be ensured that the needs of all SPs with varying needs are covered by the detailed specifications? How will those specifications be developed? Who will contribute? How is it supposed to be achieved within the proposed time frame? How will we ensure innovation in the future? How will adaptation to the needs of different service providers be supported? Will DPOs have to obtain certificates for different variants of the same equipment? ATM/ANS equipment is often software centric and very adaptable. This is different to the airborne industry.

response

*Noted*

Following the general response under this topic, EASA wishes also to clarify that the proposal tries to achieve a reasonable balance between the need to ensure the necessary interoperability and safety of critical ATM/ANS equipment and the flexibility to drive innovation and effective deployment of new technologies/functionality.

Please note also that the specifications will be prepared by EASA in close cooperation with all interested stakeholders, in particular the relevant industry, then followed by an EASA Decision adopting and issuing the respective set of the detailed (certification/declaration/SoC) specifications. S

Such specifications will provide via a single process the common requirements for the purpose of demonstration of compliance in terms of safety, functionality, interoperability, security and performance as necessary for the European aviation market.

Before the publication of such an ED Decision, the proposed specifications will be publicly consulted through a dedicated EASA NPA. EASA will aim at performance- and objective-based specifications and will refer to widely recognised standards published by industry, developed

through standards development organisations (SDOs), as far as possible, but obviously this is without prejudicing the outcome of the public consultation.

comment 494

comment by: *Karsten T. Fiane (Notodden Airport)*

- i. Notodden Airport welcomes the proposed changes that aim to streamline and simplify the assessment processes before putting equipment into service. Especially do we, as a non-complex provider REF (EU) 2017/373 ATM/ANS.OR.A.010 (b)(2), appreciate that we with the change can presume conformity, as long as the equipment provider and/or the equipment is certified or declared according to this new regulatory framework, since we have limited technical and juridical competence to assess by ourselves if a certain equipment / providers conforms to the aviation industry standard. It is also time and resource consuming for a small organisation (as non complex providers typically are) to identify the necessary documentation and compile the TF the current scheme detailed in 552/2004.
- ii. Notodden Airport will furthermore put forward, that any proposed changes or new requirements in (EU) 2017/373, or any other related regulation, regarding conformity assessment and change management procedures should continue to differentiate between complex and non-complex providers.

response *Noted*

The comment is well received.

comment 564

comment by: *MeteoSwiss*

MET service provision is considered to have no direct safety impact, as their impact on other Service Providers in the ATM/ANS context is more broadly associated with the quality of the service rather than the safety of the respective service. In this regard, the score attributed to Option 1 in Table 3 would have to be amended to 0 from a purely MET Service Provider position. Option 0 and 1 therefore score the same and none would have any positive safety impact.  
(Assumption: 0=neutral; [-]2=FBL; [-]4=MOD; [-]6=HVY)

response *Noted*

Please refer to topic 'Impact assessment', in particular to topic 'Methodology used and scoring proposed'.

comment 613

comment by: *NATS*

Although this proposal may improve the standardisation of the equipment attestation process (as EU 552/2004 provides no detail on the level of NSA oversight of manufacturers, leading to national differences... but noting that the new proposal lacks flexibility), the seeming loss of TFs for ANSPs means the proposed framework would negatively impact the currently standardised manner for ANSP attestation of compliance with the Essential Requirements and associated IRs, leading to new national differences in how this is achieved.

Note that equipment cannot be safe, and although this aspect is specifically covered by EU 2017/373, it is also necessarily covered by the ANSP's Technical Files (because the ERs require a demonstrably safe system), which are currently submitted to support changes to the Functional System in accordance with EU 552/2004 (which is about the Systems used by the ANSP to deliver their certified services).

Without a defined mechanism for ER/IR compliance, different ANSPs/NSAs will almost certainly handle them differently, e.g. some may ignore them entirely, some may try to build them into process or include them in an internal requirement set, others may submit evidence to their NSA, etc... the point of the TFs is to ensure that compliance evidence is documented and maintained for those legislative requirements applicable directly to the System, and that this is made available to the NSA to support the audit of any changes to the System (unlike EU 2017/373 compliance, which should be unaffected by changes to the functional system), including the safety aspects.

**The Essential Requirements are wider than just the safety work required under EU2017/373, and a more appropriate solution would be to update 373 to require the submission and approval of a TF to show ER compliance (including safety), i.e. a single submission to / approval from the NSA, covering all aspects of system compliance.. As the NSA may or may not choose to audit any given change, the ANSP should continue to make a Declaration on the basis of the TF evidence, as per the EU 552/2004 framework.**

response *Not accepted*

It should be noted that the certificate/declaration/SoC is a means to demonstrate design compliance. Only certain ATM/ANS equipment would be subject to certification, i.e. approval before being put into service.

In addition, the purpose of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users.

The competent authority would be able to apply enforcement measures, but as part of the oversight process and no upfront approval would be required.

However, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

615

comment by: *NATS*

Option 1

Page 30

If there is an expectation that ANSPs will reduce their verification activities on the basis of audits performed by EASA, this proposal could have a negative impact on safety, as the equipment could enter service without independent testing.

response

*Noted*

In response to the comment, please refer to topic 'Roles and responsibilities of the different actors'.

Furthermore, the commenter should consider that with the suggested proposal a more important verification role will be provided to DPO, thus leading to enhanced safety.

comment

860

comment by: *ENAV*

The mandatory application of the EASA detailed specifications(as opposed to the voluntary use of Community specifications<sup>17</sup> ) is also expected to reduce the potential for unsafe deployment.

Comment: True only if detailed specifications are harmonized thanks to a large consultation between all stakeholders.

response

*Accepted*

EASA could indeed confirm that the process to develop and maintain the detailed specifications will contain wide industry involvement and proper public consultation.

For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

1103

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Table 3: A value of "+4" contradicts section 4.1.1, where it is stated that with the current approach no safety issues have arisen. How could a new scheme perform better than no safety issues? Please explain!

response

*Noted*

The proposal is expected to improve the ability to introduce safety enablers, the ability to ensure the safe and interoperable deployment of new technologies, and the oversight of the technical requirements and the related compliance demonstration processes.

comment

1137

comment by: *EUMETNET*

Comments to chapter 4. Impact assessment (IA) provided in NPA 2022-09 (Assumption: 0=neutral; [-]2=FBL; [-]4=MOD; [-]6=HVY)

- **4.5.1 Safety Impact:** Only some constituents dedicated to MET service provision could have a direct safety impact, when other Service Providers in the ATM/ANS context should base their decisional process upon a partial MET information due to contingencies/failures in those constituents providing information that should enable the activation of ATS/AIS procedures. In general all MET Service Provider has its own QMs implemented and elements of a SMS. In this regard It is believed that from a MET SP point of view that the score attributed to Option 1 in Table 3 would have to be amended taking into account a certain gradualism in assigning the score (e.g. a score +2 for other ATM/ANS equipment or constituents subject to statement of compliance by ATM/ANS providers).

**Conclusion:** From a MET Service Providers perspective, the resulting over-all score would still provide a neutral 0 for Option 0, but would lead to a negative -10 score for Option 1 at best, but could as well lead to a score as low as -16.

response

*Noted*

Please refer to topic 'Impact assessment', In particular to topic 'Methodology used and scoring proposed'.

comment

1171

comment by: *Deutscher Wetterdienst*

MET service provision is considered to have no direct safety impact, as their impact on other Service Providers in the ATM/ANS context is more broadly associated with the quality of the service rather than the safety of the respective service.

In this regard, the score attributed to Option 1 in Table 3 would have to be amended to 0 from a purely MET Service Provider position. Option 0 and 1 therefore score the same and none would have any positive safety impact.

response

*Noted*

The draft framework 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.

The comment is considered, and for further details, please refer to topic 'Impact assessment', in particular to topic 'Methodology used and scoring proposed'.

comment

609

comment by: NATS

## Paragraph 1

Page 30

The safety criticality of equipment may vary from ANSP to ANSP, as there has not yet been any standardisation of ATM/ANS hazards, safety requirements, etc. and this is probably not as simple as it may sound, as the operational environments will have different characteristics which affect this.

Even within a single ANSP, the safety criticality / requirements can vary between different Units, Area and Terminal control, etc. and a system which is suitable for one may not be appropriate for the other. This proposal could also take away an ANSPs ability to choose between e.g. diverse AL4 components versus a single AL2 system, etc.

response

*Noted*

The flexibility for the ATM/ANS providers will remain. The proposal aims to discharge the responsibility to manufacturers.

comment

620

comment by: Austro Control

**Comment:**

"Option 1 will be compared with Option 0, which assumes that:[..]" The proposal presents a very limited, black-and-white view of the options. Between the do-nothing option and the proposed approach, there are several more light-weight options that have been disregarded.

**Proposed Change:**

Add other approaches like certification only at module interface level and assess them.

**Classification:**

Major/conceptual

response

*Noted*

The comment is considered in the Opinion.

For further details, please refer to topic 'Impact assessment', in particular to topic 'Methodology used and scoring proposed'.

comment 622

comment by: *Austro Control*

**Comment:**

"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." Does this mean that the comparison is distorted?

**Proposed Change:**

Please explain and correct.

**Classification:**

Major/conceptual

response *Noted*

The comment is considered in the Opinion.

For further details, please refer to topic 'Impact assessment', in particular to topic 'Methodology used and scoring proposed'.

comment 623

comment by: *Austro Control*

**Comment:**

"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. " Following this logic, all equipment is subject to declaration or certification. Annex VIII of the Basic Regulation mentions all ATM/ANS services including even FPD.

**Proposed Change:**

Reconsider the approach to be more proportional to the real safety and interoperability issues. For example FPD systems cannot pose an immediate safety risk to ATS provision and should therefore be excluded from attestation

**Classification:**

Major/conceptual

response *Accepted*

The commenter should pay attention to point 3 of Annex VIII to the EASA Basic Regulation that directly requires ATM/ANS systems and ATM/ANS constituents providing related information to and from the aircraft and on the ground to be properly designed, produced, installed, maintained, protected against unauthorised interference and operated to ensure



that they are fit for their intended purpose. In this context, FPD is not referenced therein. The referenced systems and constituents are almost identical to those currently addressed in Regulation (EC) No 552/2004.

For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1102

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

"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. " Following this logic, all equipment is subject to declaration or certification. Annex VIII of the Basic Regulation mentions all ATM/ANS services including even FPD.

Reconsider the approach to be more proportional to the real safety and interoperability issues. For example FPD systems cannot pose an immediate safety risk to ATS provision and should therefore be excluded from attestation.

response

*Accepted*

The commenter should pay attention to point 3 of Annex VIII to the EASA Basic Regulation that directly requires ATM/ANS systems and ATM/ANS constituents providing related information to and from the aircraft and on the ground to be properly designed, produced, installed, maintained, protected against unauthorised interference and operated to ensure that they are fit for their intended purpose. In this context, FPD is not referenced therein. The referenced systems and constituents are almost identical to those currently addressed in Regulation (EC) No 552/2004.

For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1170

comment by: *Deutscher Wetterdienst*

The proposed drafts only revise the framework for the currently applicable IOP regulation. The framework proposed allows for (easier) further extension e.g. using DS for equipment subject to certification or declaration. It does not, however, cover the equipment only subject to statement by ANSP.

No further clarification and/or definition of the general terms ATM/ANS systems, ATM/ANS constituents or EATMN are proposed - missing

response

*Accepted*

The comment is considered in the Opinion.

comment

71

comment by: *Thales Land and Air Systems*

Current regulation (EU) 2019/2153 related to fees and charges is not aligned with the future regulation linked to NPA 2022-09 and will need to be updated.

Following inconsistencies are identified between NPA2022-09 and (EU) 2019/2153:

- All fees and charges tables in (EU) 2019/2153 refer to Part 21 sections which is not applicable to ATM/ANS ground equipment
- Fees and charges defined in (EU) 2019/2153 seems not to proper apply to DPO approval model and subsequent oversight

Moreover, fees and charges applicable to ATM/ANS equipment certification and DPO approval are necessary to realistically assess the economical impact of this new regulatory framework. The Regulation Impact Assessment proposed in the NPA2022-09 has to be updated to take into consideration the applicable fees and charges structure.

response

*Accepted*

The comment is considered in the Opinion.

The additional comments will be fully considered during the separate process on the amendment of the Fees & Charges Regulation.

comment  
t

146

comment by: *DSNA*

**#1** - *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 .*

Comment: True only if the first customer does not pay all the extra-cost for certification. DPOs must follow a real product commercial policy in order to share costs between customers. One major difficulty may be that ANSPs are not buying the same products at the same time.

Proposal: EASA to provide more justifications on the compensation of additionnals cost.

**#2** - *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 % of the total cost for the acquisition of ATM/ANS equipment.*

Comment: In the previous paragraph, EASA mentions that "ATM/ANS equipment manufacturers will face additional cost ". In this paragraph, EASA mentions that the cost of acquisition will decrease.

Proposal: EASA to explain how cost can decrease if there are additional costs for manufacturers.

**#3** - *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 ; 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.*

Comment: has EASA estimated the upfront cost for organisation to be approved as a DPO ? ATM/ANS manufacturers may have small range of products and consequently costs of product development and maintenance may increase in the short term which may reduce competitiveness of EU industry in the short term.

**#4** - *Information services: AIM/AIS, MET*

Comment: Information services AIM/AIS, MET seem to be outside of perimeter of equipment to be certified/declared. It is unclear either what will be expected for services (like SWIM or cloud services).

Proposal: EASA to clarify what is expected for services. It is unclear whether certification of service are covered or not through certification of equipment.

**#5** - *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;*

Comment: so far it is impossible to quantify the possible impacts of certification on procurement of equipment, system integration and tests, maintenance. Precise list of concerned equipment is unknown. Contents of future detailed specifications is needed.

Therefore, the balance between the extra cost of procurement and the reduced cost of safety assessment cannot be quantified so far.

Proposal: EASA to define the precise list of equipment subject to certification or declaration and to publish detailed specifications to allow stakeholders to identify the possible impacts.

response *Noted*

Following the order of the comments:

- As regards #1 and #2, please refer to topic 'Impact assessment', in particular to topic 'Certification costs and impacts on the market'.
- As regards #3, the answer is affirmative, this aspect is considered.
- As regards #4, it should be noted that Regulation (EU) 2017/373 addresses the certification of ATM/ANS providers in order to provide ATM/ANS services, while the proposed framework addresses the conformity assessment of certain ATM/ANS equipment.
- AS regards #5, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

190

comment by: CANSO

Paragraph 4 – Page 33

Additional information on how the estimation of 10/15% of the total cost for acquisition has been defined (being estimation different) should be provided.

response

*Noted*

The Agency believes that the concern is addressed in topic 'Impact assessment', in particular 'Certification costs and impacts on the market'.

In case the commenter sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

191

comment by: CANSO

Paragraph 4 – Page 33

For non-critical components, Service Providers shall issue a Statement of Compliance (SoC), with inputs and support by ATM/ANS manufacturers.

We propose an approach similar to what is done today in the framework of Reg 552/2004 when issuing of Declaration of Verification (DoV). The DoV is released after the manufacturers have issued a Declaration of Suitability for Use.

For non-critical components (case 3), it should be mandatory for the ATM/ANS manufacturers to issue an equivalent declaration (e.g., DSU or DOC) that allows ANSP to provide the related Statement of Compliance.

response

*Noted*

In response to the comment, please refer to 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under considerations.

comment

192

comment by: *CANSO*

Paragraph 4 - Page 35

4-Flight is mentioned as example of equipment that needs to be certified. However, this is a system of systems with different components (network, FDP, etc). Please clarify at which level certification is needed.

response

*Noted*

The Agency believes that the concern is addressed in topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In case the commenter sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

217

comment by: *CANSO*

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.

Comment: True only if the first customer does not pay all the extra-cost for certification. DPOs must follow a real product commercial policy in order to share costs between customers. One major difficulty may be that ANSPs are not buying the same products at the same time.

Proposal : EASA to provide more justifications on the compensation of additional cost.

response

*Noted*

The Agency believes that the concern is addressed in topic 'Impact assessment', in particular 'Certification costs and impacts on the market'.

In case the commenter sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

218

comment by: *CANSO*

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 % of the total cost for the acquisition of ATM/ANS equipment.

Comment: In the previous paragraph, EASA mentions that "ATM/ANS equipment manufacturers will face additional cost ". In this paragraph, EASA mentions that the cost of acquisition will decrease.

Proposal: EASA to explain how cost can decrease if there are additional costs for manufacturers.

response

*Noted*

The Agency believes that the concern is addressed in topic 'Impact assessment', in particular 'Certification costs and impacts on the market'.

In case the commenter sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

219

comment by: *CANSO*

#3 - 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; 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.

Comment : has EASA estimated the upfront cost for organisation to be approved as a DPO ? ATM/CNS manufacturers may have small range of products and consequently costs of product development and maintenance may increase in the short term which may reduce competitiveness of EU industry in the short term.

response

*Noted*

The Agency believes that the concern is addressed in topic 'Impact assessment', in particular 'Certification costs and impacts on the market' and the answer is affirmative.

In case the commenter sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

220

comment by: *CANSO*

#4 - Information services: AIM/AIS, MET Comment: Informations services AIM/AIS, MET seem to be outside of perimeter of equipment to be certified/declared. It is unclear either what will be expected for services (like SWIM or cloud services).

Proposal: EASA to clarify what is expected for services. It is unclear whether certification of service are covered or not through certification of equipment.

response

*Noted*

In response to the comment, please refer to 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition it should be highlighted that the proposal addresses only the conformity assessment of certain ATM/ANS equipment, while the certification of ATM/ANS providers for the provision of services is stipulated in Regulation (EU) 2017/373.

comment

221

comment by: *CANSO*

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;

Comment: so far it is impossible to quantify the possible impacts of certification on procurement of equipment, system integration and tests, maintenance.  
Precise list of concerned equipment is unknown. Contents of future detailed specifications is needed.

Therefore, the balance between the extra cost of procurement and the reduced cost of safety assessment cannot be quantified so far.

Proposal: EASA to define the precise list of equipment subject to certification or declaration and to publish detailed specifications to allow stakeholders to identify the possible impacts.

response *Noted*

In response to the comment, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, RMT.0161 Subtask 3 will focus on the detailed specifications thereto. For further details, please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment 267

comment by: *CANSO*

The assessment of economic impact in 4.5.4 is extremely optimistic in promising cost reductions. Especially if all types of ATM/ANS equipment are considered for certification. For some types of equipment it is surely possible to reduce costs, but those types of equipment are not identified anywhere in the NPA. If we assume that all types of equipment can be chosen for certification there is a high risk for cost increase.

Please also note that ANSPs are obliged to comply with the Reference Periods of the Single European Sky Performance Scheme. There is already an extreme economic pressure on ANSPs which is difficult to handle in current business. A new regulation with such uncertainties as CANSO have commented on is not very helpful. The regulation would be easier for ANSPs understand and accept if it could identify specific ATM/ANS equipment or activities where it is very likely that the Agency can contribute to lower costs. For instance selection criteria for choosing ATM/ANS equipment that would fit for centralised specification, or auditing and certifying DPOs on Software Assurance (SWAL and such).

response *Noted*

The Agency believes that the concerns are addressed in topic 'Impact assessment'.

In case the commenter sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.



comment

268

comment by: *CANSO*

The goal of reducing costs is very desirable but the regulation has to be developed with regards to how this could be realised realistically in practical terms. For instance:

- What are the criteria for selecting ATM/ANS constituents for which cost really can be reduced? A too optimistic approach will most likely increase costs instead.
- How will the Agency ensure that needs and input from users (ANSPs) will be addressed? For instance user groups.
- Will there be some kind of review process together with ANSPs when developing a specification?
- How will verification and validation be performed in reality? Will ANSPs participate in some way in verification and validation which the Agency is responsible for?

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that the most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Impact assessment’, in particular ‘Certification costs and impacts on the market’.
- The proposal would not impact the procurement by the ANSP of a ‘tailor-made’ product. An ATM/ANS provider (or consortium) could develop the user requirements/specifications. The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of Regulation (EU) 2018/1139) and contractual requirements (user requirements). For further details, please refer to topic ‘Roles and responsibilities of the different actors’.
- ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.
- Please refer to topic ‘Roles and responsibilities of the different actors’.

In case CANSO sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between CANSO and the Agency, or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

322

comment by: *Nils PALMQVIST*

The assessment of economic impact in 4.5.4 is extremely optimistic in promising cost reductions. Especially if all types of ATM/ANS equipment are considered for certification. For some types of equipment it is surely possible to reduce costs, but those types of equipment are not identified anywhere in the NPA. If we assume that all types of equipment can be chosen for certification there is a high risk for cost increase.

Please also note that ANSPs are obliged to comply with the Reference Periods of the Single European Sky Performance Scheme. There is already an extreme economic pressure on ANSPs which is difficult to handle in current business. A new regulation with such uncertainties as LFV have commented on is not very helpful. The regulation would be easier for ANSPs understand and accept if it could identify specific ATM/ANS equipment or activities where it is very likely that the Agency can contribute to lower costs. For instance selection criteria for choosing ATM/ANS equipment that would fit for centralised specification, or auditing and certifying DPOs on Software Assurance (SWAL and such).

response

*Noted*

The Agency believes that the concerns are addressed in topic 'Impact assessment'.

In case the commenter sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

323

comment by: *Nils PALMQVIST*

The goal of reducing costs is very desirable but the regulation has to be developed with regards to how this could be realised realistically in practical terms. For instance:

- What are the criteria for selecting ATM/ANS constituents for which cost really can be reduced? A too optimistic approach will most likely increase costs instead.
- How will the Agency ensure that needs and input from users (ANSPs) will be addressed? For instance user groups.
- Will there be some kind of review process together with ANSPs when developing a specification?
- How will verification and validation be performed in reality? Will ANSPs participate in some way in verification and validation which the Agency is responsible for?

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that the most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- 'Impact assessment', in particular 'Certification costs and impacts on the market'.
- The proposal would not impact the procurement by the ANSP of a 'tailor-made' product. An ATM/ANS provider (or consortium) could develop the user requirements/specifications. The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of Regulation (EU) 2018/1139) and contractual requirements (user

requirements). For further details, please refer to topic 'Roles and responsibilities of the different actors'.

- 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.
- Please refer to topic 'Roles and responsibilities of the different actors'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

350

comment by: *DAC-LU*

Economic

impact:

While agreeing that the additional cost for ATM/ANS equipment manufacturers and EASA would increase in the short term, there are no tangible argument that 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.

Safety

impact:

In the present situation, Factory Acceptance Test, Site Acceptance Test and demonstrated compliance with applicable implementing rules, should ensure a high level of safety. The involvement of EASA could reinforce the requirements directly on the suppliers.

Innovation

impact:

The goal of the regulation to increase the standardization of the equipment is understood, but it could block the market for newcomers and especially for innovation.

response

*Noted*

The comment is considered in the Opinion.

The concerns are addressed in topic 'Impact assessment'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

397

comment by: *Civil Aviation Authority the Netherlands*

4.5.4 Economic impact  
“- promote cost-efficiency”

The economic benefits in this impact assessment may be applicable for large manufacturers. What is the economic impact for smaller manufacturers that deliver one or two products to one service provider?  
What is the economic impact for service providers that would be labeled as DPO in the proposed regulation?

response *Noted*

The concerns are addressed in topic ‘Impact assessment’, in particular ‘Certification costs and impacts on the market’.

comment 398

comment by: *Civil Aviation Authority the Netherlands*

Page 33, 6th paragraph: “the total decrease in the workload and the associated cost could be quantified in the average of 10-15% of the total cost for the acquisition of ATM/ANS equipment.”

footnote: “Based on feedback collected via interviews and surveys to some ATM/ANS providers and ATM/ANS equipment manufacturers.”

Can this substantial claim be substantiated with a financial report?

response *Noted*

The concerns are addressed in topic ‘Impact assessment’, in particular ‘Certification costs and impacts on the market’.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment 399

comment by: *Civil Aviation Authority the Netherlands*

Page 34, “Impact on competent authorities, including EASA”

“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.”

This implies that all costs due to the implementation of the proposed, extensive regulation will result in higher prices for ATM/ANS equipment, ATM/ANS services and ticket prices.

response

*Noted*

The concerns are addressed in topic 'Impact assessment', in particular 'Certification costs and impacts on the market'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

400

comment by: *Civil Aviation Authority the Netherlands*

Page 34, "Furthermore, for certain ATM/ANS equipment, the certification cost, where applicable, would also impact on the aggregated equipment design and production cost."

Both the costs and the required effort to become certified may limit access to the market for smaller manufacturers. How will this risk be mitigated?

response

*Noted*

Please refer to topic 'Access to the market' as well as to topic 'Impact assessment', in particular 'Certification costs and impacts on the market'.

comment

401

comment by: *Civil Aviation Authority the Netherlands*

Page 34, "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."

As local specificities are required to optimise performance the expected cost reduction is unsure. It should be noted here that the market for ATM/ANS equipment cannot be compared with the market for airworthiness equipment.

response

*Noted*

It is confirmed that even though progress has been achieved during the last few years towards seamless operation of the EATMN, the situation still remains unsatisfactory, with a low level of integration between national air traffic management systems and a slow pace in the introduction of new concepts of operation and technology necessary to deliver the additional required capacity.

The comment is considered in the Opinion and the proposed framework.

comment

402

comment by: *Civil Aviation Authority the Netherlands*

Page 35, “- 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”

This argument confirms the concerns that the proposed regulation will put smaller manufacturers at a disadvantage.

response

*Noted*

The concerns are addressed in topic ‘Impact assessment’, in particular topics ‘Proportionality’ and ‘Level playing field and benefits’.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

403

comment by: *Civil Aviation Authority the Netherlands*

Based on our comments on the paragraph on Economic Impact, we believe the economic impact cannot be +6. The economic effect of the proposed regulation tends to be negative for smaller manufacturers and for service providers.

response

*Not accepted*

Please refer to topic ‘Impact assessment’, in particular ‘Methodology used and scoring proposed’.

comment

433

comment by: *Tern Systems*



**Fair competition is harmed and innovation hindered**

The NPA favours DPOs that can distribute the cost for approval and attestation over many customers and larger competitors that are already more experienced in regulated domains. As a result, the market will change (less DPOs overall) and competition will be reduced. This will likely hinder innovation and create monopolies in the future.

The assumption that EASA detailed specifications and guidance from EASA will in the long-term reduce design and production cost so much that these reductions cover the additional

cost of attestation is not sufficiently demonstrated. Quite in contrast, considering how much equipment is adapted for different customers, we fear that we might have to obtain a certificate/ issue a declaration for each variant of the equipment delivered, that means, basically for each deployment - very much as the current EC-declaration approach - just way more expensive.

response

*Noted*

The comment is duly considered in the Opinion.

The concerns are addressed in topic 'Impact assessment', in particular topics 'Level playing field and benefits' and 'Proportionality'.

In response to the second comment, the proposal put forward a framework that certain ATM/ANS equipment should be subject of conformity assessment, establishing three different attestation instruments considering the nature and the risk of the operation or functionality enabled by the particular equipment. For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, a DPO approval is required in order for an organisation to be able to apply for the certification or to declare the design compliance of ATM/ANS equipment. This will be required only for a subset of functionalities supporting the provision of ATM/ANS services, and the organisation taking responsibility for the design and production compliance will need to be approved as a DPO. Suppliers of a DPO will not need to be approved, but the integration/use of the subcontracted products and/or services to produce the ATM/ANS equipment will be under the control/management system of the approved DPO. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

441 ❖

comment by: *Tern Systems*

**Claim of reduction of cost is not proven**

When justifying the cost of approval and certification for the DPO in this NPA, guidance from EASA to DPOs is promised. Also, EASA detailed specifications are named several times as a cost-reducing factor. However, it remains unclear what the guidance would entail and how detailed the EASA detailed specifications can be expected to be. With the currently available information it is hard to predict the long-term effect this has on development costs. It is unclear if the availability of detailed specifications counterweights the additional regularly reappearing approval and attestation costs that are likely higher than the current costs for declarations of constituent conformity or suitability for use. It is likely that equipment cost will increase permanently - relatively more for DPOs with fewer customers. In the end, this cost will be carried by the service providers (in the end the travellers).

For ATM/ANS providers, reduced testing and equipment verification activities are promised. But the service provider is and stays accountable for the service offered. Additionally, issues usually surface during the integration with equipment from other DPOs and the operational

environment. ATM/ANS providers will still test the equipment to gain trust and experience with the equipment in its operational environment and to ensure the quality and safety of services provided. It is doubtful that those efforts will be reduced considerably.

response

*Noted*

The concerns are addressed in topics 'Detailed certification/declaration/SoC (technical) specifications and their development/availability' and 'Roles and responsibilities of the different factors'.

comment

443 ❖

comment by: *Tern Systems*

**Costs for service providers that are also DPOs increase**

Many ATM/ANS providers are DPOs themselves. Adding attestation costs to their costs will not decrease their costs as promised.

response

*Noted*

The comment is considered in the Opinion.

Please refer to topic 'Roles and responsibilities of the different factors'.

comment

454

comment by: *NAV Portugal E.P.E*

**Paragraph 4 – Page 33**

*"For non-critical components, Service Providers shall issue a Statement of Compliance (SoC), with inputs and support by ATM/ANS manufacturers."*

We support CANSO's proposal to have an approach similar to what is done today in the framework of Reg. 552/2004 when issuing the Declaration of Verification (DoV). The DoV is released after the manufacturers have issued a Declaration of Suitability for Use.

For non-critical components (case 3), it should be mandatory for the ATM/ANS manufacturers to issue an equivalent declaration (e.g., DSU or DOC) that allows ANSPs to provide the related Statement of Compliance.

The NPA states that 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 % of the total cost for the acquisition of ATM/ANS equipment.

However, in the previous paragraph, EASA mentions "**ATM/ANS equipment manufacturers will face additional cost**". In this paragraph, EASA mentions that the cost of acquisition will



decrease which seems to be in contradiction with the previous statement. Therefore, EASA needs to explain how cost can decrease if there are additional costs for manufacturers.

response *Noted*

In response to the comment, please refer to topic 'Roles and responsibilities of the different factors'. In addition, taking into account the comment, the development of the associated AMC/GM is under consideration, in particular to ATM/ANS.OR.A.045 (g).

In response to the second comment, please refer to topic 'Impact assessment', in particular to topic 'Costs and impact on the market'.

comment

463

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**4.5.4, page 32**

Comment on the impact assessment.

EASA do not account for any quantities in terms of approximately how many organisations believed to apply for a certificate DPO. Nor the appreciated costs to be certified DPO, or to certify/declare equipment.

response *Noted*

Please refer to topic 'Impact assessment', in particular to topic 'Methodology used and scoring proposed'. In this context, it should be highlighted that the approval costs depend on the complexity of the manufacturers and respective production.

comment

464

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**4.5.4, page 32**

Do EASA consider any non-complex organisation as described in (EU) 2017/373 ATM/ANS.OR.A.010, regarding DPO certificates for the smaller organisations to apply for?

response *Noted*

If the question is well understood, the answer is negative. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

465

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**4.5.4, page 32**

What will be the fee for DPO certification according?

response

*Noted*

The subject Regulation on Fees & Charges will be subject to amendment and at this stage the question is not possible to be responded accurately.

comment

495

comment by: *Karsten T. Fiane (Notodden Airport)*

- i. Notodden Airport welcomes the proposed changes that aim to streamline and simplify the assessment processes before putting equipment into service. Especially do we, as a non-complex provider REF (EU) 2017/373 ATM/ANS.OR.A.010 (b)(2), appreciate that we with the change can presume conformity, as long as the equipment provider and/or the equipment is certified or declared according to this new regulatory framework, since we have limited technical and juridical competence to assess by ourselves if a certain equipment / providers conforms to the aviation industry standard. It is also time and resource consuming for a small organisation (as non complex providers typically are) to identify the necessary documentation and compile the TF the current scheme detailed in 552/2004.
- ii. Notodden Airport will furthermore put forward, that any proposed changes or new requirements in (EU) 2017/373, or any other related regulation, regarding conformity assessment and change management procedures should continue to differentiate between complex and non-complex providers.

response

*Noted*

The comment is well received.

comment

506

comment by: *Belgian NSA*

Text of the NPA page 35

*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.*

It is not clear how they could be cost savings for AIS and MET, because the proposed ATM equipment certification scheme does not address those points.

response	<p><i>Noted</i></p> <p>In response to the comment, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'. The commented ATM/ANS equipment is proposed to be subject to SoC.</p>
comment	<p>510 <span style="float: right;">comment by: <i>Deutscher Wetterdienst</i></span></p> <p>The fact that any kind of technical attestation - no matter which tier - will become applicable on top of the already existing certification requirements for service providers will have an impact on cost is not addressed sufficiently. Even if EASA claims, that the certification and declaration processes are cost neutral from their perspective it would be naïve to believe the cost generated by such attestation requirements would not be cost recovered in one way or another and inevitably would lead to such systems being more expensive and therefore end up with increased costs of service provision.</p>
response	<p><i>Noted</i></p> <p>Please refer to topic 'Impact assessment', in particular to topic 'Costs and impact on the market'.</p>
comment	<p>535 <span style="float: right;">comment by: <i>Copenhagen Airports</i></span></p> <p>The economic impact analysis does not seem to reflect the impact on ATM/ANS providers due to the approval of the DPO and certifications. Expenses related to the approval of organisations and ATM/ANS equipment certifications are likely to be mirrored in the cost of the DPO's products and thus have an impact on ATM/ANS providers. This should be included in the impact analysis.</p>
response	<p><i>Noted</i></p> <p>Please refer to topic 'Impact assessment', in particular to topic 'Costs and impact on the market'.</p>
comment	<p>544 <span style="float: right;">comment by: <i>FOCA Switzerland</i></span></p> <p>Please see our comment #543</p>
response	<p><i>Noted</i></p>

comment

565

comment by: *MeteoSwiss*

The market for MET equipment is already today rather small and limited to a few suppliers. In this regard, the risk of creating monopolies or at least less competition, leading to higher (instead of lower) costs and less (and slower) innovation is imminent and must be taken into account accordingly. On top of that, also the risk that established suppliers might decide not take the burden of having specific equipment certified or to bother receive a declaration by an approved organisation upon them because the potential mark is too small must also be addressed. This will apply to 'in house-developments' to even a greater degree. The risk that existing systems and/or constituents will have to be phased-out eventually due to lack of adequate attestation as well as that adequately attested systems and/or constituents might not be available on the marked must be considered as a serious and non-negligible risk for MET Service providers. Taking into account the statements above, the score for Option 1 in Table 4 would have to be amended to -4 or even -6 from a purely MET Service Provider position. Option 0 would therefore score better than Option 1 and should be prioritised. With regard to the potential inability to provide some service, the impact on other Service Provides could even develop into a negative one, thus lowering the score of Option 1 in Table 3 (ref. 4.5.1 above) to -2 or even -4.  
(Assumption: 0=neutral; [-]2=FBL; [-]4=MOD; [-]6=HVY)

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'. In this context, the ATM/ANS equipment required to support MET services functions and services is proposed to be subject to SoC.

comment

616

comment by: *NATS*

Option 1

Page 32

In some situations, DPO organisational certification could provide an efficiency, but it should not be made mandatory in all situations. I see little other opportunity for cost savings, either for the ANSP or DPO.

response

*Noted*

The comment is agreed.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

624

comment by: *Austro Control*

**Comment: Page 35**

"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;" Can you elaborate on the envisioned granularity of equipment to be certified? Is the ATM system considered one single building block for example?

**Proposed Change:**

Please explain how this matches the current trend to modularity of systems.

**Classification:**

Major/conceptual

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

636

comment by: *NATS*

Paragraph 2

Page 34

ANSPs are already allowed to assume equipment is compliant on the basis of the EU 552/2004 DoC/DSU, but ANSP testing builds on the manufacturer declaration and identifies "real-world" problems with products, noting also that most specifications include end-to-end aspects which cannot be verified by the DPO.

ANSPs will almost certainly not be able to reduce any of their current verification activities on the basis of the proposed EASA certification / DPO declaration, especially as these will not be based on independent testing (which could have been achieved under EU 552/2004 by requiring the use of a Notified Body to assess conformity).

The Technical File contains evidence that the System deployed by an ANSP to provide a certifiable Service is compliant with the applicable legislative requirements, and it necessarily (and appropriately) provides evidence of integration (including people and procedures) to support compliance with the Essential Requirements... Trying to write the Technical File for the equipment in isolation would leave a shortfall in ER/IR compliance, especially as ANSPs move to modern solutions from the IS domain (i.e. procuring software-only products from DPOs, to be integrated into the ANSP's own execution environment).

Organisational certification could provide some benefits, but it could also increase procurement costs, prevent suppliers/ANSPs from developing innovative ways to assure ATM/ANS products, and lock SMEs out of the market.

There is a view that forcing suppliers into using specific processes which are otherwise unfamiliar to them can result in poorer quality products... e.g. if an organisation has been successfully delivering safety critical products in other markets, forcing them to do something different to develop an ATM product means we could lose the benefit of their engineering experience

response *Noted*

The comment is duly considered in the Opinion. The Agency believes that most of your general concerns are addressed in the topics in Section 2. In case NATS sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters.

comment 638

comment by: NATS

Paragraph 3  
Page 34

The Essential Requirements could certainly be improved, but they are fundamentally exactly what they say: essential things that an ANSP needs to do before putting something into service, e.g. installed properly, staff trained, maintainable, safe, secure, sufficient availability, use of standardised interfaces, timely sharing of data, etc. Most of these are not fully demonstrable by the DPO, and they go outside the domain of "safety"; Removing the Technical Files on the basis of equipment certification and EU 2017/373 approval of the safety argument is a misunderstanding of the role the TF performs and/or what ANSPs actually do in terms of developing and deploying a change (i.e. only a subset of ERs would be covered by the safety assurance required under EU2017/373, but the TF contains the full set of evidence supporting compliance, which includes the safety assurance).

Although administrative burden for ANSPs may be reduced, this appears to be because the proposed framework leaves a hole around demonstration of compliance with Essential Requirements (and the end-to-end requirements which are commonly found in the current specifications). The TF provides a simple mechanism for NSAs to audit ANSP compliance, and removing this mechanism (while retaining the requirement to comply with the ERs) could easily lead to national differences in how these are handled.

response *Noted*

The comment is considered in the Opinion.

The aim of the proposal is to discharge the responsibility of the equipment to be deployed to the various players including competent authorities as well as manufacturers and users, such as ATM/ANS providers. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

Taking into account the comment, the development of the associated AMC/GM is under consideration. The associated AMC/GM to Regulation (EU) 2017/373 will be developed to address how the evidence of compliance is to be managed by the AMT/ANS providers, and when relevant, presented to their respective competent authority.

comment

640

comment by: *NATS*

Paragraph 7

Page 34

This proposal may increase overall costs in the name of a level playing field.

ANSPs may only need different subsets of messages to be implemented; would an EASA-approved FDP need to implement the full specification, thus costing ANSPs more to procure? Further, ANSPs may need to send "legacy" OLDI messages to some adjacent centres, and it is not clear how these would be certified under this proposal, but it sounds like this would be more difficult and potentially expensive.

response

*Noted*

It is believed that the most of concerns are addressed in the following topics, which have been duly considered in the Opinion:

- 'Categorisation of ATM/ANS equipment subject to conformity assessment';
- 'Transitional provisions'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or in a dedicated forum.

comment

769

comment by: *EUROCONTROL*

Cost for SPs

- The evaluation of the cost for SPs for procuring “certified” or “subject to Declaration of Compliance” ATM/ANS equipment is “quantified in the average of 10-15%” (p.33). This is heavy cost for no benefit and is still just a part of the overall cost.
- The evaluation of the additional cost for becoming a DPO (many if not all SPs are developing parts of their ATM/ANS equipment (e.g.: SW)) is not provided in the NPA.
- The evaluation of the additional costs associated to oversight if a SP is certified as a DPO is not provided in the NPA.
- The evaluation of the additional cost for currently running contracts is not provided in the NPA.
- No information is provided on the potential impact on the training, endorsement, licensing (certification?) of ATSEP intervening on that equipment. We understand this to represent >100M€ industry (Service Providers) wide.
- All those costs are significant and have not been integrated in the latest discussions and agreements related to Performance RP. This will have an impact on the Unit Rate, the airspace users and consequently the travelers.

Proposed action:

EASA should review its impact assessment on Service Providers and provide associated evidence.

response

*Noted*

Please refer to topic ‘Impact assessment’.

comment

770

comment by: *EUROCONTROL*

Loss of revenue for CAs

The NPA fails to provide an evaluation of the lost revenue for the CAs due to the shift of oversight towards EASA

Is it planned that the NCAAs would reduce their staff to reduce their costs?

Proposed action:

EASA should review its impact assessment on CAs and provide associated evidence.

The States shall acknowledge this.

response

*Noted*

Please refer to topic ‘Impact assessment’.

comment

771

comment by: *EUROCONTROL*

Cost for the manufacturers:



The NPA fails to provide information on the cost for the manufacturers:

- - To achieve the compliance with the NPA requirement to become a DPO
- - On the associated additional oversight (to receive the approval and the on-going oversight)
- - To receive (and retain after each modification) the CERT or DoC for concerned equipment

Those costs will lead to an increase in the price of the concerned equipment

Proposed action:

EASA should review its impact assessment on manufacturers (DPOs) and provide associated evidence.

response

*Noted*

Please refer to topic 'Impact assessment'.

comment

774

comment by: *EUROCONTROL*

Cost on EASA evolution:

The NPA does not provide any detail on the plan of EASA:

- To recruit, train staff in sufficient number and in time;
- To assess the cost of the oversight for the "approval" as DPO and the related oversight for getting CERT and DoC for concerned equipment;
- To continuously oversee all those considerations.

The associated costs will be cascaded down to the SPs and airspace users

Proposed action:

EASA should review its impact assessment and provide associated evidence.

response

*Noted*

Please refer to topic 'Impact assessment'.

comment

775

comment by: *CAA-Denmark*

In the economic impact analysis, no negative impact seems to be on the ATM/ANS service providers. However, it seems likely that ATM/ANS providers would have to bear some of the costs imposed on DPO's in connection with the requirement for approval of the DPO and certification or declaration of the DPO's products in terms of higher prices, at least in the short term.

	This matter needs to be clarified.
response	<p><i>Noted</i></p> <p>Please refer to topic 'Impact assessment', in particular to topic 'Certification costs and impacts on the market'.</p>

comment	<p>781 <span style="float: right;">comment by: <i>EUROCONTROL</i></span></p> <p><u>About National CAs:</u>  The NPA claims that "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."; the NPA does not quantify the revenue that will be removed from the National CAs in favor of EASA (the cost will not disappear for the industry (DPOs and SPs) or the travelers but the revenue will go to EASA).  The NPA does not provide details on the required coordination between EASA and the national CAs; for the verification of the different acts (approval, CERT, DEC, Statement of Compliance) and the associated new cost those will create.</p> <p><u>Proposed action:</u>  EASA should include in its assessment the revenue reduction for the different actors</p>
response	<p><i>Noted</i></p> <p>Please refer to topic 'Impact assessment'.</p>

comment	<p>861 <span style="float: right;">comment by: <i>ENAV</i></span></p> <p>Paragraph 4 – Page 33</p> <p>Additional information on how the estimation of 10/15% of the total cost for acquisition has been defined (being estimation different) should be provided.</p>
response	<p><i>Noted</i></p> <p>Please refer to topic 'Impact assessment'.</p>

comment	<p>862 <span style="float: right;">comment by: <i>ENAV</i></span></p> <p>Paragraph 4 – Page 33</p>
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For non-critical components, Service Providers shall issue a Statement of Compliance (SoC), with inputs and support by ATM/ANS manufacturers.  
We propose an approach similar to what is done today in the framework of Reg 552/2004 when issuing of Declaration of Verification (DoV). The DoV is released after the manufacturers have issued a Declaration of Suitability for Use. For non-critical components (case 3), it should be mandatory for the ATM/ANS manufacturers to issue an equivalent declaration (e.g., DSU or DOC) that allows ANSP to provide the related Statement of Compliance.

response

*Noted*

The comment is considered in the Opinion.

Taking into account the comment, the development of the associated AMC/GM is under consideration. The associated AMC/GM to Regulation (EU) 2017/373 will be developed to address how the evidence of compliance is to be managed by the AMT/ANS providers, and when relevant, presented to their respective competent authority.

comment

863

comment by: ENAV

Paragraph 4 - Page 35

4-Flight is mentioned as example of equipment that needs to be certified. However, this is a system of systems with different components (network, FDP, etc). Please clarify at which level certification is needed.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

864

comment by: ENAV

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.

Comment: True only if the first customer does not pay all the extra-cost for certification. DPOs must follow a real product commercial policy in order to share costs between customers. One major difficulty may be that ANSPs are not buying the same products at the same time.

Proposal : EASA to provide more justifications on the compensation of additional cost.

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topic 'Certification costs and impacts on the market'.

comment

865

comment by: ENAV

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 % of the total cost for the acquisition of ATM/ANS equipment.

Comment: In the previous paragraph, EASA mentions that "ATM/ANS equipment manufacturers will face additional cost ". In this paragraph, EASA mentions that the cost of acquisition will decrease.

Proposal: EASA to explain how cost can decrease if there are additional costs for manufacturers

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topic 'Certification costs and impacts on the market'.

comment

866

comment by: ENAV

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; 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.

Comment : has EASA estimated the upfront cost for organisation to be approved as a DPO ? ATM/CNS manufacturers may have small range of products and consequently costs of product development and maintenance may increase in the short term which may reduce competitiveness of EU industry in the short term

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topic 'Certification costs and impacts on the market'.

comment 867

comment by: ENAV

Information services: AIM/AIS, MET Comment: Information services AIM/AIS, MET seem to be outside of perimeter of equipment to be certified/declared. It is unclear either what will be expected for services (like SWIM or cloudservices).

Proposal: EASA to clarify what is expected for services. It is unclear whether certification of service are covered or not through certification of equipment

response *Accepted*

The commenter is kindly invited to consider that Regulation (EU) 2017/373 lays down common requirements for providers of air traffic management/air navigation services, i.e. it addresses the certification of ATM/ANS providers for the provision of ATM/ANS services, while this proposal puts forward 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. For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 868

comment by: ENAV

#5 -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;

Comment: so far it is impossible to quantify the possible impacts of certification on procurement of equipment, system integration and tests, maintenance.  
Precise list of concerned equipment is unknown. Contents of future detailed specifications is needed.

Therefore, the balance between the extra cost of procurement and the reduced cost of safety assessment cannot be quantified so far.

Proposal: EASA to define the precise list of equipment subject to certification or declaration and to publish detailed specifications to allow stakeholders to identify the possible impacts.

response *Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 869

comment by: ENAV

The assessment of economic impact in 4.5.4 is extremely optimistic in promising cost reductions. Especially if all types of ATM/ANS equipment are considered for certification. For some types of equipment it is surely possible to reduce costs, but those types of equipment are not identified anywhere in the NPA. If we assume that all types of equipment can be chosen for certification there is a high risk for cost increase.

Please also note that ANSPs are obliged to comply with the Reference Periods of the Single European Sky Performance Scheme. There is already an extreme economic pressure on ANSPs which is difficult to handle in current business. A new regulation with such uncertainties as ENAV has commented on is not very helpful. The regulation would be easier for ANSPs to understand and accept if it could identify specific ATM/ANS equipment or activities where it is very likely that the Agency can contribute to lower costs. For instance selection criteria for choosing ATM/ANS equipment that would fit for centralised specification, or auditing and certifying DPOs on Software Assurance (SWAL and such).

response *Noted*

The Agency believes that the concerns are addressed in topic 'Impact assessment'.

In case the commentator sees that there are aspects in the comment which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment 870

comment by: ENAV

The goal of reducing costs is very desirable but the regulation has to be developed with regards to how this could be realised realistically in practical terms. For instance:

What are the criteria for selecting ATM/ANS constituents for which cost really can be reduced? A too optimistic approach will most likely increase costs instead.

How will the Agency ensure that needs and input from users (ANSPs) will be addressed? For instance user groups.

Will there be some kind of review process together with ANSPs when developing a specification?

How will verification and validation be performed in reality? Will ANSPs participate in some way in verification and validation which the Agency is responsible for?

response *Noted*

The comment is duly considered in the Opinion.

The Agency believes that most of the general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- 'Impact assessment', in particular 'Certification costs and impacts on the market'.
- 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.
- During the committee procedure for the adoption of the implementing/delegated acts proposed with the Opinion, EASA will continue the work with the preparation of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specification, which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DS will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161). In the development thereof, the RMG for RMT.0161 will be duly involved.
- 'Roles and responsibilities of the different actors'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment 924

comment by: AESA

In 4.5.4, it is stated: "[...] even if no Declaration of 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".

Regarding that and concerning Article 6, will it no longer be mandatory for the manufacturer to provide a DoC or DSU as before? What will these inputs be? Are these inputs supposed to be related with the "statement of conformity", mentioned in DPO.OR.C.001 (Organisations involved in the design and/or production of ATM/ANS equipment) and ATM/ANS.EQMT.CERT.035 (Inspection and testing), or with the "declaration of design" mentioned in DPO.OR.C.001 as well?

response *Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

The formal responsibilities for the issue of SoC will lay within the ATM/ANS providers' remit.

The concerns raised will be addressed at AMC/GM level; thus, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

925

comment by: AESA

In page 34, second paragraph, it is stated: "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)."

With this assumption, it seems User Requirements might not be tested and verified by the provider any more. Does it mean that the concept of "V Model" of development will not be considered?

response

*Noted*

The proposal would not impact the ATM/ANS providers' 'tailor-made' product.

An ATM/ANS provider (or consortium) could develop the user requirements/specifications. The DPO will need to ensure compliance with both the regulatory requirements (DS, i.e. demonstrating compliance with the essential requirements of Regulation (EU) 2018/1139) and contractual requirements (user requirements).

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

1058

comment by: DGAC (French CAA)

Reference: §4.5.4 – Promote cost efficiency

Comment: implementation of the principles described in this paragraph is not really clear in Appendix 2 Article 4 which does not make any difference between the different kinds of equipment. "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" basically includes almost all ATM/ANS equipment but those of article 5.

Proposal: Amend Articles 4, 5 and 6 of Appendix 2 to make a reference to a certification eligibility related to safety/operation continuity/costs considerations.

response

*Partially accepted*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1104

comment by: Federal Ministry for Climate Action, Environment, Energy, Mobili



"promote internal and external market opportunities": Please explain why competition is considered unfair in the current approach. Please explain how the proposal ensures fair competition.

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topic 'Level playing field and benefits'.

comment

1105

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

p. 35:

"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, [...]"

Reversing this argument a new market entrant can never be competitive, because it cannot split the upfront costs to a range of products, but has to add it to a single product.

Please explain how this significant market entry barrier can be lowered or removed and how the proposal will ensure an open and growing market.

response

*Noted*

The comment is considered in the Opinion.

The Agency believes that the concerns are addressed in topic 'Impact assessment', in particular to topic 'Level playing field and benefits' as well as in topic 'Access to the market'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

1106

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

p.35:

"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;"

Can you elaborate on the envisioned granularity of equipment to be certified? Is the ATM system considered one single building block for example?

Please explain how this matches the current trend to building modular systems that consist of re-usable building blocks.

response

*Noted*

The comment is well received and duly considered during the finalisation of the proposal resulting in Opinion No 01/2023.

The proposal does not prevent the integration of different modules/products by the ATM/ANS providers. When such modules/products contain functionalities subject to certification or declaration, they must have been designed and produced under the responsibility of an approved DPO. Such DPOs can place freely their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and their business cases. Additionally, it is important to highlight that any ATM/ANS provider could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

comment

1107

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Table 4: Please explain the score of "+6" that seems very biased. Please explain how this matches the assessment given on p.35 that additional costs related to approval and certification are certain while the cost reduction on the medium term is only seen as a possibility.

response

*Noted*

Please refer to topic 'Impact assessment, in particular 'Methodology used and scoring proposed'.

comment

1108

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Request to stakeholders: Given the short timeframe and the available manpower compared to an EASA RMT, it is impossible to completely elaborate an alternative proposal with quantified justifications. This should have been done by the RMT group upfront.

One option to consider would be to assume a modular systems approach, where functional, temporal and non-functional requirements are placed on the interfaces of the modules/building blocks only as it is good practice in architecture design. These modules could be subject to certification and their integration by a DPO or the ANSP/ATSP subject to a DoC.

response

*Noted*

The comments are well received and duly considered during the finalisation of the proposal resulting in Opinion No 01/2023.

The proposal does not prevent the integration of different modules/products by the ATM/ANS providers. When such modules/products contain functionalities subject to certification or declaration, they must have been designed and produced under the responsibility of an approved DPO. Such DPOs can place freely their products in the market, comprising the set of functionalities they consider more appropriate, according to market demand and their business cases. Additionally, it is important to highlight that any ATM/ANS provider could also be approved as a DPO, and then assume the responsibility for the design and production activities.

For further details, please refer to topics:

- ‘Impact assessment’; and
- ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment

1142

comment by: *Romanian CAA*

We considered that it is needed to clarify how these changes will impact the revenues of CAAs, that remain responsible only for a part of the integration of ATM/ANS equipment, and also on the ATM/ANS providers’ costs related to their systems and constituents / equipment. There was no consultation with Member States on the aspects stated at this paragraph.

response

*Noted*

Please refer to topic ‘Impact assessment’, in particular to topics ‘Methodology used and scoring proposed’ and ‘Certification costs and impacts on the market’.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

1196

comment by: *FerroNATS*

Cost for SPs: The evaluation of the cost for SPs for procuring “certified” or “subject to Declaration of Compliance” ATM/ANS equipment is not provided

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topic 'Certification costs and impacts on the market'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or in another forum.

#### 4.5.5. Proportionality issues

p. 36

comment 145

comment by: DSNA

*The development of harmonised equipment subject to formal attestation is likely to have a more positive impact on non-complex ATM/ANS providers*

Comments: see comments on 4.5.4. Has EASA made the analysis of financial benefits or drawbacks for complex ATM/ANS providers?

Proposal: EASA to clarify cost impact between non-complex and complex ATM/ANS providers.

response

*Noted*

The Agency believes that most of the concerns raised are addressed in topic 'Impact assessment' and in particular:

- 'Level playing field and benefits';
- 'Proportionality';
- 'Certification costs and impacts on the market'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment 222

comment by: CANSO

The development of harmonised equipment subject to formal attestation is likely to have a more positive impact on non-complex ATM/ANS providers

Comments: see comments on 4.5.4. Has EASA made the analysis of financial benefits or drawbacks for complex ATM/ANS providers?

Proposal : EASA to clarify cost impact between non-complex and complex ATM/ANS providers.

response

*Noted*

The Agency believes that most of the concerns raised are addressed in topic 'Impact assessment' and in particular:

- 'Level playing field and benefits';
- 'Proportionality';
- 'Certification costs and impacts on the market'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

324

comment by: *Nils PALMQVIST*

Regarding the text "*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.*" There is no obstacle today for DPOs to upgrade their processes or internal company structure to improve on cost-efficiency, customer service and more. The new regulation is not a prerequisite for improving customer (ANSP) satisfaction or efficiency in European ATM/ANS system.

response

*Noted*

comment

404

comment by: *Civil Aviation Authority the Netherlands*

4.5.5 Proportionality issues  
Option 1: Impact on ATM/ANS providers.

The impact assessment does not take into account that many service providers may be classified as DPOs. The impact of this regulation for them would be large: they should apply for certification, write declarations and facilitate oversight by EASA. The same is applicable for small ATM/ANS equipment DPOs.

response

*Noted*

The Agency believes that most of the concerns raised are addressed in topic 'Impact assessment' and in particular:

- 'Level playing field and benefits';

- ‘Proportionality’;
- ‘Certification costs and impacts on the market’.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

405

comment by: *Civil Aviation Authority the Netherlands*

Page 37, Table 5: Proportionality impact

Based on our comment on this paragraph the proportionality impact cannot be +4. The effect of the proposed regulation tends to be negative for smaller manufacturers and for service providers.

response

*Noted*

Please refer to topic ‘Impact assessment’, in particular to topics ‘Methodology used and scoring proposed’ and ‘Proportionality’.

comment

433 ❖

comment by: *Tern Systems*

**Fair competition is harmed and innovation hindered**

The NPA favours DPOs that can distribute the cost for approval and attestation over many customers and larger competitors that are already more experienced in regulated domains. As a result, the market will change (less DPOs overall) and competition will be reduced. This will likely hinder innovation and create monopolies in the future.

The assumption that EASA detailed specifications and guidance from EASA will in the long-term reduce design and production cost so much that these reductions cover the additional cost of attestation is not sufficiently demonstrated. Quite in contrast, considering how much equipment is adapted for different customers, we fear that we might have to obtain a certificate/ issue a declaration for each variant of the equipment delivered, that means, basically for each deployment - very much as the current EC-declaration approach - just way more expensive.

response

*Noted*

The comment is duly considered in the Opinion.

The concerns are addressed in topic 'Impact assessment', in particular topics 'Level playing field and benefits' and 'Proportionality'.

In response to the second comment, the proposal put forward a framework that certain ATM/ANS equipment should be subject of conformity assessment, establishing three different attestation instruments considering the nature and the risk of the operation or functionality enabled by the particular equipment. For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, a DPO approval is required in order for an organisation to be able to apply for the certification or to declare the design compliance of ATM/ANS equipment. This will be required only for a subset of functionalities supporting the provision of ATM/ANS services, and the organisation taking responsibility for the design and production compliance will need to be approved as a DPO. Suppliers of a DPO will not need to be approved, but the integration/use of the subcontracted products and/or services to produce the ATM/ANS equipment will be under the control/management system of the approved DPO. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

496

comment by: *Karsten T. Fiane (Notodden Airport)*

- i. Notodden Airport welcomes the proposed changes that aim to streamline and simplify the assessment processes before putting equipment into service. Especially do we, as a non-complex provider REF (EU) 2017/373 ATM/ANS.OR.A.010 (b)(2), appreciate that we with the change can presume conformity, as long as the equipment provider and/or the equipment is certified or declared according to this new regulatory framework, since we have limited technical and juridical competence to assess by ourselves if a certain equipment / providers conforms to the aviation industry standard. It is also time and resource consuming for a small organisation (as non complex providers typically are) to identify the necessary documentation and compile the TF the current scheme detailed in 552/2004.
- ii. Notodden Airport will furthermore put forward, that any proposed changes or new requirements in (EU) 2017/373, or any other related regulation, regarding conformity assessment and change management procedures should continue to differentiate between complex and non-complex providers.

response

*Noted*

The comment is well received.

comment

566

comment by: *MeteoSwiss*

With regard to a neutral or even negative safety impact combined with a negative or even catastrophic economic impact, the score for Option 1 in Table 5 must also be amended to -4 or even -6.  
(Assumption: 0=neutral; [-]2=FBL; [-]4=MOD; [-]6=HVY)

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topics 'Methodology used and scoring proposed' and 'Proportionality'.

comment

625

comment by: *Austro Control*

**Comment:**

"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." This sentence is without any meaning and not understandable.

**Proposed Change:**

Please rephrase or better remove

**Classification:**

Editorial

response

*Accepted*

comment

627

comment by: *Austro Control*

**Comment:**

"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" Small, non-complex ATM/ANS providers are the minority on the market.

**Proposed Change:**

Please explain the impact on traditional complex ATM/ANS providers

**Classification:**

Major/conceptual

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topics 'Proportionality' and 'Certification costs and impacts on the market'.



comment

642

comment by: *NATS*

Paragraph 2 (option 1)

Page 36

Under these proposals, multinational suppliers of safety critical systems for various industries could potentially need to rewrite all of their processes etc. in order to sell a single ATM product in the EU, and similarly, an SME with an innovative new ATM product would have to implement the same processes etc. as these multinational organisation; is this proposal really "proportional"?

It should not be assumed that guidance – based on experience in the (very different) airworthiness domain – will result in better / cheaper ATM/ANS products.

response

*Noted*

In addition to topic 'Access to the market', please refer to topic 'Impact assessment', in particular to topics 'Proportionality' and 'Certification costs and impacts on the market'.

comment

871

comment by: *ENAV*

The development of harmonised equipment subject to formalattestation is likely to have a more positive impact on non- complex ATM/ANS providers

Comments: see comments on 4.5.4. Has EASA made the analysis of financial benefits or drawbacks for complex ATM/ANS providers?

Proposal : EASA to clarify cost impact between non-complexand complex ATM/ANS providers.

response

*Noted*

In addition to topic 'Access to the market', please refer to topic 'Impact assessment', in particular to topic 'Proportionality'.

comment

1109

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

"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." This sentence is without any meaning and not understandable. Please remove!

response

*Accepted*

comment

1110

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Table 5: A score of "+4" seems overly optimistic and biased. Small, non-complex ATM/ANS providers are the minority on the market. Please elaborate on the impact on traditional complex ATM/ANS providers.

response

*Noted*

Please refer to topic 'Impact assessment', in particular to topics 'Methodology used and scoring proposed' and 'Proportionality'.

comment

1111

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Table 5: The statement regarding new entrants contradicts the assumption on p.35 that costs can be split to a greater range of products, which does not apply to new entrants. For new entrants the approval/certification process will entail prohibitively high cost and constitute a major market entry barrier.  
Please revise the justification.

response

*Noted*

In addition to topic 'Access to the market', please refer to topic 'Impact assessment', in particular to topics 'Proportionality' and 'Certification costs and impacts on the market'.

comment

1172

comment by: *Deutscher Wetterdienst*

- With regard to a neutral safety impact combined with a negative economic impact, the score for Option 1 in Table 5 must be amended to -4 or at least neutral.

(Understand that might be different for other (non-MET) service providers.)

response

*Accepted*

Please refer to topic 'Impact assessment', in particular to topic 'Methodology used and scoring proposed'.

## 4.6. Conclusion

p. 37

comment

406

comment by: *Civil Aviation Authority the Netherlands*

Based on our comments on the impact assessment the impact of Option 1, the proposed regulation, should in our view not be as positive as concluded. Instead the effects tend to be negative.

response

*Noted*

The concerns are addressed in topic 'Impact assessment'.

comment

567

comment by: *MeteoSwiss*

From a MET Service Providers perspective, the resulting over-all score would still provide a neutral 0 for Option 0, but would lead to a negative -10 score for Option 1 at best, but could as well lead to a score as low as -16.

response

*Noted*

Please refer to topic 'Impact assessment', in particular 'Methodology used and scoring proposed'.

comment

1173

comment by: *Deutscher Wetterdienst*

Impact assessment (IA) provided in NPA 2022-09 (Assumption: 0=neutral; [-]2=FBL; [-]4=MOD; [-]6=HVY)

From a MET Service Providers perspective, the resulting overall score would still provide a neutral 0 for Option 0, but would lead to a negative score (-4) for Option 1, neutral at best, but could as well lead to a score as low as -16.

response

*Noted*

Please refer to topic 'Impact assessment', in particular 'Methodology used and scoring proposed'.

## 5. Proposed actions to support implementation

p. 39

comment

144

comment by: *DSNA*

*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)

Proposal: preferred option "thematic workshop". EASA to support the implementation involving ANSPs more directly, planning dedicated thematic workshop with a large representation of different ANSPs (complex and non-complex).

response

*Accepted*

The comment is well received.

comment

223 comment by: *CANSO*

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)

Proposal: preferred option "thematic workshop". EASA to support the implementation involving ANSPs more directly, planning dedicated thematic workshop with a large representation of different ANSPs (complex and noncomplex).

response

*Noted*

Taking into account the comment, EASA will consider implementation support.

comment

872 comment by: *ENAV*

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)

Proposal: preferred option "thematic workshop". EASA to support the implementation involving ANSPs more directly, planning dedicated thematic workshop with a large representation of different ANSPs (complex and noncomplex).

response *Noted*

The comment is well received.

### 6.1. Related EU regulations

p. 40

comment 1144

comment by: *Romanian CAA*

Considering the relationship of this proposal with Regulation (EU) 2018/1139, there is a need to clarify the civil-military cooperation aspects, especially where ATM/ANS systems and constituents / equipment are made available by the military to air traffic to which Regulation (EC) 549/2004 applies, therefore where there is a need to offer a level of interoperability with civil systems in the application of essential requirements.

response *Accepted*

It should be noted that according to Article 2(3), the referenced ATM/ANS systems and ATM/ANS constituents are out of the scope of the EASA Basic Regulation and its implementing/delegating acts. However, Member States should ensure that the ATM/ANS referred to in Article 2(3)(c) of Regulation (EU) 2018/1139 that are provided to air traffic to which Regulation (EC) No 549/2004 applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements set out in Annexes VII and VIII to Regulation (EU) 2018/1139.

### 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

p. 42

comment 1

comment by: *Civil Aviation Directorate of the Republic of Serbia*

General comment on terms : **Approval and Certificate** for organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents.

Are they the same document? Based on the text of the draft, it is no quite clear. Approval is the dominant term, but there are some points like :

***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**.*

which may cause confusion if the certificate is the same as approval or some other document.

response

*Noted*

The term 'approval' is used for organisations involved in the design and/or production of ATM/ANS equipment, when as the result of a certification attesting compliance with the applicable requirements, an approval is issued.

The term 'certificate' is used for ATM/ANS equipment, when as the result of ATM/ANS equipment certification attesting compliance with the applicable requirements, a certificate is issued.

comment

9

comment by: *DFS Deutsche Flugsicherung GmbH*

Question 8.1 #1

There appears to be no option for a supplier to develop ATM/ANS equipment without organisational approval, which presents a barrier to entry for (also European) SMEs and potentially for the use of equipment produced by non-EU DPOs. Some derogation is desirable. To our knowledge no other States are taking a similar approach for manufacturers of ATM/ANS equipment.

Any derogation, in particular from agreed equipment standards, needs to be easily accessible for potential customers. Unknown derogations for avionic equipment have caused serious issues for international air traffic in the past.

However, this article rather seems to be about allowing access to European market by non-European DPOs. So it should not contain derogations for equipment standards (as the text could imply).

response

*Noted*

The comment is considered in the Opinion.

The concerns raised are addressed in topic 'Categorisation of ATM/ANS equipment subject to conformity assessment' as well as 'Access to the market'.

comment	11	comment by: <i>DFS Deutsche Flugsicherung GmbH</i>
	Article 4 The requirement includes “maintenance”. By mistake? There is no DP" M"O approval foreseen.	
response	<i>Accepted</i>	
	The text is amended accordingly.	

comment	12	comment by: <i>DFS Deutsche Flugsicherung GmbH</i>
	<p>Article 4</p> <p>The requirement asks the organisation to fulfil the Annex (Part DPO.OR). However, it does not say, that upon compliance the Agency will issue the approval. In contradiction, ATM/ANS.EQMT.AR.A.065 Regulation Cert/Decl (Appendix 2) asks the Agency to issue the approval when the applicant has shown compliance with Annex II and III of that Regulation. Is this confusing? And EQMT.AR.C.010 requires the declarant to commit to undertake the activities of Annex III. The necessity to differ between this implementing act and the other delegated act creates a lot of confusion and potential inconsistency.</p>	
response	<i>Noted</i>	
	<p>The comment is considered. However, it should be noted that:</p> <p>Article 47(1) of the Basic Regulation empowers the Commission to adopt delegated acts, in accordance with Article 128 of that Regulation, laying down detailed rules with regard to:</p> <ul style="list-style-type: none"> <li>— the conditions for establishing and notifying to an applicant the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents for the purposes of certification in accordance with Article 45(2) of that Regulation;</li> <li>— the conditions for issuing, maintaining, amending, limiting, suspending or revoking the certificates referred to in Article 45(2) of the same Regulation, and for the situations in which, with a view to achieving the objectives set out in Article 1 of that Regulation and while taking account of the nature and risk of the particular activity concerned, such certificates are to be required or declarations are to be permitted, as applicable;</li> <li>— the privileges and responsibilities of the holders of certificates referred to in Article 45(2) of that Regulation;</li> <li>— the privileges and responsibilities of the organisations issuing declarations in accordance with Article 45(1) and (2) of that Regulation;</li> <li>— the conditions and procedures for the declaration by ATM/ANS providers, in accordance with Article 45(1), and for the situations in which, with a view to achieving the objectives set out in Article 1 of that Regulation and while taking account of the</li> </ul>	

nature and risk of the particular activity concerned, such declarations are to be required;

- the conditions for establishing the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents which are subject to a declaration in accordance with Article 45(1) and (2) of that Regulation.

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

On the other side, the Commission should adopt implementing acts laying down detailed provisions concerning the rules and procedures for issuing, maintaining, amending, limiting, suspending or revoking the certificates for organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents.

In conclusion, the commenter is invited to note that the split and allocation of the various provisions between delegated versus implementing acts are stipulated in the EASA Basic Regulation (EU) 2018/1139.

comment

13

comment by: *DFS Deutsche Flugsicherung GmbH*

DPO.OR.A.015

A description should be incorporated on the delivery process and how the customer will be involved (Interface: delivery <-> installation)

response

*Partially Accepted.*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

14

comment by: *DFS Deutsche Flugsicherung GmbH*

DPO.OR.B001

The content of the Management System is very detailed. This should rather be subject to AMC

response

*Not accepted*



The level of granularity of elements and components of the management system is considered balanced and similar to other aviation domains.

comment 15 comment by: *DFS Deutsche Flugsicherung GmbH*

DPO.OR.C.001 (b) refers to EASA.AOA.GND.xxx. The NPA does not contain any part for AOA.GND. Is this a wrong reference?

response *Noted*

The reference refers to EASA initials.

comment 16 comment by: *DFS Deutsche Flugsicherung GmbH*

DPO.OR.C001 (b) (c) and (d) seem to be the summary of requirements that the DPO has to fulfil under the other Regulation (Appendix 2 of the NPA and its Annexes II and III). The necessity to differ between this implementing act and the other delegated act creates a lot of confusion and potential inconsistency. We need AMC/GM that clarify what exactly the applicant for an approval has to demonstrate. Overlap, duplication and inconsistency between Regulation DPO Part C and Regulation Cert/Decl Annex II and III has to be avoided.

response *Noted*

The comment is considered. However, it should be noted that:

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

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

- the conditions and procedures for the declaration by ATM/ANS providers, in accordance with Article 45(1), and for the situations in which, with a view to achieving the objectives set out in Article 1 of that Regulation and while taking account of the nature and risk of the particular activity concerned, such declarations are to be required;
- the conditions for establishing the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents which are subject to a declaration in accordance with Article 45(1) and (2) of that Regulation.

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

On the other side, the Commission should adopt implementing acts laying down detailed provisions concerning the rules and procedures for issuing, maintaining, amending, limiting, suspending or revoking the certificates for organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents.

In conclusion, the commenter is invited to note that the split and allocation of the various provisions between delegated versus implementing acts are stipulated in the EASA Basic Regulation (EU) 2018/1139.

comment

44

comment by: *German NSA (BAF)*

BAF's legal research came to the conclusion that EASA is only responsible for DPO that design and produce ATM/ANS equipment for pan-european services (and for DPO sited in third countries). For all other cases NSA is seen as responsible authority, see comment 36.

Therefore, BAF proposes to rephrase the article as follows:

- EASA is responsible for certification of DPO that design and produce ATM/ANS equipment for pan-European services and for DPO sited in third countries
- the national competent authority of the Member State where the natural or legal person applying for the certificate or making the declaration has its principal place of business or, if that person has no principal place of business, where it has its place of residence or place of establishment, shall be responsible for the certification of DPO

- Member States that do not want to take this task may mandate EASA.

response *Not accepted*

The subject is addressed in topic 'EASA acting as competent authority for all DPOs'.

comment 59

comment by: *ENAIRE*

**Original text:**

**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.

**Proposed amended text:**

**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. **Additionally, An organisation involved in the design or production of ATM/ANS equipment shall facilitate the collaboration with the ANSP in the evidence process of compliance of the requirements (i.e. Safety Requirements) according to their Management System and the requirements of their NSA.**

**Comment/Rationale:**

Sometimes will be necessary to perform audits or inspections to evidence requirements of the documentation related to Installation, transfer into operation (entry into service) and maintenance/operation phases from ANSPs.

response *Accepted*

The comment is considered, and the text amended accordingly.

comment 60

comment by: *ENAIRE*

**Original text:**

(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.

**Proposed amended text:**

(2) inform all known users (**specially ANSPs**) 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.

**Comment/Rationale:**

ANSP should be mentioned specially.

response

*Partially Accepted*

Taking into account the comment, associated GM is under consideration.

comment

61

comment by: *ENAIRE*

**Original text:**

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.

**Proposed amended text:**

The approval holder shall report to the Agency **and the users fo the ATM/ANS equipment (specially ANSPs)** 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.

**Comment/Rationale:**

ANSP should be reported.

response

*Not accepted*

The commenter is invited to refer to point (a)(2) of DPO.OR.A.045 Failures, malfunctions, and defects that is considered to address the subject.

comment

62

comment by: *ENAIRE*

**Original text:**

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.

**Proposed amended text:**

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 **and the**

users for the ATM/ANS equipment (specially ANSPs) the results of its investigation and any action it intends to take or proposes to take to correct these deficiencies.

**Comment/Rationale:**

ANSP should be reported.

response *Not accepted*

The commenter is invited to refer to point (a)(2) of DPO.OR.A.045 Failures, malfunctions, and defects that is considered to address the subject.

comment 63

comment by: ENAIRE

**Original text:**

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.

**Proposed amended text:**

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. For ATM/ANS equipment integrated in the Funcional System of an ANSP, this shall be included in the notification.

**Comment/Rationale:**

ANSP should be reported.

response *Noted*

The Agency took note of the comment.

However, the topic requires further consideration and understanding. Therefore, the commenter is kindly invited to further elaborate on the subject and put forward a proposal.

comment 64

comment by: ENAIRE

**Original text:**

the satisfactory coordination, with the appropriate arrangements, between design and production activities, as appropriate;

**Proposed amended text:**

the satisfactory coordination, with the appropriate arrangements, between design and production activities, as appropriate, and as well with ANPS in cases that the equipment was integrated in their functional system;

**Comment/Rationale:**

ANSP should be reported.

response

*Partially Accepted.*

Taking into account the comment, point (b) of the same provision is amended to address the subject.

comment

65

comment by: *ENAIRE*

**Original text:**

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.

**Proposed amended text:**

following the approval by the Agency of the proposal referred to in point (a), make available to all known users (*specially ANPSs*) 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.

**Comment/Rationale:**

ANSP should be reported.

response

*Partially Accepted*

Taking into account the comment, the development of associated GM is under consideration.

comment

72

comment by: *Thales Land and Air Systems*

Part-DPO.OR	Article 2 - A definition is missing for the term "maintenance" used in Article 4. This definition is needed to provide further clarity in explanations provided in §2.3.2. Indeed, section §2.3.2 does not limit 'maintenance' to a repair operations but encompasses "correcting problems".
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response

*Partially accepted*

A recital on the subject is included.

comment

73

comment by: *Thales Land and Air Systems*

Part-DPO.OR	Article 2 - A definition is missing for the term "production" to clarify the scope of the production activity. Does it apply to hardware only, or does it also apply to software? If production applies also to a software constituent, the associated production activities and regulatory requirements need to be clarified.
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response

*Noted*

The subject is partially addressed in point (10) to DPO.OR.B.001 Management system.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

74

comment by: *Thales Land and Air Systems*

Part-DPO.OR	Article 4 - Is the scope of approval for a given legal entity limited to activities conducted by that legal entity? Can the organisation be an approved DPO for equipment designed and/or produced by other legal entities of the same group located in other countries (including countries outside Europe)?
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response

*Noted*

In response to the comment, please refer to topic 'Roles and responsibilities of the different actors'.

An organisation approval will specify the privileges granted to organisations involved in the design and/or production of ATM/ANS equipment.

Based on the information provided, the answer could be affirmative.

comment 75

comment by: *Thales Land and Air Systems*

Part-DPO.OR	<p><b>Comment on Question 8.1#1</b></p> <p>Like for a delegation granted to qualified entities, the regulation should include requirements applicable to the Agency which should ensure that a system is put in place to initially and continuously assesses that the non-Member State complies with this Regulation.</p> <p>Clarification should be provided on the derogation implications, does the derogation grant full delegation of responsibilities for the approval of organisation and for the certification of equipment to the non-Member State or does EASA remain responsible?</p>
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response *Accepted*

The comment is considered in the Opinion.

Please refer to Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' in Delegated Regulation on ATM/ANS equipment conformity assessment.

comment 76

comment by: *Thales Land and Air Systems*

Part-DPO.OR	<p><b>DPO.OR.A.001 Scope</b></p> <p>NPA 2022-09 section 2.3.2 provides clear guidance on the different types of maintenance activities, the organisation responsible for those activities and the subsequent impact on a certificate, declaration or SoC. But this clarity is lost when it comes to the regulation proposed in Appendix 1.</p> <p>The scope described in DPO.OR.A.001 is inconsistent with Article 4 which encompasses the maintenance aspect.</p> <p>If maintenance activities are included in the scope of the DPO approval (which is not consistent with DPO.OR.A.001), a paragraph similar to DPO.OR.B.001 Management system (a) (10) need to be added to define the maintenance</p>
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	activities control procedures for the maintenance aspect. The same issue is identified in DPO.OR.C.001 where maintenance activities would need to be considered when requirements apply to a maintenance organisation.
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response *Accepted*

The comment is considered in the Opinion.

In addition to topic 'Roles and responsibilities of the different actors', please refer to a dedicated recital on the subject in the proposed Implementing Regulation on DPO approval.

comment 77

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.010: Title - "Demonstration of compliance" should be replaced by "Demonstration of capability" when dealing with organisation. Title and subsection b) may be confusion as some may consider those items address the demonstration of compliance of the design activities on the certified product, in compliance with its performance standard, where it should address the capabilities of an organisation to become approved DPO.
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response *Accepted*

The text is amended accordingly.

comment 78

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.010: Application : sub-section a) - similar to part21 subpart J or subpart O, the form and manner are outlined into a subsequent 21.A.243 (Data) and 21.A.605 (Data requirements). There is no Data Requirement subsection in this part-DPO, why ? It sounds to be spread between DPO.OR.A.015 Organisation Exposition, DPO.OR.B.001 Management System, or any other subsection ?
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response

*Noted*

The subject will be considered at AMC level.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

79

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.015 : Organisation Exposition : its content seems to be based on the Part-21 Subpart G POA exposition manual, on which (8) and (9) have been added for design and maintenance of equipment and its technical data and records. However, this content seems also to be very similar ot (ii) and (iii) of the DPO.OR.B.001 Management System. Is there any redundancy here ? Do we comply with DPO.OR.A.015 implicitly when complying with the DPO.OR.B.001 ? or vice versa ? We would like to avoid duplicated compliance demonstration in management system or exposition manual
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response

*Noted*

The exposition is a formal document, which describes how an approved organisation is structured to achieve delivery of its activity, while the management system provisions are the requirements with which the organisation should demonstrate compliance; thus, both provisions are aligned.

comment

80

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.015 : (1) statement signed by accountable manager [...], are complied with at all times; it should be "will be" complied with. There is a kind of 2-steps process here : the exposition manual establishes procedures for organisation and how organisation will apply this manual and show compliance to it when designing/producing a certified ATM/ANS equipment. Second step is the statement of compliance to exposition manual when releasing a statement of conformity for the quipement certification
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response

*Partially Accepted*

The commented provision is amended accordingly.

comment

81

comment by: *Thales Land and Air Systems*

Part-  
DPO.OR

DPO.OR.A.015 : (8) The word "verification" is confusing here, and not defined; we assume it deals with the independent monitoring of compliance of design of an equipment with its applicable certification basis including performance standards. It should not be confused on the technical verification of the product requirements, which should not be part of an organisation exposition manual.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

82

comment by: *Thales Land and Air Systems*

Part-  
DPO.OR

DPO.OR.A.015 (13): Contractors management and oversight processes shall be described by the DPO when applying for approval. Nevertheless, as the list of contracted organisation varies from one product to another and can vary from one project to another, this list is difficult to maintain at organisation level. This requirement for providing the list of contracted organisation should be removed from the organisation exposition DPO.OR.A.015 and replaced by the need for the DPO to describe its contractors management and oversight processes. The list of contracted organisation could be managed at equipment declaration/certification level.

response

*Accepted*

The text is amended accordingly.

comment

83

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.015 : Means of Compliance : redundant identifier .015, could be named 015B
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response

*Partially accepted*

The text is amended to promote clarity.

comment

84

comment by: *Thales Land and Air Systems*

Part-DPO.OR	Compared to Part-21 Subpart G, there is no section regarding PO approval requirements with regards to facilities, working conditions, equipment and tools, or with regards to management and staff.
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response

*Accepted*

The subjects raised are addressed in DPO.OR.B.010 Facility requirements and DPO.OR.B.001 Management system of the proposed Implementing Regulation on DPO approval

comment

85

comment by: *Thales Land and Air Systems*

Part-DPO.OR	PDO.OR.A.020 : Error in identifier, change PDO by DPO
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response

*Accepted*

comment

86

comment by: *Thales Land and Air Systems*

Part-DPO.OR	PDO.OR.A.020 : There is no description of the action or events that will trigger an approval suspension or revocation, except the compliance to applicable requirements of this regulation. Compared to part 21 subpart G, J or O, there is no mention of prevention of agency inspection, no considerations on unsatisfactory control of the manufacture of products, no considerations regarding the lack of control and supervision of the design of products.
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response

*Noted*

The subject is addressed in point ATM/ANS.EQMT.AR.C.050 Findings, corrective actions, and enforcement measures of the draft Delegated act.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The stakeholder is invited to consider making a proposal during the AMC/GM development as part of the activity of RMG for RMT.0161 Subtask 3.

comment

87 comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.030 : should refer to ATM/ANS.EQMT.AR.C.02 for findings definition or define it in this Implementation Regulation. Findings should be raised during inspections and audits, but sources of findings is missing in this sub section, so one might understand that findings may occur at any time; if it is the case, then process for handling findings raised by the agency out of audits and inspections need to be explicitly stated
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response

*Accepted*

comment

88 comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.040: (c) What about organisations that do not have their principal place of business in a Member State ? How will they report ? (b) is mentioning regulation 376/2014 for certain organisation only
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response

*Noted*

For organisations that do not have their principal place of business in a Member State, point (d) of the commented provision applies.

comment

89

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.A.040: occurrence reporting characterisation based on 376/2014 relies on operational consequences of the occurrence. As DPO are not operators of the equipment, they cannot directly assess the operational consequences of occurrences, only the operator of the equipment has the capacity to assess such consequences. DPO occurrence reporting shall be made against the certification/declaration baseline.
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response

*Noted*

The Agency takes note of the proposal.

This consultation cannot be seen as clearly supporting this proposal. Therefore, the commenter is kindly invited to consider a more detailed rulemaking proposal on the issue, preferably via the relevant rulemaking activity of RMG for RMT.0161 Subtask 3.

comment

90

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.001 : Management System : Is it linked to the exposition manual presented above ? Should the DPO Management System be fully detailed into the exposition manual. How is it linked to the DPO approval described above ?
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response

*Noted*

The exposition is a formal document, which describes how an approved organisation is structured to achieve delivery of its activity, while the management system provisions are the

requirements with which the organisation should demonstrate compliance; thus, both provisions are aligned.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

91

comment by: *Thales Land and Air Systems*

Part-DPO.OR	<p>DPO.OR.B.001 : Management System : (5) what means "certain" here ? Typology of equipment should be defined in the EU regulation, or at least, equipment for which performance standards requirements are defined and approved by the Agency, otherwise, letting the AMC/GM define this may lead to unlevelled playing field in ATM/ANS industry, since alternate Means of Compliance may be sought.</p> <p>NOTE: There is a definition in Appendix 2 Article 4(1), however "equipment that processes and delivers data for the purpose of the provision of ATM" is quite a large definition.</p> <p>There is also another definition in article 5(1), similar but still different : "ATM/ANS equipment which generates, receives, and transmits data and/or signals in space for the purpose of ensuring safe and interoperable air navigation" (see comment on Appendix 2 - Article 5 below)</p>
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response

*Accepted.*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

92

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.001 : Management System : (ii) and (iii) seem redundant with the exposition manual added sections (8) and (9)
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response *Noted*

The exposition is a formal document, which describes how an approved organisation is structured to achieve delivery of its activity, while the management system provisions are the requirements with which the organisation should demonstrate compliance; thus, both provisions are aligned.

comment 93

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.001 : Management System : (d) What means "proportionate" to the size of the organisation ? Is it a question of number of roles or individuals ? An alternate possibility for independent checks and verification of the demonstration of compliance ? AMC and GM are needed to propose criteria to set as proportionate the management system with respect to the organization involved in the design.
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response *Noted*

It should be noted that according to point 5.1.(c) of Annex VIII to the EASA Basic Regulation (EU) 2018/1139, as appropriate for the type of activity undertaken and the size of the organisation, the service provider shall implement and maintain a management system to ensure compliance with the essential requirements set out in this Annex, manage safety risks and aim for continuous improvement of this system.

It is also well considered that the associated AMC/GM will be developed to support the implementation of the requirements in question.

comment 94

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.001. point a.(9).(ii)v & point a.(9).(iv) & point a.(9).(v) AMC and GM are needed to clarify the kind of evidences expected to achieve compliance to those points.
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response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

95

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.005 - Change Management : (b) deals with equipment changes and notification to the Agency : how are changes classified and approved ? Is there any privilege for applicants to approve minor changes or changes that needs urgent fixes, for which a new certificate by the agency would jeopardize the changed equipment entry into service in time. The DPO.OR.B.005 shall focus on defining the approved DPO privileges with regards to certification of equipment changes. But the change management of ATM/ANS equipment shall be moved from Appendix 1 DPO.OR to Appendix 2 ATM/ANS.
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response

*Accepted*

The text is amended to promote clarity.

comment

96

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.010 : Please confirm that as soon as facilities are adequate and suitable, the certificate remains valid
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response

*Noted*

The answer is affirmative provided that the organisation remains in compliance with the other applicable requirements as well.

comment

97

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.015 : Contracted activities : both sections (a) and (b) describe the same idea : supervision has to be put in place for subcontractors that are not approved by the agency : is there any difference between those 2 subsections ? Otherwise, consider simplifying this paragraph
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response

*Noted*

Point (a) considers the need to comply with the applicable requirements, whereas point (b) requires the contracted organisation to work under the approval and oversight of the approved DPO.

comment

98

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.B.020 : Personal requirement : Also sounds redundant with the exposition manual, signed by an accountable manager or is it actually different ?
-------------	--

response

*Noted*

The exposition is a formal document, which describes how an approved organisation is structured to achieve delivery of its activity, while the management system provisions are the requirements with which the organisation should demonstrate compliance; thus, both provisions are aligned.

comment

99

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.C.001 : same comment as per DPO.OR.B.001 : the word "certain" is misleading in a EU regulation
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response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

100

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.C.001 : There are missing section in Part-DPO regarding privileges, minor changes and approval for a series of part numbers that could encompass several minor changes of a certified product. This could lead to a bottleneck effect when certificates are expected for each change of an ATM/ANS product. Except if section DPO.OR.B.005 related to change management implies that changes to certified equipment are only notified to the Agency, based on the initial Declaration of Design for "certain" equipment. This needs to be explicitly clarified in the regulation.
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response

*Accepted*

The text is amended to promote clarity.

comment

101

comment by: *Thales Land and Air Systems*

Part-DPO.OR	DPO.OR.C.001 (a) : This paragraph is difficult to understand, consider rewording and simplifying this paragraph.
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Response

*Partially Accepted*

The text is amended to promote clarity.

comment

102

comment by: *Thales Land and Air Systems*

Part-DPO.OR	By comparison with part-21 subpart G, J or O, sections such as "Data", "obligation of the holder", "privileges" are missing in part-DPO. Some information may be found, but it seems scattered in the part-DPO (e.g. for data to be submitted). However, privileges are not addressed; is it on purpose ?
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response

*Accepted*

Considering the comment, the text is amended to promote clarity.

comment

138

comment by: *DSNA*

**#1** - 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.*

Comment: From ANSP point of view, there should be no extra cost to integrate an equipment which has been certified in a non-member State. The integration cost should be the same as for a equipment directly certified by EASA.

**#2** - 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.*

Comment: can an a part of an organisation be DPO for a specific equipment only?

Proposal: EASA to clarify.

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

Comment: Equipment (software or hardware) are frequently updated. Which criteria will be put in place to launch or not a re-certification of an equipment after an update?

**#4** -PDO.OR.A.020 Continued validity of an organisation approval

Proposal: Correction of PDO by DPO in the reference of the article

response

*Partially Accepted*

Following the order of the comments:

- Please refer to topic 'Access to the market' as well as to Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the proposed Delegated act on the ATM/ANS equipment conformity assessment.
- The answer is affirmative; the privileges will be clearly indicated into the DPO approval. Taking into account the comment, the development of a associated GM is under consideration.
- In addition to topic 'ATM/ANS equipment change management', it should be noted that the concept of major/minor changes of ATM/ANS equipment will be further illustrated at AMC level.
- Accepted.

comment

172

comment by: *Prof. Filippo Tomasello*

No comment to change Article 1.

However, it is understood that constituents are those for which detailed certification specifications issued by EASA (e.g. ILS ground constituents). These constituents would comprise a myriad of

'parts' as defined by Art. 3(4) of BR 2018/1139.

Putting these parts and respective manufacturer under oversight is also important for safety. But aviation rules may be disproportionate.

In this case hence, like for aircraft 'standard parts' industry verification mechanisms, based on EU Regulation 765/2008 and associated Council Decision 768 of the sane year would suffice.

It is suggested that this could be explained in a GM.

response

*Noted*

Taking into account the comment, the development of the associated GM is under consideration.

comment

173

comment by: *Prof. Filippo Tomasello*

Art, 3 (EASA competent Authority) is fully supported by SMEs providing parts to ATM/ANS manufacturers, since this will greatly contribute to internal EU market and therefore

facilitation of expert by SMEs located anywhere in the EU, not subject to possible divergent or at least non uniform interpretation by competent authorities at national level.

response *Accepted*

The comment is well received.

comment 174

comment by: *Prof. Filippo Tomasello*

Question 8.1 #1: the intention of recognising organisational approvals to ATM/ANS manufacturers issued by third countries is supported.  
However, it should be made clear, at the level of GM, that, in the absence of that certificate, the EASA approval of the organisation would be necessary.  
In this case, at the level of AMC, ISO 9001 could be the minimum requirement, possibly complemented by additional industry standards from ASTM or from ISO or from the series EN 9100.

response *Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 175

comment by: *Prof. Filippo Tomasello*

DPO.OR.A.015 Means of compliance, at the level of AMC, requires something similar to AIR-OPS AMC1 ARO.GEN.305(b);(c);(d);(d1) Oversight programme, to credit certification based on industry standards, so avoiding duplication of inspections and audits.

response *Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 176

comment by: *Prof. Filippo Tomasello*

DPO.OR.B.001 Management system, (a)(10)(3) could be completed by adding: based on conformity assessment procedures compliant with Regulation 765/2008 and related Council Decision 768/2008

response *Partially accepted*

Taking into account the proposal, the references could be provided at AMC level.

comment	177	comment by: <i>Prof. Filippo Tomasello</i>
	<p>DPO.OR.B.015 Contracted activities.  Add letter (c): For the purposes of (a) and (b) the DPO may take advantage of demonstration of compliance based on Regulation 765/2008</p>	
response	<p><i>Partially accepted</i></p> <p>Taking into account the proposal, the references could be provided at AMC level.</p>	

comment	178	comment by: <i>Prof. Filippo Tomasello</i>
response	<p><i>Noted</i></p>	

comment	193	comment by: <i>CANSO</i>
	<p>Annex (Part-DPO.OR) – Page 45</p> <p>Regarding the “organization approval”, we would like to know if international certification (e.g., CMMI) can be considered as acceptable means of compliance to ease and speed up the process instead of identifying specific requirements for the single organization.</p>	
response	<p><i>Noted</i></p> <p>The proposal will be considered during the development of the AMC/GM (under the activity of RMT.0161 Subtask 3).</p>	

comment	198	comment by: <i>CANSO</i>
	<p>Annex (Part-DPO.OR) – Page 49</p> <p>Equipment may have changes related to the natural evolution of the technology in use or bug fixing, in order to avoid a continuous notification flow to EASA that might be time consuming, it is necessary to clarify the “ATM/ANS equipment change” criteria for which such kind of notification is necessary</p>	
response	<p><i>Accepted</i></p> <p>The comment is supported and considered in the Opinion.</p>	

The concept of 'major/minor' changes' will be provided at AMC/GM level.  
For further details, please refer to topic 'ATM/ANS equipment change management'.

comment

226

comment by: *CANSO*

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.

Comment: From ANSP point of view, there should be no extra cost to integrate an equipment which has been certified in a non-member State. The integration cost should be the same as for a equipment directly certified by EASA.

response

*Noted*

The comment is considered.

Please refer to topic 'Access to the market' as well as to Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the proposed Delegated act on the ATM/ANS equipment conformity assessment.

comment

227

comment by: *CANSO*

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.

Comment: can an a part of an organisation be DPO for a specific equipment only?

Proposal : EASA to clarify.

response

*Noted*

The answer is affirmative; the privileges will be clearly indicated into the DPO approval.



Taking into account the comment, the development of the associated GM is under consideration.

comment

228

comment by: *CANSO*

ATM/ANS.EQMT.CERT.020

Changes that require the issue of a new ATM/ANS equipment certificate

Comment : Equipment (software or hardware) are frequently updated. Which criteria will be put in place to launch or not a re-certification of an equipment after an update?

response

*Noted*

In addition to topic 'ATM/ANS equipment change management', it should be noted that the concept of major/minor changes of ATM/ANS equipment will be further illustrated at AMC level.

comment

229

comment by: *CANSO*

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

Proposal: Correction of PDO by DPO in the reference of the article

response

*Accepted*

The text is amended accordingly.

comment

246

comment by: *Indra Navia*

**DPO.OR.B.001 (a), (9), (i):** "control procedure(s) for the design of ATM/ANS equipment, and for changes to its design"

Comment: The term "Control procedure" is not widely used in management systems. It is not clear what the concept is. Suggest to use better term, or to clarify what concept this is meant to be. We are not able to propose a more precise term.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

247

comment by: *Indra Navia*

**DPO.OR.B.001 (a), (9), (iv):** “staff involved in the design of ATM/ANS equipment are of sufficient numbers and have considerable experience.”

Comment: to say that all staff shall have considerable experience will change the definition of considerable. Sufficient experience, necessary experience or required experience would be more appropriate. Also it should be clarified whether the requirement applies to a team on a collective level, or individual basis.

response

*Partially accepted*

The text is amended accordingly.

comment

248

comment by: *Indra Navia*

**DPO.OR.C.001 (e) (3)** “its serial number”

Comment: (e) requires a statement of conformity for each equipment down to serial number. (both its part number and its serial number). Is that the intention? Would not a statement of conformity for each part number be sufficient?

response

*Noted*

The answer is affirmative.

The development of the associated AMC/GM is under consideration to support the implementation.

comment

270

comment by: *CANSO*

ATM/ANS.EQMT.AR.A.040

To what level of detail will the Agency establish detailed technical specifications? As an ANSP it is difficult to believe that these specifications can be so detailed that they reduce the work for ANSPs and DPOs with specification. It is suspected that the specifications from the Agency will be either too generic to be of practical use, or contain too detailed solutions which are not what is needed or preferred by ANSPs and DPOs

response

*Noted*

In response to the question, please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

comment

276

comment by: *CANSO*

Proposed amended text

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. **Additionally, An organisation involved in the design or production of ATM/ANS equipment shall facilitate the collaboration with the ANSP in the evidence process of compliance of the requirements (i.e. Safety Requirements) according to their Management System and the requirements of their NSA.**

Comment/Rationale

Sometimes will be necessary to perform audits or inspections to evidence requirements of the documentation related to Installation, transfer into operation (entry into service) and maintenance/operation phases from ANSPs.

response

*Accepted*

The text is amended accordingly.

comment

277

comment by: *CANSO*

Page 47

Proposed amended text

(2) inform all known users (**especially ANSPs**) 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.

response

*Partially Accepted*

Taking into account the comment, the development of the associated GM is under consideration.

comment

278

comment by: *CANSO*

Proposed amended text

The approval holder shall report to the Agency **and the users of the ATM/ANS equipment (specially ANSPs)** 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.

response *Partially Accepted*

Taking into account the comment, the development of the associated GM is under consideration.

comment 279

comment by: *CANSO*

Page 50

Proposed amended text

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. **For ATM/ANS equipment integrated in the Functional System of an ANSP, this shall be included in the notification.**

response *Noted*

The Agency took duly note of the comment.

However, the topic requires further consideration and understanding. Therefore, the commentator is kindly invited to further elaborate on the subject and put forward a proposal.

comment 280

comment by: *CANSO*

Page 52

Proposed amended text

the satisfactory coordination, with the appropriate arrangements, between design and production activities, as appropriate, **and as well with ANPS in cases that the equipment was integrated in their functional system;**

response *Accepted.*

Taking into account the comment, the respective provision was amended. Please refer to DPO.OR.C.005(b)

comment 295

comment by: *CANSO*

Question 8.1 #1 Any derogation, in particular from agreed equipment standards, needs to be easily accessible for potential customers. Unknown derogations for avionic equipment have caused serious issues for international air traffic in the past. However, this article rather seems to be about allowing access to European market by non-European DPOs. So it should not contain derogations for equipment standards.

response

*Noted*

The comment is considered in the Opinion.

The concerns raised are addressed in topic 'Categorisation of ATM/ANS equipment subject to conformity assessment' as well as 'Access to the market'.

comment

296

comment by: *CANSO*

DPO.OR.A.015

A description should be incorporated on the delivery process and how the customer will be involved (Interface: delivery <-> installation)

response

*Partially Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

302

comment by: *ENAIRE*

NPA text (page 42):

**Appendix 1**

**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.

Comment:

Please confirm whether the ATM/ANS "system" and "constituent" definitions include or not equipment used by ATM/ANS providers, but not used to support the provision of certified ATM/ANS services (for instance, working R&D prototypes).

This is considered especially relevant in relation to the proposed ATM/ANS.EQMT.AR.A.040 and 045, as experimental equipment does not always comply with consolidated versions of recognised technical specifications.

Experimental / ancillary equipment does not support directly the provision of ATM/ANS services, but may have an impact on the performance of other ATM/ANS equipment which does, as both are normally installed in the same physical environment.

response

*Noted*

The answer is affirmative and for further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

303

comment by: *ENAIRE*

NPA text (page 43):

**Appendix 1**

**DPO.OR.B.001 Management system (a) (9) (v)**

(9) (v) assurance that there is close and efficient coordination between departments and within departments;

Comment:

It is suggested that this requirement encompasses not only internal, but also external coordination activities regarding equipment design. Specifically, the coordinations between ATM/ANS DPOs and ATM/ANS service providers.

This would ensure that a mechanism exists so that ATM/ANS service providers and other aviation undertakings impacted by the DPO's activities can directly convey safety/operational feedback, feasibility assessments, etc. to ATM/ANS DPOs during the design process.

New proposed text:

*assurance that there is close and efficient coordination between departments; within departments, and, if applicable, between the organisation and any aviation undertakings impacted by ATM/ANS equipment design activities, specially ATM/ANS service providers.*

response

*Partially accepted*

The comment is considered. The commentator is invited to refer to DPO.OR.C.005 'Coordination'.

comment

304

comment by: *ENAIRE*

NPA text (page 52):

**Appendix 1**

**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.

Comment:

DPO.OR.C.005 does not introduce provisions so that DPOs coordinate with ATM/ANS service providers and other undertakings.

In particular, it is suggested that the weight of ensuring such coordination be not exclusively assigned to the service providers (as per Regulation (UE) 2017/373 ATM/ANS.OR.B.005 (f), where DPOs can be considered as “aviation undertakings”). It is suggested that DPOs are required to take an active part in coordination activities involving ATM/ANS equipment.

New proposed text:

*(d) the proper coordination with the relevant ATM/ANS service providers and aviation undertakings.*

response

*Accepted*

Taking duly account of the comment, the text is amended to promote clarity.

comment

305

comment by: ENAIRE

NPA text (page 54):

**Appendix 2**

*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[...]

Comment:

The scope of the current text may perhaps be too wide. Depending on how it is interpreted, this could be considered applicable to ATM/ANS equipment addressed by Article 5 as well.

A similar text included in section 2.3 “How we want to achieve it” seems perhaps clearer. EASA is invited to consider the following alternative proposal, which is based on it:

*(1) 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, including equipment necessary for the purpose of certain ATS functionalities, as trajectory management, collision avoidance, separation management, aerodrome situational awareness, surface guidance and routing, air traffic flow management and voice communications, shall be issued [...]*

Note that the explanation of the “ATS” acronym in section 2.3 has been omitted from this proposal, being already defined by Commission Implementing Regulation (EU) No 923/2012.

response

*Noted*

The comment is considered in the Opinion.

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment

306

comment by: *ENAIRE*

NPA text (page 55):

**Appendix 2**

*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 [...]

Comments:

a)The current text requires that applicable systems perform all three functions (i.e. generate AND receive AND transmit data and/or signals). Some applicable ATM/ANS equipment may only perform some of them (e.g. relay equipment would only receive and transmit data or signals, but not generate them). Would these pieces of equipment be addressed by Article 5?

b) Only three phases in the processing of aeronautical ATM/ANS data (i.e. generation, reception and transmission) have been considered. However, the recommended standard for aeronautical data management by both ICAO and the CE, EUROCAE ED-76A / RTCA/DO-200B (see e.g. Regulation 2017/373 GM1 ATM/ANS.OR.A.085(b)) defines the following five phases: Origination, Transmission, Preparation, Application Integration and End-Use. We suggest that EASA assesses whether these phases should be used instead of the current ones.

c) Please assess whether the “or” in “data and/or signals in space” may impact low-criticality, data management-only equipment.

response

*Noted*

The comment is considered in the Opinion.

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment

307

comment by: *ENAIRE*



NPA text (page 80):

**Appendix 3**

**Article 1**

(4) the following points (g) and (h) are added to point ATM/ANS.OR.A.045:

[...]

(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.’.

Comment:

Why has it been considered necessary to specify that ATM/ANS providers shall “meet all the applicable requirements that stem from the safety assessment or the safety support assessment”? This would already seem guaranteed by the current edition of Regulation 2017/373, specifically ATM/ANS.OR.A.045 (c) and ATM/ANS.OR.B.010.

It is assumed that a competent Authority will not approve the entry into service of any functional change which does not comply with all requirements stemming from safety/safety support assessments.

New proposed text:

*(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.*

response *Partially accepted*

Taking duly account the comment, the text is amended to promote clarity.

comment 331

comment by: *Nils PALMQVIST*

DPO.OR.A.015 (8)

The detailed specifications and requirements are crucial to see. When will they be in place and who decide the level on them?

response *Noted*

During the committee procedure for the proposal, EASA will continue the work with the issue of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specifications (DS) which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DSs will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

In response to the question, please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

comment 353

comment by: DAC-LU

**- Question 8.1 #1**

Mutual recognition of ATM/ANS equipment DPO certificates between states will be time and cost efficient, provided that the system of that State includes the same independent level of checking of compliance as provided for by this Regulation. Therefore the recognition at EASA Level is highly appreciated.

**- DPO.OR.A.040 a) and b)**

These articles require DPOs to establish an occurrence reporting system. However, there is no requirement for personnel of DPOs to report any safety occurrences into that system (mandatory reporting).

Regulation (EU) 376/2014, Art. 4.6 should be amended to establish a mandatory reporting requirement for personnel of DPOs.

These articles require DPOs to establish an occurrence reporting system. However, there are no defined types of safety occurrences that are mandatory to report for their personnel.

Regulation (EU) 2015/1018 to be amended to include a list of types of occurrences that are mandatory to report for personnel of DPOs.

**- DPO.OR.A.040 e)**

A system meeting the requirements of (EU) 376/2014, would already require the investigation of occurrences in its Article 13.

The added value of this paragraph is therefore not clearly understood.

Additionally, if included, a deadline of 3 months for the final investigation and 1 month for the preliminary report should be included.

**- DPO.OR.B.001 a) 7)**

Proposal to further clarify the link with (EU) 2017/373, Part-PERS requirements when it comes to evolutive maintenance performed by a DPO.

**- DPO.OR.B.025 d)**

Proposal to include the equipment deployed and its version in the register.

**- DPO.OR.C.005 c)**

It is not clear what this requirement adds to DPO.OR.C.005 b).

If its aim is further precision, it is not clear why only design is mentioned and not production.

response *Accepted*

The text is amended accordingly.

comment 356

comment by: CAA - Norway

The proposed DPO.OR.A.045 states:

**"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."*

It is somewhat difficult to understand what this exception includes. Would not any transfer of an approval be a change in the ownership of the approval?

(Would it be more to the point to state that "An organisation approval is not transferable, except only as a result of a change in the ownership of the **organisation**."?)

response *Accepted*

The text is amended accordingly.

comment 382 ❖

comment by: *Tern Systems*

**Single competent authority is a risk for overall safety, innovation and a business risk for DPOs**

The NPA proposes EASA as the single competent authority for all DPOs and the provided equipment: This creates a single point of failure and bottleneck in the production of future ATM/ANS equipment.

If the EASA infrastructure is not sufficient, this will delay delivery of equipment. This can influence safety of operations and can hinder DPOs to fulfil their contracts with ANSPs. Neither Appendix 1 or 2 of the NPA define any restrictions for the duration of the process of obtaining approval for a DPO or certification and declaration of compliance for equipment.

ATM/ANS.EQMT.CERT.015 Application for an ATM/ANS equipment certificate (d): "An application for the issue of an ATM/ANS equipment certificate shall be valid for 5 years" could indicate processing times of several years. For a software DPO, development cycles of several years are unrealistic and not supportive of innovation.

Were other options considered to achieve consistent regulation of ATM/ANS equipment throughout Europe by the national regulators? Guidance by EASA to the national regulators for example? Using the existing infrastructure of national regulators allows for distributing the load of approval/certification/ ... Could the competence issue be solved by better knowledge distribution and sharing of EASA expertise? These questions have to be addressed also internally at EASA to ensure consistent evaluation of all DPOs and equipment.

response *Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

407

comment by: *Civil Aviation Authority the Netherlands*

Page 43, Art. 3(1)

It is stated that EASA will be responsible for the certification and approval of DPOs. However (EU)2018/1139 Article 80(b) and (c) limits the responsibility of EASA concerning DPOs of ATM/ANS equipment used by providers of pan-European services. Can you indicate to what extent you agree to this point of view?

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

408

comment by: *Civil Aviation Authority the Netherlands*

Page 43, Art. 3(1)

Currently national CAs keep oversight of the correct implementation of the interoperability regulation. Additionally EASA keeps oversight of CAs. When EASA takes over the CAs' substantive tasks, EASA logically should become subject to oversight over these activities.

Could you indicate how this will be taken care of?

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

445

comment by: *Tern Systems*

**Several times in the NPA leaves the impression that EASA believes that equipment can be defined as safe or unsafe - but if equipment is safe depends on its usage**

If equipment is safe or unsafe depends on its operation, the concept of operations and the operational environment it is used in. A DPO and also EASA cannot reasonably judge if it is safe to use a certain equipment in a certain environment. However, the service provider using the equipment can. DPOs can provide information on the characteristics of the equipment, for example, possible failure modes that help a service provider build the argument.

Examples where the impression is created that the DPO is supposed to demonstrate the safety of equipment:

- DPO.OR.A.015 Organisation exposition: *"shall establish and maintain an exposition, which provides the following information: ... (8) the procedure(s) for the verification*

*and demonstration that the design of ATM/ANS equipment, or changes to it ... has no unsafe features”*

- DPO.OR.B.001 Management system (d): *“The management system shall be proportionate ... taking into account the hazards and associated risks inherent in those activities.”*
- 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: ... (3) no feature or characteristic has been identified that may render the equipment unsafe for the intended use.”*

There might be more instances.

It seems ATM/ANS.EQMT.AR.A.055 (b) is supposed to address this *“The ATM/ANS equipment certificate shall include the operating limitations ... and any other conditions or limitations prescribed for the product”*. Will this result in certificates adapted to certain ANSP’s operational environments?

response

*Noted*

The comment is considered.

In response to the question, please refer to topic ‘Roles and responsibilities of the different actors’. Depending on the specific case, the answer could be affirmative.

comment

449

comment by: *Tern Systems*

**For which changes of the quality management system or the equipment does EASA need to be informed - when is re-attestation necessary?**

This question remains unanswered but has huge effects on the estimated costs for DPOs and the ability of DPOs to react to the need for change, for example, to fix bugs, to address necessary updates of software for example to address security issues. Innovation and improvement of the DPO’s management system and products is hindered and made expensive.

*“DPO.OR.B.005 Change management (a) ... any change to the management system **that is significant** for the demonstration of compliance shall be approved by the Agency before it is implemented. - that is significant is too vague.*

*(b) **Each change made to the ATM/ANS equipment shall be notified to the Agency ...”** - this will slow down reaction to security issues for example and generally reduce innovation due to the increased bureaucracy.*

response

*Noted*

Taking into account the comment, the text is amended to promote clarity.

comment

455

comment by: NAV Portugal E.P.E

**Annex (Part-DPO.OR) – Page 49**

Equipment may have changes related to the natural evolution of the technology in use or bug fixing, in order to avoid a continuous notification flow to EASA that might be time consuming and risk to have the same situation as airlines; therefore, it is necessary to clarify the “ATM/ANS equipment change” criteria for which such kind of notification is necessary

response

*Accepted*

The comment is supported and considered in the Opinion.

The concept of ‘major/minor’ changes’ will be provided at AMC/GM level.

For further details, please refer to topic ‘ATM/ANS equipment change management’.

comment

459

comment by: CANSO

Article 2 on page 42

As Systems and Constituents are treated identically under this proposal, and noting the activities which fall in scope of DPO approvals and the scope/applicability of the Essential Requirements to Systems, **the text as written could be interpreted to suggest** that most ANSPs will need to certify as DPOs, resulting in oversight by both their NSA and EASA.

- The framework should ensure that ANSPs – who necessarily retain responsible for the compliance of the overall integrated System used to provide their Service – do not need to certify as DPOs by amending (EU) 2017/373 to establish a common mechanism for ANSPs to demonstrate compliance of their Systems with the ERs and associated regulations and specifications; the most efficient mechanism would be to retain the need for Technical Files.

response

*Noted*

Please refer to topic ‘Roles and responsibilities of the different actors’.

comment

460

comment by: CANSO

Article 4 / Question 8.1 #1 on page 43

There appears to be no option for a supplier to develop ATM/ANS equipment without organisational certification, but this presents a significant barrier to entry for SMEs, and potentially for the use of equipment produced by non-EU DPOs. Question 8.1 #1 suggests

derogation where a non-EU state has an equivalent mechanism but – to our knowledge – no other States are taking a similar approach for manufacturers of ATM/ANS equipment.

- Organisational certification could instead be used to enable the production of self-declarations of compliance, while non-certified organisations could instead opt for an approach based on product certification. This would introduce more flexibility into the framework, enabling SMEs and non-EU manufacturers to provide products to the EU, while allowing DPOs and ANSPs to benefit from organisational certification as appropriate.

response

*Not accepted*

The comment is considered in the Opinion.

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’; consequently, ATM/ANS equipment subject to SoC could be manufactured by non-approved DPOs, as the ATM/ANS provider will take the responsibility for the conformity assessment of that equipment. For further details, please refer to topic ‘Roles and responsibilities of the different actors’.

In addition, the aspect on non-EU manufacturers is addressed in the new Article 7 ‘Third-country organisations involved in the design and/or production of ATM/ANS equipment’ of the draft Delegated Regulation.

comment

467

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**Question 8.1 #1, page 43**

EASA to verify the equipment, independent of origin.

response

*Accepted*

The comment is considered in the Opinion.

Only the aspect on non-EU manufacturers is addressed in the new Article 7 ‘Third-country organisations involved in the design and/or production of ATM/ANS equipment’ of the draft Delegated Regulation.

comment

468

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**General 8.1, page 42**

Will EASA notify CA when a DPO is certified?

response *Noted*

There are no notification requirements as such.

However, the same approach as for the approved by EASA ATM/ANS provider will apply; the list with approved ATM/ANS equipment manufacturers, including the scope of their activities, will be publicly available.

comment 469 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**DPO.OR.A.015, page 45**  
Printing error, two times DPO.OR.A.015.

response *Accepted*

comment 470 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**PDO.OR.A.020, page 46**  
Printing error, PDO.

response *Accepted*

The text is amended accordingly.

comment 471 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**DPO.OR.A.045, page 48**  
On what level does ownership change, 50 % ?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under considerations.

comment 486 comment by: *DGAC (French CAA)*



Reference: draft DPO IR: article 4 “Organisations involved in the design, and/or production of ATM/ANS equipment”

Comment: there is no explicit requirement for DPOs to be approved.

Article 42 of regulation 2018/1139 states that:

“1. Taking into account the objectives and principles set out in Articles 1 and 4, and in particular the nature and risk of the activity concerned, organisations involved in the design, production or maintenance of ATM/ANS systems and ATM/ANS constituents, **may be required**, in accordance with the implementing acts referred to in Article 43, to:

[...]

(b) hold a certificate.”

This wording (“may”) implies that at this stage the certificate is not systematically necessary for DPOs.

The draft DPO IR in NPA 2022-09 does not mention any certificate granting process but an “approval” process. It is assumed that the approval process described in the DPO IR results in the granting of a certificate by EASA (but this is not explicitly mentioned in the regulation). The only requirement in article 4 of the DPO IR is “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.”

There does not seem to be any requirement in the DPO IR for DPOs to be approved.

Proposal: Confirm that the approval process results in the granting of a certificate pursuant to article 42.1.(b) of regulation 2018/1139. Include in the draft DPO IR an explicit requirement for such organisations to be approved: “DPOs shall be approved by EASA” (or any equivalent wording as long as it is explicit.

response

Noted

It should be noted that according to Article 3(12) of Regulation (EU) 2018/1139, ‘certificate’ means any certificate, approval, licence, authorisation, attestation or other document issued as the result of a certification attesting compliance with the applicable requirements.

The answer to the question is affirmative, i.e. the organisation approval is the prerequisite for ATM/ANS equipment certification or the organization shall issue declaration of ATM/ANS equipment design compliance. For further details, please refer to topic ‘Roles and responsibilities of the different actors’.

comment

487

comment by: DGAC (French CAA)

Reference: article 1 “Subject matter”

Comment: we understand that ATM/ANS ground systems and constituents used by military ATM/ANS providers are not in the scope of the proposed regulation, as well as the organisations involved in the design and/or production of such systems and constituents, pursuant to point 3(c) of article 2 of regulation (EU) 2018/1139:

*“3. This Regulation shall not apply to:*

*[...]*

*(c) ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military;”*

Proposal: get confirmation of the assumption above.

response

*Noted*

The answer is affirmative.

The commented proposed framework is DA/IA on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e. it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military; However, Member States should ensure that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 of the European Parliament and of the Council applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

comment

488

comment by: DGAC (French CAA)

Reference: question 8.1#1

Comment: In France, much equipment come from European Member States. Some exceptions are pieces of equipment coming from US, Canada and maybe (to be confirmed) Switzerland. French CAA agrees with the establishment of bilateral working arrangements to offer the possibility for derogation from the provisions of the draft DPO IR for DPOs based in a non-Member State. That being said, it is of utmost importance that EASA ensures that all DPEs providing GE in the UE, whichever countries they are based in (inside or outside the Union) to be subject to equivalent requirements, for fair trade's sake and in order to avoid any competition distortion that would hinder European DPEs. It is therefore expected from EASA, in absence to bilateral agreements, to deliver European DOA to those DP organisations and certify their equipment.

response

*Accepted*

The comment is considered. Please refer to Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the draft Delegated Regulation on ATM/ANS equipment conformity assessment.

comment

491

comment by: DGAC (French CAA)

**Geographic** scope of the new regulatory framework

Comment: the scope of the ATM/ANS GE concerned by the present NPA is set in article 2 of the proposed draft DPO regulation and article 2 of the draft EQMT delegated regulation.

A reference is made to the definitions of article 3(6) of regulation 2018/1139 that states:

*(6) 'ATM/ANS constituent' means tangible objects such as hardware and intangible objects such as software upon which the interoperability of the EATMN depends;*"

Therefore, the geographic scope of the NPA is directly linked to the EATMN, that is commonly understood to be the continental European territory and overlying airspace and not to extend to overseas territories, even if they are ultraperipheral regions. Nevertheless, the notion of EATMN seems to be only defined in regulation (EC) n°549/2004:

*17. 'European air traffic management network' (EATMN) means the collection of systems listed in Annex I to 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) (1) enabling air navigation services in the Community to be provided, including the interfaces at boundaries with third countries;*

Regulation 549/2004 therefore refers to regulation (EC) n°552/2004 in the definition of the EATMN, but this last regulation is going to be repealed definitively.

Proposal: specify the geographic scope of both draft regulations on DPO and EQMT in terms of territories on which the ATM/ANS GE are implemented and limit this scope to continental EU MS's territories.

response

*Partially accepted.*

In response to the proposal:

- please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.
- the definition on EATM is added.

comment

511

comment by: Deutscher Wetterdienst

The clear limitation of "safety-relevance" in the explanatory text and to equipment used in the EATMN cannot be found in the draft regulation.

Missing definition (in Article 2)

(see also general comment of missing definition of EATMN and the system categories within EATMN)

response

*Accepted*

The definition is added.

comment

516

comment by: *Belgian NSA*

Belgium is opposed to organization approval for the design and/or production of ATM/ANS equipment. This is considered to be relevant for mass-produced products such as aeronautical parts, and is excessive for the ATM/ANS market because products are tailored to the user and quantities are limited. Besides, this prevents any local development carried out by the ATM/ANS provider, and will generate a lack in reactivity.

Additionally, the added value of organization approvals for organisations designing and/or manufacturing ATM/ANS equipment subject only to “*statement of compliance*” is very limited.

Article 4, page 43: Please align the title “design, and/or production of ATM/ANS equipment” with the text. Consider adding a recital on what is to be understood here under “maintenance”, as explained in section 2.3.2 of the NPA.

response

*Partially accepted*

The position is well noted. In response thereto, please refer to topic ‘Access to the market’. Furthermore, the proposal would not impact the development and procurement by the ATM/ANS provider of a ‘tailor-made’ product.

It should be noted that the statement of compliance is issued by the ATM/ANS provider and only to provide further flexibility, the text was amended to allow as a possibility to be issued by an approved manufacturer.

The subject recital is added.

comment

520

comment by: *Belgian NSA*

Question 8.1 Ok with proposal

response

*Accepted*

The final proposal results in Article 7 ‘Third-country organisations involved in the design and/or production of ATM/ANS equipment’ of the draft Delegated Regulation.

comment	534	comment by: <i>Copenhagen Airports</i>
	Regarding	Question
	Copenhagen Airports has No Comments.	
response	<i>Noted</i>	

comment	536 ❖	comment by: <i>Copenhagen Airports</i>
	<p>What is the definition of "airborne". Does that mean "during flight" or does it mean "in the airplane"?</p> <p>Phrase "excluding airborne constituents" is used, but what about other "mobiles" such as VLT/vehicles?</p>	
response	<p><i>Noted</i></p> <p>According to Article 3(7) of Regulation (EU) 2018/1139, 'ATM/ANS system' means the aggregation of airborne and ground-based constituents, as well as space-based equipment, that provides support for air navigation services for all phases of flight.</p> <p>In this context, airborne constituents are excluded from the scope of the proposal.</p>	

comment	628	comment by: <i>Austro Control</i>
	<p><b>Comment: Page 43</b></p> <p>Art. 3 of the "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" contradicts/violates Art. 80(1)(c) of Regulation (EU) 2018/1139.</p> <p><b>Proposed Change:</b> Remove Art. 3</p> <p><b>Classification:</b> Major/conceptual</p>	
response	<p><i>Not Accepted</i></p> <p>Please refer to topic 'EASA acting as competent authority for all DPOs'.</p>	

**Article 4**

1. Either Article 4 or DPO.OR.A.001 or both shall clearly define the scope of Part-DPO.OR applicability, i.e. only organisations involved in the design and/or production of ATM/ANS equipment or systems requiring either declaration or certification shall be in the scope of Part-DPO.OR.

**Justification 1:**

There shall be no room for any misinterpretation related to organisations, designing and/or manufacturing ATM/ANS systems which need no certification nor declaration.

2. Furthermore, based on the title of Article 4 and on the explanatory text of NPA 2022-09 word 'maintenance' shall not be included in Article 4 and needs to be deleted, as to also be consistent with Articles 1 and 3.

**Justification 2:**

Most ATM/ANS providers take care of 'maintenance' themselves. Based on the draft text only some dedicated changes will require work and/or assistance from DPO. Notable is, that word 'maintenance' is in a general sense associated with normal, everyday maintenance work - not with changes.

\*\*\*\*\*

**Article 5**

Applicability date cannot be same as 'entry into force', as there will be significant impact and totally new requirements for both DPOs and ATM/ANS providers.

Maybe even up to 2 years is needed, especially for ATM/ANS equipment, requiring either declaration or certification and DPO organisations.

Applicability date needs to be defined and added for Article 5. See e.g. time schedules set for future Part-IS regulation.

**Justification:**

Planned scope of ANS systems and ANS providers affected by forthcoming regulation is significantly larger than in (EU) 552/2004. E.g. MET systems have typically not been in the scope.

Furthermore, there is currently no regulation concerning DPOs.

\*\*\*\*\*

**DPO.OR.A.001 Scope**

Either Article 4 or DPO.OR.A.001 or both shall clearly define the scope of Part-DPO.OR applicability, i.e. only organisations involved in the design and/or production of ATM/ANS

equipment or ATM/ANS systems requiring either declaration or certification shall be in the scope of Part-DPO.OR.

**Justification:**

There shall be no room for any misinterpretation related to organisations, designing and/or manufacturing ATM/ANS systems which need no certification nor declaration.

\*\*\*\*\*

response

*Partially Accepted.*

The commenter is invited to note that the issues raised are addressed in Articles 4 and 5 of the Delegated Regulation.

In response to the comments, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

Article 4(2)(a) of the draft Delegated Regulation clearly addresses the commented aspect.

comment

650

comment by: NATS

Article 2  
Definitions

Page 42

"Equipment" feels like the wrong choice of word as we move towards the procurement of software-only products. This also seems to be overlooking the fact that there is a difference between a Constituent (a product created by a manufacturer and providing functionality to support safe/seamless/efficient ATM/AMS) and the System (the aggregation/integration of Constituents to provide a certifiable Service, normally produced by the ANSP). Most of the Essential Requirements are aimed at the System, e.g. a System must be safe etc. while a Constituent can only have a failure rate / assurance level.

This is one of the key differences between ANSPs and Airline Operators which seems to have been overlooked in this proposal, and the implication is that ANSPs will need to certify as DPOs as well.

response

*Noted*

The Agency believes that the concerns are addressed in the following topics, which have been duly considered in the Opinion:

- 'Categorisation of ATM/ANS equipment subject to conformity assessment';
- 'Roles and responsibility of the different actors'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a

dedicated session to discuss these matters. This could take place bilaterally or in another forum.

comment

653

comment by: NATS

Article 3  
Competent authority requirements

Page 43

Article 80(1)(c) only seems to make EASA responsible for certification of those organisations producing products for pan-European ATM/ANS service providers; the proposal here for EASA to certify all DPOs does not seem consistent with this article?

response

*Noted*

In response to the comment, please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

655

comment by: NATS

Article 4  
Organisations involved in the design, and/or production of ATM/ANS equipment  
Page 43

How will this apply to non-EU DPOs?

Note that proposals to allow derogation from this requirement for non-EU DPOs where their state has an equivalent certification scheme may not work, primarily on the basis that no other state has taken this approach for their ATM/ANS manufacturers.

response

*Noted*

In response to the market, please refer to topic 'Access to the market'.

Furthermore, Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' is introduced to address this aspect.

comment

656

comment by: NATS

**DPO.OR.A.010**  
(b)



Page 45

As worded, this could be interpreted as stating a DPO only needs to comply with the requirements relating to e.g. investigation of failures if the DPO intended to do this (rather than actually requiring that they investigate), which is presumably not the intent of the requirement?

response *Noted*

The commenter is invited to propose a better wording for the commented provision.

comment 657

comment by: *NATS*

**DPO.OR.A.015**

(a)

Page 45

It is not clear how these requirements have been derived, or why they are considered important to ensuring compliance of ATM/ANS products with the relevant specifications? Each of these adds cost, and some do not seem particularly necessary to address the alleged problem.

These requirements also seem more stringent than those imposed on ANSPs (who are ultimately responsible for the safety of the service)!

response *Noted*

The commenter is invited to propose a better wording for the commented provision.

comment 659

comment by: *NATS*

**DPO.OR.A.040**

(b)

Page 47

The inclusion of mandatory occurrence reporting in this system and reference to 376/2014 is confusing, given that the DPO would potentially have no knowledge of how their system is being used operationally by ANSPs / how its failure may or may not have affected safety of civil aircraft.

Is this suggesting that ANSPs will have an obligation (under law?) to report failures to the manufacturer, or that the manufacturer has to comply with 376/2014 even though they are not providing any kind of operational service?

response

*Noted*

Point (c) of ATM/ANS.OR.A.065 already regulates the subject applicable to ATM/ANS provider, while the respective mirroring provision is proposed in DPO.OR.A.045 Failures, malfunctions, and defects.

comment

661

comment by: *NATS*

**DPO.OR.A.040**

(c)

Page 47

It wouldnt necessarily be standard procedure to expect an ANSP to tell a DPO whether a failure of their product resulted in an unsafe condition operationally (which may depend entirely on the wider System), just that e.g. there is a bug which needs fixing.

This seems to be confusing the roles of the ANSP and the DPO (and noting the requirement is to report every failure/bug which "may" result in an unsafe condition, EASA may end up having to deal with every bug of every Constituent and every failed LRU!).

response

*Noted*

Point (c) of ATM/ANS.OR.A.065 already regulates the subject applicable to ATM/ANS provider, while the respective mirroring provision is proposed in DPO.OR.A.045 Failures, malfunctions, and defects.

Taking not account the comment, the development of the associated AMC/GM is under consideration.

comment

662

comment by: *NATS*

**DPO.OR.A.045 Approval transferability**

Noting that equipment certification seems to only be valid while the organisational approval is valid, this needs some careful thought and management (or ideally remove the need for continued organisational certification from the validity of equipment certification).

response

*Not accepted.*

Please refer to topic 'Roles and responsibilities of the different actors' as well as to topic 'DPO approval discontinuation'.

comment

663

comment by: NATS

**DPO.OR.B.001**

9 (ii)

Page 49

The apparent loss of the requirement for independent verification of compliance within ANSPs seems like a backwards step, especially in light of the 737 MAX disaster, and noting that responsibility for compliance of the System providing the Service can only ever sit with the ANSPs

response

*Noted*

The comment is considered and will be addressed during the development of the associated AMC/GM to ATM/ANS.OR.A.045 (g) and (h).

comment

664

comment by: NATS

**DPO.OR.B.001**

9 (iv)

Page 49

Having sufficient numbers of staff in the context of a DPO feels like a timeliness of delivery issue, with little obvious impact on compliance with the ERs / technical specifications. The requirement for "considerable experience" to be "involved" in the design of ATM/ANS equipment also seems restrictive; where are staff to gain such experience?

response

*Noted*

The commented provision is one of the essential elements of each management system and this particular one relates to the design activities. It is up to the organisation to demonstrate compliance.

comment

665

comment by: NATS

**DPO.OR.B.001**

10 (iii)

Page 49

Noting the statements that ANSPs are not to perform further verification of certified equipment, presumably this would not be necessary for DPOs receiving products, parts, materials or equipment which are themselves certified?

response

*Noted*

In response to the question, please refer to topic 'Roles and responsibilities of the different actors'.

comment

666

comment by: *NATS*

**DPO.OR.B.001**

(d)

Page 50

Does this requirement suggest that DPOs need to understand the hazards and risks associated with the use of their equipment in the provision of an ATM/ANS service?

This would not be easy, given that there is no agreed set of hazards for ATM/ANS, and the DPO will not be aware of the wider context in which their equipment may be used (noting that DPOs currently design/build to an assurance level determined by the ANSP, and different ANSPs may have different requirements).

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

667

comment by: *NATS*

**DPO.OR.B.005**

(b)

Page 50

What is defined as a "change"? Would a bug fix be a "change" which would need notifying? This needs clarification.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

669

comment by: *NATS*

**DPO.OR.B.015**

(b)

Page 50

To confirm, is this requiring that any organisation which is contracted by a DPO in relation to the design/production of ATM/ANS equipment must themselves be capable of obtaining DPO certification, i.e. be compliant with all of these requirements, and the contracting organisation is responsible for ensuring this?

response *Noted*

The same principle as ATM/ANS.OR.B.015 of Regulation (EU) 2017/373 would be applicable for contracted activities in the design and/or production of ATM/ANS equipment.

comment 670

comment by: *NATS*

**DPO.OR.B.025**

(d)

Page 51

What is the intent of this register?

Given that a DPO may not be aware of the operational status of their equipment (or e.g. if it has been sold on?), would this technically only be a register of organisations that have procured each of their products?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 671

comment by: *NATS*

**DPO.OR.C.001**

(e)

Page 52

To confirm, this means that the Statement of Conformity is for a specific instance of the product (with serial number), i.e. it is not generic and each ANSP would need a different Statement of Conformity for each instance of the product? How would this work with software products?

response *Noted*

The commented provision would apply to DPOs that would be privileged to hold ATM/ANS equipment certificate or issue declaration of design compliance. While the issue of SoC is a privilege for the ATM/ANS providers and in specific cases for DPOs.

In addition, considering the comment, the development of the associated AMC/GM is under consideration.

comment

672

comment by: NATS

**DPO.OR.C.005**

(c)

Page 52

Does "Continued suitability" suggests that DPOs will have a legal responsibility to ensure that even products they have stopped selling are updated to align with the latest regulations/specifications/etc.? Does this include providing updates to ANSPs? Who is paying for this? How do they "retire" a product?

response

*Noted*

Continued suitability is used in the context of the continued fitness/availability/adequacy of the equipment.

In addition, considering the comment, the development of the associated AMC/GM is under consideration.

comment

676

comment by: NATS

· Article 4 / Question 8.1 #1 on page 43

There appears to be no option for a supplier to develop ATM/ANS equipment without organisational certification, but this presents a significant barrier to entry for SMEs, and potentially for the use of equipment produced by non-EU DPOs. Question 8.1 #1 suggests derogation where a non-EU state has an equivalent mechanism but – to our knowledge – no other States are taking a similar approach for manufacturers of ATM/ANS equipment

**Organisational certification could instead be used to enable the production of self-declarations of compliance, while non-certified organisations could instead opt for an approach based on product certification. This would introduce more flexibility into the framework, enabling SMEs and non-EU manufacturers to provide products to the EU, while allowing DPOs and ANSPs to benefit from organisational certification as appropriate.**

response

*Not accepted.*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'; consequently, ATM/ANS equipment subject to SoC could be manufactured by non-approved DPOs, as the ATM/ANS provider will take the responsibility for the conformity assessment of that equipment. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, the aspect on non-EU manufacturers is addressed in the new Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the draft Delegated Regulation.

comment

706

comment by: IAA Aviation Regulator

*Article 3(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."*

NPA 2022-09; P13/14 also refers.

*The NPA considers that "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".*

EASA BR Art.80(1)(b)/(c) states that EASA shall be responsible for the tasks related to certification, oversight and enforcement w.r.t organisations that are *"involved in the design, production or maintenance of ATM/ANS systems and ATM/ANS constituents, including where they contribute to Single European Sky ATM Research (SESAR) implementation, used in the provision of the services" where such services are provided by ATM/ANS providers on a "pan-European ATM/ANS basis"*.

Considering the current content of EASA BR Art.80(1), clarification should be provided regarding the basis of planned EASA competent authority role for a DPO, for instances where their ATM/ANS equipment is not being used by ATM/ANS providers to support the provision of services on a *"pan-European ATM/ANS basis"*.

response

*Noted*

In response to the comment, please refer to topic 'EASA acting as competent authority for all DPOs'.

comment 707 comment by: IAA Aviation Regulator

Annex; point "*PDO.OR.A.020 Continued validity of an organisation approval*"

Editorial - Reference should be to "DPO.OR.A.020" to align with title of other points.

response *Accepted*

comment 708 comment by: IAA Aviation Regulator

Annex; point "*DPO.OR.A.035 Immediate reaction to a safety and interoperability problem*"

Suggest reword to include security to align with objective set out in NPA; Section 2.2 and EASA BR; Annex VIII; Section 3.3.1 security requirement - "*Systems and constituents shall be designed to meet applicable safety and security requirements*".

response *Accepted*

comment 709 comment by: IAA Aviation Regulator

Annex; point "*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 [...]*"

Suggest that proposed AMC and if appropriate GM, to specify criteria to be used by DPOs to determine what constitutes a "*significant*" change to the organisations certificate, to ensure a consistent and transparent approach.

response *Accepted.*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 750 comment by: POL CAA LOZ-4

Some of the provisions in SUBPART A, B and C look duplicated from 373, such as those on non-compliance procedures, management system or change management. I guess this should be harmonized to the maximum extent possible with PART-ATM/ANS.OR. Otherwise, under 373, there will be additional provisions of a general nature, but concerning tylo DPOs. If so, there would have to be a stipulation in 373 that PART-ATM/ANS.OR does not apply to DPOs.



response

*Noted*

The commenter is invited to note that the respective Articles 1 of the two Regulations, new Implementing act on DPO approval and Regulation (EU) 2017/373 define the scope, subject matter, and applicability of the relevant Regulations.

comment

776

comment by: *EUROCONTROL*

Reference to "EATMN".

This NPA makes many references (Article 2 of draft Part-DPO.OR) to this term, more importantly in the definition of "ATM/ANS equipment" itself by reference to "constituents" and "systems" (and EASA BR EU.2018/1139).

But the only place where EATMN is defined is in EC.552/2004. Parts of this regulation have already been repealed and what is remaining of it will be repealed by the result of this NPA.

"Equipment"

Question: Why was the term equipment introduced for ATM/ANS although this does not exist in the BR, which refers to systems and constituents? The term 'equipment' is used by EASA in tother context than ATM. (e.g.) « Article 13 Design of non-installed equipment ».

Proposed actions:

Replace equipment by systems and constituents in alignment with the BR terminology for ATM/ATN

"EATMN" should be defined in the proposed regulation

Replace equipment by systems and constituents in alignment with the BR terminology for ATM/ATN

response

*Partially accepted*

The definition of EATMN is introduced and for further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

779

comment by: *EUROCONTROL*

Article 4 of draft Part-DPO.OR: In this article the reference to safety criticality has disappeared. Moreover, the definition of these equipment is extremely broad. It could encompass any

system or constituent used during ATM operations, monitoring of its performance, or back-office tasks.

Proposed action:

Suggestion re-introduce the reference to EATMN as in the BR:

(6) 'ATM/ANS constituent' means tangible objects such as hardware and intangible objects such as software upon which the interoperability of the EATMN depends;

(7) 'ATM/ANS system' means the aggregation of airborne and ground-based constituents, as well as space-based equipment, that provides support for air navigation services for all phases of flight;

response

*Partially accepted*

The definition is added in the proposed Delegated Regulation on the ATM/ANS equipment conformity assessment.

comment

785

comment by: *EUROCONTROL*

DPO.OR.B.001 Management System

- - No reference made to Security Management System; DPO are and will remain subject to security threats that may have an impact on the products they deliver
- The Management System should be proportionate to... "taking into account the hazards and associated risks inherent in those activities"

Is this about health and safety? DOP are providing products, DPO have no idea of what are the hazards and associated risks..."

- Point (9)(ii) "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"

This needs to be clarified, what is meant by "independent" function? How independent? Different company demonstrating no other commercial relationship?

Proposed action:

Include a definition of "independent checking function"

response

*Noted*

The alignment with Part-IS is considered in the Opinion.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

786

comment by: *EUROCONTROL*

DPO.OR.B.015 Contracted Activities

“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.”

EASA will plan oversight (audits, reviews...) of the contractor of a contractor of an ATSP or even of a “SP other than ATS”. This starts to be very very far from the real subject matter expertise of EASA inspectors (of course to be defined in the non published competency scheme of those future inspectors).

This has to stop somewhere.

Proposed action:

Limit the contracted activities scope of applicability

response

*Not accepted*

comment

814

comment by: *EUROCONTROL*

**Part.DPO.OR**

For large organization with multiple divisions/organizations/facilities based on several countries and different processes and tools involved in the production of ATM/ANS systems, will the DPO approval be granted to the ‘lead’ division/organizations, will the individual organizations each receive a DPO for their particular contribution, or something else?

Proposed action:

Clarify how the DPO will be granted to large organisations manufacturing ATM/ANS system

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that the most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Roles and responsibilities of the different actors’;
- ‘Access to the market’.

In case Eurocontrol sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between Eurocontrol and the Agency or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

815

comment by: *EUROCONTROL*

With respect to **DPO.OR.A.005 Eligibility**: Is there a mechanism intended to constrain the type of ATM/ANS equipment a particular DPO is capable of designing and producing (e.g a manufacturer capable of designing and producing equipment for digital towers isn't necessarily capable of designing and producing a CNS equipment).

Proposed action:

Clarify the scope of activities of a DPO.

response

*Noted*

The comment is considered in the Opinion.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

823

comment by: *EUROCONTROL*

**Question 8.1 p. 43:**

The question could be interpreted in different manners:

1. if the main objective is about working arrangements, then EASA could make best use of EUROCONTROL NM working arrangements notably the Joint Common Stakeholders Platform which aims at providing a single value chain among all network stakeholders.
2. If the main objective is to address non-EU manufacturers, we see a risk that the proposed EASA framework may be too complex or expensive and refrain some manufacturers to comply. This could leave us in difficult situations, potentially non availability of services.
3. If the question is about offering a derogation framework, we would like to take the opportunity to discuss further this option with EASA.

response

*Noted*

Taking into account the consultation feedback, the aspect on non-EU manufacturers is addressed in the new Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the draft Delegated Regulation on ATM/ANS equipment conformity assessment.

In case Eurocontrol sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between

Eurocontrol and the Agency or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

875

comment by: ENAV

Annex (Part-DPO.OR) – Page 45

Regarding the “organization approval”, we would like to know if international certification (e.g., CMMI) can be considered as acceptable means of compliance to ease and speed up the process instead of identifying specific requirements for the single organization.

response

*Noted*

The proposal will be considered during the development of the AMC/GM (under the activities of RMT.0161 Subtask 3).

comment

876

comment by: ENAV

Annex (Part-DPO.OR) – Page 49

Equipment may have changes related to the natural evolution of the technology in use or bug fixing, in order to avoid a continuous notification flow to EASA that might be time consuming, it is necessary to clarify the “ATM/ANS equipment change” criteria for which such kind of notification is necessary

response

*Accepted*

The comment is supported and considered in the Opinion.

The concept of ‘major/minor’ changes’ will be provided at AMC/GM level.

For further details, please refer to topic ‘ATM/ANS equipment change management’.

comment

877

comment by: ENAV

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.

Comment: From ANSP point of view, there should be no extracost to integrate an equipment which has been certified in a non-member State. The integration cost should be the same as for a equipment directly certified by EASA.

response

*Noted*

The comment is considered.

Please refer to topic 'Access to the market' as well as Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the proposed Delegated act on the ATM/ANS equipment conformity assessment.

comment

878

comment by: ENAV

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.

Comment: can an a part of an organisation be DPO for aspecific equipment only?

Proposal : EASA to clarify.

response

*Noted*

The answer is affirmative; the privileges will be clearly indicated into the DPO approval.

Taking into account the comment, the development of the associated GM is under consideration.

comment

879

comment by: ENAV

ATM/ANS.EQMT.CERT.020

Changes that require the issue of a new ATM/ANS equipment certificate

Comment : Equipment (software or hardware) are frequently updated. Which criteria will be put in place to launch or not are-certification of an equipment after an update?

response

*Noted*

In addition to topic 'ATM/ANS equipment change management', it should be noted that the concept of major/minor changes of ATM/ANS equipment will be further illustrated at AMC level.

comment

880

comment by: ENAV

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

Proposal: Correction of PDO by DPO in the reference of the article

response

*Accepted*

comment

881

comment by: ENAV

ATM/ANS.EQMT.AR.A.040

To what level of detail will the Agency establish detailed technical specifications? As an ANSP it is difficult to believe that these specifications can be so detailed that they reduce the work for ANSPs and DPOs with specification. It is suspected that the specifications from the Agency will be either too generic to be of practical use, or contain too detailed solutions which are not what is needed or preferred by ANSPs and DPOs

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

882

comment by: ENAV

Proposed amended text

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.

**Additionally, An organisation involved in the design or production of ATM/ANS equipment shall facilitate the collaboration with the ANSP in the evidence process of compliance of the requirements (i.e. Safety Requirements) according to their Management System and the requirements of their NSA.**

Comment/Rationale

Sometimes will be necessary to perform audits or inspections to evidence requirements of the documentation related to Installation, transfer into operation (entry into service) and maintenance/operation phases from ANSPs.

response

*Partially accepted*

The text is amended accordingly.

comment

883

comment by: ENAV

Page 47

Proposed amended text

(2) inform all known users (**specially ANSPs**) 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.

response

*Partially accepted.*

Taking into account the comment, the development of the associated GM is under consideration.

comment

884

comment by: ENAV

Proposed amended text

The approval holder shall report to the Agency **and the users of the ATM/ANS equipment (specially ANSPs)** 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.

response

*Partially accepted.*

Taking into account the comment, the development of the associated GM is under consideration.

comment

885

comment by: ENAV

Page 50

Proposed amended text

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. **For ATM/ANS**



**equipment integrated in the Functional System of an ANSP, this shall be included in the notification.**

response *Noted*

The Agency took duly note of the comment. However, the topic requires further consideration and understanding. Therefore, the commenter is kindly invited to further elaborate on the subject and put forward a proposal.

comment 886

comment by: ENAV

Page 52

Proposed amended text

the satisfactory coordination, with the appropriate arrangements, between design and production activities, as appropriate, **and as well with ANPS in cases that the equipment was integrated in their functional system;**

response *Partially accepted*

Taking into account the comment, point (b) of the same provision is amended to address the subject.

comment 887

comment by: ENAV

Question 8.1 #1 Any derogation, in particular from agreed equipment standards, needs to be easily accessible for potential customers. Unknown derogations for avionic equipment have caused serious issues for international air traffic in the past.

However, this article rather seems to be about allowing access to European market by non-European DPOs. So it should not contain derogations for equipment standards.

response *Noted*

The comment is considered in the Opinion.

The concerns raised are addressed in topic 'Categorisation of ATM/ANS equipment subject to conformity assessment' as well as 'Access to the market'.

comment 888

comment by: ENAV

DPO.OR.A.015

A description should be incorporated on the delivery process and how the customer will be involved (Interface:delivery <-> installation)

response *Partially accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment 889

comment by: ENAV

Article 2 on page 42

As Systems and Constituents are treated identically under this proposal, and noting the activities which fall in scope of DPO approvals and the scope/applicability of the Essential Requirements to Systems, the text as written could be interpreted to suggest that most ANSPs will need to certify as DPOs, resulting in oversight by both their NSA and EASA.

The framework should ensure that ANSPs – who necessarily retain responsible for the compliance of the overall integrated System used to provide their Service – do not need to certify as DPOs by amending (EU) 2017/373 to establish a common mechanism for ANSPs to demonstrate compliance of their Systems with the ERs and associated regulations and specifications; the most efficient mechanism would be to retain the need for Technical Files.

response *Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment 890

comment by: ENAV

Article 4 / Question 8.1 #1 on page 43

There appears to be no option for a supplier to develop ATM/ANS equipment without organisational certification, but this presents a significant barrier to entry for SMEs, and potentially for the use of equipment produced by non-EU DPOs. Question 8.1 #1 suggests derogation where a non-EU state has an equivalent mechanism but – to our knowledge – no other States are taking a similar approach for manufacturers of ATM/ANS equipment.

Organisational certification could instead be used to enable the production of self-declarations of compliance, while non-certified organisations could instead opt for an approach based on product certification. This would introduce more flexibility into the framework, enabling SMEs and non-EU manufacturers to provide products to the EU, while allowing DPOs and ANSPs to benefit from organisational certification as appropriate.

response *Not accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'; consequently, ATM/ANS equipment subject to SoC could be manufactured by

non-approved DPOs, as the ATM/ANS provider will take the responsibility for the conformity assessment of that equipment. For further details, please refer to topic 'Roles and responsibilities of the different actors'.

In addition, the aspect on non-EU manufacturers is addressed in the new Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the draft Delegated Regulation.

comment 926

comment by: AESA

In page 42, Article 2, it is necessary to include the definition of "statement of conformity".

response *Not accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 927

comment by: AESA

In page 42, Article 2, it is necessary to include the definition of "declaration of design", since it doesn't seem to be the same as "declaration of design compliance" stated in article 5 Appendix 2.

response *Not accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

In response to the comment, the terms are equal and refer to the same subject.

comment 928

comment by: AESA

In page 43, Article 4, Question 8.1 #1:  
Does this case refer only to manufacturers from a third country?.

response *Noted*

Taking into account the consultation outcome, the provision results in Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the draft Delegated Regulation on ATM/ANS equipment conformity assessment.

comment 929

comment by: AESA

Regarding page 43, Article 4, the IR applies to "An organisation involved in the design, production or maintenance of ATM/ANS equipment". Will all ATM/ANS equipments manufacturers, including those who manufacture equipment which does not require certificate or declaration but only SoC, have to be certified as DPOs?

response *Noted*

Only manufacturers of ATM/ANS equipment subject to certification and/or declaration of design compliance should be required to be an DOP approval holder.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment 930

comment by: AESA

In page 45, DPO.OR.A.015a), testing facilities and equipments should be considered.

response *Accepted*

The text is amended accordingly.

comment 931

comment by: AESA

In page 45, DPO.OR.A.015 a)2), who are the key managers? What are their roles? Is it referring only to the roles specified in DPO.OR.B.020? If so, a reference should be included.

response *Accepted*

comment 932

comment by: AESA

In page 45, DPO.OR.A.015 a) 5), in addition to the "general description of the organisation's human resources", some kind of demonstration of the staff capabilities and training programmes (same as DPO.OR.B.001 a) 7)) should be considered as well as training programmes.

response *Noted*

The comment will be considered during the development of the associated AMC/GM under RMT.0161 Subtask 3.

comment 933 comment by: AESA

In page 46, DPO.OR.A.015 "Means of compliance", there is an error in the numbering of the requirement. It is repeated with respect to the previous one: "DPO.OR.A.015 Organisation exposition".  
This may affect the numbering of all the requirements below.

response *Accepted*

comment 934 comment by: AESA

In page 46, PDO.OR.A.020 "Continued validity of an organisation approval", there is an error in the code of the requirement. It should be "**DPO**.(...)" instead of "**PDO**.(...)"

response *Accepted*

comment 935 comment by: AESA

Regarding Part-DPO.OR, once the scheme based on certificates/declarations of compliance is established, based on our experience it is very likely that the DPOs will limit access to the ANSPs to information necessary to comply with the obligations established by de Regulation (EU) 2017/373 using reasons such as intellectual property or security. DPOs must facilitate access to the necessary information when justified from the point of view of R373/2017, and this shall be addressed through a new requirement.

An organisation involved in the design or production of ATM/ANS equipment shall cooperate with ANSP in order to facilitate compliance with any obligations arising from de Regulation (EU) 2017/373 and shall provide the ANSP with the means by which such compliance can be demonstrated.

response *Accepted*

Taking into account the comment, point (b) of DPO.OR.A.030 Facilitation and cooperation is amended to address the subject.

comment	936	comment by: AESA
	In page 47, DPO.OR.A.035, there is an error in the reference to point "ATM/ANS.EQMT.AR.025". It should be the point "ATM/ANS.EQMT.AR.A.025".	
response	<i>Accepted</i>	

comment	937	comment by: AESA
	In page 47, DPO.OR.A.030, regarding letter c), why is the demonstration of the effectiveness of the corrective action not considered as well?	
response	<i>Noted</i>	
	This aspect is addressed in point (a) of ATM/ANS.EQMT.AR.C.050 Findings, corrective actions, and enforcement measures of the proposed Delegated Regulation.	

comment	938	comment by: AESA
	In page 47, DPO.OR.A.040 a) 2), how will the DPO inform the different users about failures, malfunctions, defects or other occurrences which have caused or might cause adverse effects on the continuing compliance?	
response	<i>Noted</i>	
	The means for demonstration of compliance will be provided at AMC/GM level and will be developed as part of RMT.0161 Subtask 3.	

comment	939	comment by: AESA
	In page 47, DPO.OR.A.040, why the occurrence report to the Competent Authorities of the ATM/ANS provider that use the ATM/ANS equipment is not considered? Competent Authorities have acknowledge safety problems because of Regulation (EU) 376/2014, but it is not the case of interoperability problems nor other problems that are not considered safety problems. Such information is necessary for the supervision activities carried out by de Competent Authority.	
response	<i>Noted</i>	
	The provision requires the organisation to take or propose corrective actions against the deficiencies in question, and these are the measures that need to be reported/addressed to	

users, i.e. the ATM/ANS providers using their equipment, and possibly to their competent authorities.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 940 comment by: AESA

In page 48, DPO.OR.A.040 d), what could be the "exceptional circumstances" mentioned in this point?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 941 comment by: AESA

In page 48, DPO.OR.A.040 e), why the results of occurrence investigations are not reported to users and relevant Competent Authorities ?

response *Noted*

If the question is well understood, the aspect is addressed in point (a)(2).

comment 942 comment by: AESA

In page 48, DPO.OR.B.001 a) 9) i), it would be appropriate to specifically mention testing procedures.

response *Partially accepted*

It is considered that this aspect is addressed in DPO.OR.B.001 (a)(9)(ii). Please refer to 'including independent checking function'.

comment 943 comment by: AESA

In page 48, DPO.OR.B.001 a) 5), there is need for clarification: which ones are the "certain ATM/ANS equipments"? Those for which a certification/declaration specification is to be issued?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

945

comment by: AESA

In page 50, DPO.OR.B.005 a), regarding "Change to the management system". Does it include changes in production facilities and related equipments?

response

*Noted*

It covers any change to the components and elements of the management system. Thus, the answer is affirmative.

comment

948

comment by: AESA

In page 50, DPO. OR.B.005 a), what does imply "significant"? Clarification needed.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

949

comment by: AESA

In page 50, DPO.OR.B.010, it would be appropriate to update the title of this requirement, from "Facility requirements" to "Facility and equipment requirements".

response

*Not accepted*

comment

950

comment by: AESA

Regarding page 50, DPO.OR.B.010, this article should need further development. Will it be done by AMCs/GMs?

response

*Noted*



Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 951 comment by: AESA

In page 51, DPO.OR.B.025 b), no specific retention period is established. It has to be considered that the record-keeping of the information related to every ATM/ANS equipment should cover its whole lifecycle (i.e., until its withdrawal from service).

response *Partially accepted*

The comment will be considered during the development of the associated AMC/GM as part of the activity of RMT.0161 Subtask 3.

comment 952 comment by: AESA

In page 51, DPO.OR.B.025 c), should a backup system be considered?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 953 comment by: AESA

In page 51, DPO.OR.B.025 d), for the register, maybe it should be added that it will include data related to the deployed equipment, such as P/N, S/N, software (or firmware) version, etc.

This is very important to assure the right management of reports received about failures, malfunctions, etc. and the correction of them.

Maybe EASA is already considering to include this as AMC/GM.

response *Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 954 comment by: AESA

In page 51, DPO.OR.C.001 b)1), there is need for clarification: which ones are the "certain ATM/ANS equipments"? Those for which a certification/declaration specification is to be issued?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

955

comment by: AESA

In page 51, DPO.OR.C.001 b)1), clarification about the concept of ""declaration of design"" is needed, since it doesn't seem to be the same as the ""declaration of design compliance"" stated in article 5 Appendix 2.

In addition, will be the content of this declaration of design established in AMCs/GMs?

response

*Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

In response to the comment, the terms are equal and refer to the same subject.

comment

956

comment by: AESA

In page 51, DPO.OR.C.001 b)3) and c)2), the reference to ""each model of each product"", does it include software version? Maybe, a reference to ""software version"" would be appropriate."

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

957

comment by: AESA

In page 52, SUBPART C — TECHNICAL REQUIREMENTS (DPO.OR.C), it is unclear whether there are specific requirements that a DPO shall fulfill to obtain the privileges to issue declarations, or these privileges are directly obtained once the organization is certified.

response

*Noted*

Please refer to point DPO.OR.A.025 Duration, continued validity and privileges of an organisation approval of the draft Implementing Regulation on DPO approval.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment

958

comment by: AESA

In page 52, DPO.OR.C.001 e), it is established the information that the statement of conformity shall contain at least. Clarification about the concept of statement of conformity is needed. Besides, it should be considered in the provided list: production facilities, testing facilities, quality controls and requirements for the chain suppliers,...

In addition, will be the content of the statement of conformity further detailed in AMCs/GMs?

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

959

comment by: AESA

In page 52, DPO.OR.C.001 e)2) and 3), maybe, a reference to software version would be appropriate.

response

*Noted*

In case the software version is changed, the organisation should change the part number as well; consequently, this aspect is considered as already addressed.

comment

960

comment by: AESA

In page 52, DPO.OR.C.010 b), how does the DPO inform users and owners of the instructions to comply with the directive?

response

*Noted*

The means for demonstration of compliance will be illustrated at AMC/GM level as part of the activities of RMT.0161 Subtask 3.

comment

1050

comment by: Fintraffic Air Navigation Services

It needs to be further detailed which changes in SW/HW require new ATM/ANS equipment certificate and for which one's statement of compliance would be sufficient (what are the triggers for changes to be an update).

response

*Accepted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'ATM/ANS equipment change management'.

comment

1060

comment by: DGAC (French CAA)

Reference Article 4 – Organisations involved in the design, and/or production of ATM/ANS equipment

Correction: Any organisation involved in the design/production or maintenance. "Maintenance" should be suppressed for consistency with the whole framework which mentions design or production only.

"Evolutive maintenance" should be implicitly, or with the help of AMC/GM, considered as design or production modifications. Recurrent maintenance (or simply "maintenance") remains the sole responsibility of ATM/ANS providers.

response

*Not accepted*

A recital on the subject is proposed in the draft Implementing Regulation to promote clarity on the subject.

comment

1061

comment by: DGAC (French CAA)

Reference DPO.OR.A.015 – Organisations exposition

Reference DPO.OR.C.001 – Organisations involved in the design, and/or production of ATM/ANS equipment

Comment for alinea (9) to DPO.OR.A.015: "each model of each piece of equipment".

Comment for Alinea (3) and (5) to Reference DPO.OR.C.001 : "each model of each product" and "each article"

The meaning of such different levels of identification (model, piece, product, article, equipment" should be clarified and simplified.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1062

comment by: DGAC (French CAA)

Reference: DPO.OR.B.001 Management System (a) (5)

Comment: What is the associated risk to be identified within the scope of a change? If it relates to safety risk, DPOA owners may not have the knowledge of the actual usage of the equipment and as such cannot assess the safety risk due to a change.

Proposal: Explicit the kind of risk to be identified within the assessment of the scope of a change. If not dealing with economic, safety or other kind of risk which is a combination of severity of effect and a likelihood of occurrence, prefer the term "impacts", which may be functional, performance, dependability, interoperability, and so forth impacts.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1063

comment by: DGAC (French CAA)

Reference: DPO.OR.B.001 Management System (a) (5)

Comment: This activity consisting of an impact assessment, being risk based or not, should be included in a change control process. This point (5) should be integrated in a dedicated objective aiming at controlling changes i.e.:

- · Assessing the scope of the change
- · Assessing the impact of the change i.e. potential improvements and regression, loss of compatibility, interface changes, etc.
- · Authorising the change i.e. ensuring that every single aspect of a change is shared within the organisation and accepted and will be communicated to users
- · Performing the change, i.e. changing all lifecycle documents/components/equipment impacted by the change and providing and up-to-date set of evidence
- · Assessing the change, verifying the efficiency of the change and the actual implementation of all foreseen modifications

Proposal: Separate the objectives for the initial design/production processes from those dedicated to a change. Interactions between system engineering design/production lifecycle and change control process are well known and the regulation should only emphasize on the fact that a change control process shall ensure that compliance evidence developed during the initial design/production are maintained correctly.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1064

comment by: DGAC (French CAA)

Reference: DPO.OR.B.001 Management System (a) (9) and (10)

Comment: Objectives related to change control should not be mixed up with initial design/production activities objectives. Change control should be a dedicated objective among these points as change control process is far more complete than what is presented here and include at least:

- · Assessing the scope of the change
- · Assessing the impact of the change i.e. potential improvements and regression, loss of compatibility, interface changes, etc.
- · Authorising the change i.e. ensuring that every single aspect of a change is shared within the organisation and accepted and will be communicated to users
- · Performing the change, i.e. changing all lifecycle documents/components/equipment impacted by the change and providing an up-to-date set of evidence
- · Assessing the change, verifying the efficiency of the change and the actual implementation of all foreseen modifications

Proposal: Separate the objectives for the initial design/production processes from those dedicated to a change. Interactions between system engineering design/production lifecycle and change control process are well known and the regulation should only emphasize on the fact that a change control process shall ensure that compliance evidence developed during the initial design/production are maintained correctly.

response

*Noted*

It is considered that the subject is addressed in point DPO.OR.B.005 Change management of the draft Implementing Regulation on the DPO approval.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1065

comment by: DGAC (French CAA)

Reference: DPO.OR.B.001 Management System (a) (9) (i)

Comment: What is meant by “control procedures”? Point (ii) requires assurance in design and assurance design processes shall already include process control (quality process and product assurance).

Proposal: Clarify what is meant by control procedure.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1066

comment by: DGAC (French CAA)

Reference: DPO.OR.B.001 Management System (a) (9) (ii)

Comment: Management system should define system engineering processes in order to ensure an adequate level of assurance for equipment. This is not the management system itself which provides the assurance.

Proposal: Reword : system/software engineering processes and methods in order to ensure an adequate level of assurance that the design of ATM/ANS equipment comply with ... etc.

response *Not accepted*

However, the commenter is invited to promote the proposal during the committee procedure.

comment

1067

comment by: DGAC (French CAA)

Reference: DPO.OR.B.001 Management System (d)

Comment: Which hazards and risks are considered in this sentence? DPO are not dealing with aviation risks and cannot assess the safety impact of the equipment they design/produce except if they are explicitly mentioned in the certification baseline. Moreover, proportioning the management system to both the complexity of the organization and the potential safety impact will create high discrepancies in costs and actual assurance level between two identical pieces of equipment designed/produced by a two-persons DPO or a large one. Assurance level and compliance demonstration rigor should not depend on the size of the organisation.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1068

comment by: DGAC (French CAA)

Reference: DPO.OR.B.005 Change management

Comment: This requirement gathers two different topics dealing, for the first one, with management system changes and, for the second one, with equipment design/production changes. Even if it's dealing with "changes", processes at stake are completely different and involve activities of different natures.

Proposal: Separate these two considerations and address them in a more detailed way (cf Part-21 – Reg EU 748/2012). At least change the title of this requirement which deals only with change **notifications**.

response

*Partially accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

In addition, taking due consideration of the comment, the text is amended to promote clarity.

comment

1069

comment by: DGAC (French CAA)

Reference: DPO.OR.C.001 Organisations involved in the design and/or production of ATM/ANS equipment (b) (3)

Comment: "a current file of complete technical data and records" does not have a universal meaning and indeed the actual set of evidences developed today for IOP or safety are highly heterogeneous and does not provide an equivalent level of assurance. Additional guidance or AMC have to be developed.

Proposal: Develop specific AMC/GM to promote a common standard for ensuring that the "current file of complete technical data and records" is sufficient to achieve a level of assurance proportionate with what is expected in the certification basis.

response

*Accepted*

Taking into account the comment, the development of the associated AMC/GM is under development.

comment

1070

comment by: DGAC (French CAA)



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

Comment: What is being considered as production? Does software release (physically or virtually) is a kind of production? This again questions the scope of what is considered as being an equipment. If software release is production, then some of the objectives below doesn't apply (marking each article par instance).

Proposal: Clarify the definition of equipment, the scope of a certificate/declaration and the consequence on the production process.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In reference to the first question, taking into account the definition of 'functional system' (that means a combination of procedures, human resources and equipment, including hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions; in accordance with point 56 of Annex I to EU IR 2017/373), the answer is that equipment should be considered the hardware as well as software. However, considering the comment, the development of the associated AMC/GM is under consideration.

comment

1071

comment by: DGAC (French CAA)

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

Comment : the term used for statement of conformity in this article and the one used for statement of compliance used throughout all the regulation may lead to confusion, particularly in French (and perhaps in other Latin languages) for which conformity and compliance are translated with only one word "conformité".

response

*Noted*

The Agency duly noted the concern.

The stakeholder is invited to make a concrete proposal during the committee procedure.

comment

1112

comment by: Federal Ministry for Climate Action, Environment, Energy, Mobili

Art. 3 contradicts/violates Art. 80(1)(c) of Regulation (EU) 2018/1139. law the latter EASA is the competent authority only for the certification of "Design and Production Organizations producing ATM/ANS systems and ATM/ANS constituents, [..], **used in the provision of the**

**services referred to in point (b)** of this paragraph". Art. 80(1)(b) deals with pan-European service provision. The certification of Design and Production Organizations producing equipment not being used in pan-European service provision is not in the remits of EASA iaw the Basic Regulation.  
Please remove or correct this Article.

response *Not accepted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment *1135* comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art. 4: Please clarify whether an ATSP/ANSP involved in the identification of functional requirements for ATM/ANS equipment requires a DPO certificate.

response *Noted*

The comment is duly considered.

Please refer to topic 'Roles and responsibilities of the different actors'.

The answer to the question is negative; there is no need for DPO approval in order to define ATM/ANS equipment functional requirements.

comment *1145* comment by: *Romanian CAA*

Annex DPO.OR.B.015, we consider that it is needed to rethink the concept of ensuring acces to contracted organisations of DPO contracted organisations.

response *Noted*

comment *1163* comment by: *Deutscher Wetterdienst*

the regulation should take into account that ANSP might apply for approval, thus AMC should cross-reference the applicable requirements already covered by the applicants' certification. The certificate issued by the responsible NSA should be considered sufficient for demonstration of compliance with those requirements.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under development.

## 8. Appendices

p. 42

comment

254

comment by: *Romanian CAA*

Related to Question 8.1#1, we believe that the proposed text is too vague, as a non-EU organisation may or may not provide a certificate that resembles the EU certificate (no provisions can be related to these as rules do not apply), while EASA would have to demonstrate somehow that those non-EU state's systems and mechanisms related to ATM/ANS equipment are similar to the ones in EU. Also, the text considers that some sort of competent authorities exist in non-EU states that are home to equipment producers, which may or may not be the case. An alternative to integrating equipment made in EU should be clearer.

response

*Noted*

Taking into account the consultation outcome, the provision results in Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' of the draft Delegated Regulation on ATM/ANS equipment conformity assessment.

For further details, please refer to topic 'Access to the market'.

comment

568

comment by: *FOCA Switzerland*

Regarding the process to determine technology that has to be certified or declared, the draft regulations refers to article 76 (3) of regulation (EU) 2018/1139. Article 76 (3) refers to article 115, which leads in the end to the EASA Management Board Decision 01-2022. This decision however does not give the necessary information on how the working group(s) for detailed certification/declaration specification are composed. In our view, these groups determine in the end which type of equipment should be certified or declared.

We understand the functioning of the determination as followed: If there is neither a detailed certification specification nor an detailed declaration specification available, the ANSP has to elaborate a Statement of Compliance (SoC), what is similar to a DoV. If a detailed declaration specification for a special type of equipment is available, a Manufacturer (DPO) has to issue a declaration. And finally, if a detailed certification specification is available, EASA certifies the covered technology.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

583

comment by: A4E

The objective and desired benefit of this Regulation should be clearly focused on bringing costs down while increasing flexibility and interoperability by introducing certified standards. It is not yet clear if and how these objectives can be achieved by the current draft.

- The Certification needs to be limited to pan-European systems and the definition must hence accordingly clear as to avoid ambiguity.
- The Certification must be based on agreed functional requirements as stated by the ATM Masterplan and the relevant deployment regulations (e.g. Common Project 1) for the European ATM modernization process. A synchronization with ICAO and major regulators outside Europe (e.g. FAA) must be ensured. Interoperability is key and standards should be set accordingly. Modular system should be encouraged as to allow for flexible systems and the certification should not impede this development.
- The planned transition periods for existing systems of 5 years as referred to in article 7 is too short to avoid eventually shutdowns of already running systems that are considered as safe. New investments in modern and up to date systems are essential to reach a new era of efficiency maintaining or even increasing high safety standards. The time frame may be too short for ANSPs to replace their legacy systems. ANSPs should be generally required to verify their investment plans against the ATM Masterplan and subsequent deployment regulations (e.g. Common project 1).
- Continuous and agile development has to stay possible without delays in time to market. Such continuity would only be possible if additions and updates to already certified systems do not require a renewed certification.
- The certification processes shall not be too prescriptive and must not create a de facto market barrier for new entrants in the (already rather limited) market of ATM system suppliers.
- Double work and conflicting certification approaches between national regulators and EASA must be avoided. Smaller businesses and scalable innovation as well as new procedures must not be slowed or de facto blocked by the introduction of certification and the required pre-requisites. The processes and administrative effort need to be minimalized and streamlined.
- Only a competitive market environment can ensure that industry efficiency goals incl. environmental objectives can be reached. Therefore, the amendment needs to enable standardization and efficiency gains without slowing down innovation or an increase in cost.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that most of the general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Categorisation of ATM/ANS equipment subject to conformity assessment’;
- ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’;
- ‘Transitional provisions’; and
- ‘Access to the market’.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or in another format.

comment

1059

comment by: *DGAC (French CAA)*

Reference: Article 2 – Definition of ATM/ANS equipment

Comment: the scope of a piece of equipment which is to be certified/declared is not clear. What is the exact scope of the certificate? Can it apply to a full complex system including multiple individual components, can it apply to a single software delivered without any hardware platform? To what extent can it be valid with Virtual Machines and Cloud-based systems?

Proposal: Clarify the scope of an equipment and the limits of the certification.

response

*Accepted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

**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**

p. 53

comment

2

comment by: *Civil Aviation Directorate of the Republic of Serbia*

**- Article 3 – Competent authority**

The second paragraph of this article clearly states that ATM/ANS provider issues statement of compliance and who is competent authority responsible for the oversight. But, the first paragraph states only who is responsible for the oversight (including certification) and not who is subject to oversight. One has to look deep into references to find that „vendor“ (organisations involved in the design and/or production of ATM/ANS equipment) has to apply for the certificate or issue declaration of compliance. It is confusing as somebody could think that ATM/ANS provider should do that. This possible confusion should be avoided by stating clearly who is subject to oversight in this case.

-

response

*Accepted*

Taking into account the comment, the text is amended accordingly.

comment

3

comment by: *Civil Aviation Directorate of the Republic of Serbia*

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

Generally, EASA should develop some AMC or guidelines which closely define which equipment is subject to certification, declaration of design compliance and statement of compliance respectively.

For example in Article 5: *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*

A lot of ATM/ANS systems and equipment can be in this scope (ATIS system, meteorological equipment...Surveillance equipment also receives, and transmits signals in space for the purpose of safe air navigation). It would be much easier for all stakeholders if affected ATM/ANS equipment is more closely defined.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

4

comment by: *Civil Aviation Directorate of the Republic of Serbia*

**Article 6 Statement of compliance**

Statement of compliance is required for ATM/ANS equipment which is neither subject to certification nor to a declaration of compliance. This might neglect all the requirements for

ATM/ANS equipment that make sense only on system level, when equipment is installed, configured, interconnected with other constituents. Current interoperability regulation (552/2004) recognize Declarations of compliance and Declarations of suitability for use issued by manufacturers. Declaration of Verification is top level declaration that declares the whole: installed, configured, interconnected system. This system level perspective is lost in the proposed regulation and it is very important.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, the comment will be considered during the development of the associated AMC/GM as part of RMT.0161 Subtask 3.

comment

5

comment by: *Civil Aviation Directorate of the Republic of Serbia*

**ATM/ANS.EQMT.DEC.020 and ATM/ANS.EQMT.DEC.020** (Record-keeping) stipulate that manufacturers shall provide records and made them available to the Agency. This records are somewhat similar to the content of technical file in the current regulation. This records also should, together with manuals and maintenance instructions also be provided to users (ATM/ANS providers) and NSA (national competent authorities) Furthermore, similar records (design, tests) should be collected on system level by ATM/ANS provider and all that kept in the technical file. That should document all that is done on particular site, installation, configuration, connections. Technical file should be made available to the NSA. Technical files are very useful for ATM/ANS providers and also for NSAs.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

6

comment by: *Civil Aviation Directorate of the Republic of Serbia*

**ATM/ANS.EQMT.CERT.055** Point (a) states that change shall be identified as 'minor' or 'major'. Point (b) says 'All other changes...' which is not clear. Other than what?

response

*Noted*

In addition to topic 'ATM/ANS equipment change management', it should be noted that the concept of major/minor changes of ATM/ANS equipment will be further illustrated at AMC level.

comment 7

comment by: *Civil Aviation Directorate of the Republic of Serbia*

**Article 7, points 7(2) , 7(3) and ATM/ANS.EQMT.AR.A.015(2)** stipulate information exchange between EASA and NSAs which is not very clear. How will this exchange of information happen, which information will be exchanged and when. It might help if this is more specific, for example that the information will be provided upon consultations/request. Or if some kind of information should be provided without request as the other party might not be aware of the existence of the information. Etc.

response *Noted*

The development of the associated AMC/GM is under consideration as part of the activities of RMT.0161 Subtask 3.

comment 17

comment by: *DFS Deutsche Flugsicherung GmbH*

General comment: in order to achieve the specific objectives as outlined in Section 2.2 of this NPA, it is important that no additional national regulations complicate market access, create additional administrative burden, and ultimately disadvantage the affected ATM/ANS providers.

response *Noted*

The comment is agreed.

comment 18

comment by: *DFS Deutsche Flugsicherung GmbH*

Article 4

Does this mean that each single ATS-system will require a certificate? What about the possibility to certify a model/type and then make several products from that? In order to achieve a harmonised system landscape and defragment local solutions a (each) product certificate does not promise the expected benefit.

response *Noted*



Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 19

comment by: *DFS Deutsche Flugsicherung GmbH*

Article 5

Question 8.2#1:

The NAV perspective:

an ILS may be well specified and produced and declared compliant with all provisions. However, when erected at the wrong place of the aerodrome, it is useless or worst case produces harm. This is the ultimate responsibility of the ANSP, that no declaration can take over.

The SUR perspective:

Performance of surveillance sensors is heavily dependent on the surrounding environment. Even functionality and interoperability may be influenced by environmental or temporal conditions. The knowledge of these dependencies lies within the operating organization. Therefore, this organization will usually develop or propose acceptance tests specific to the given environment. A declaration by an approved ATM/ANS equipment manufacturer will cover general functionalities. Testing and tuning to achieve the required performance and ensure coverage and interoperability is a site specific task to be carried out with the ATM/ANS provider.

This thought also applies to VHF (COM) stations.

In addition, while a lot of functionalities of surveillance sensors may be required for all installations, some specific functions may be required for certain site installations. These additional functions will also need specific testing.

A declaration by an approved ATM/ANS equipment manufacturer shall state conformance with certain functionalities documented in generally accepted standards for that equipment. However, experience shows that

- on site testing will be required to ensure interoperability and appropriate performance after installation, e.g. since the declaration-related test-bed is in laboratory condition
- manufacturers may implement not all items addressed in the related standards or implement them only partially.

General conclusion:

The effort of the ANSP will not evidently reduce compared to the additional cost that the new approach seems to create. The danger to have non-professionals selling such equipment AND professionals buying it is very low. The Declaration of those products is meaningful in separating it from those products that need certification. We are still not convinced that this approach enables the expected noticeable reduction in costs and significant gain in flexibility.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Categorisation of ATM/ANS equipment subject to conformity assessment’;
- ‘Roles and responsibilities of the different actors’; and
- ‘Access to the market’.

In case DFS Deutsche Flugsicherung GmbH sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between DFS Deutsche Flugsicherung GmbH and the Agency or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

20

comment by: *DFS Deutsche Flugsicherung GmbH*

Article 6

This regulation stipulates that Statement of Compliance is made against detailed specifications adopted by EASA. It ceases to be valid if (in accordance with point 2. a)) the equipment no longer complies with the essential requirements.

Many detailed specifications, however, do not apply on some essential requirements. Wouldn't it be more consistent to indicate in point 2. a) "no longer complies with the detailed specifications adopted by the Agency..." ?

We understand that the intent of the rule is that the ATM/ANS provider is no longer obliged to show compliance with the essential requirements, but only compliance with the detailed specifications for the equipment he purchases. (Thanks to ATM/ANS.EQMT.AR.A.020). By the way, also the relevant changes to Reg. 373 only refer to the "applicable technical standards...". The existing regulatory framework requires compliance with essential requirements but does not clarify how this has to be handled by ANSPs. There is danger that manifold national different ways will (continue to) exist.

If and how the ATM/ANS provider has to show compliance with essential requirements (applicable to the equipment) in addition (which occurs to be a duplication of effort), this should be made clearer.

response

*Noted*

Please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

comment

21

comment by: *DFS Deutsche Flugsicherung GmbH*

Article 6

“technical standards established by recognised standardisation bodies and listed...”

I am not sure that Eurocontrol belongs to those recognised standardisation bodies. How can EASA ensure the ongoing applicability of current specifications?

response

*Noted*

Please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

The issue will be further considered and discussed during the activities of RMT.0161 Subtask 3.

comment

22

comment by: *DFS Deutsche Flugsicherung GmbH*

Article 7

The Regulation for DPO applies immediately, but for sure will take time until such approval is issued. I understand that, once approved, the DPO is obliged to issue certificate/declaration (for relevant equipment). If not yet approved, the ATM/ANS provider is to issue the SoC in the meanwhile. This can last until Sept. 2028 at the latest. From then, no relevant equipment can be put on the market without certificate or declaration, right? Even the development of a relevant product only once for one user is no longer possible without DPO approval?

response

*Noted*

Please refer to topic ‘Transitional provisions’.

comment

23

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.AR.020

As for derogation it will be very important for potential customers to have access to information which (parts of) AltMoC have been used for a compliance statement and understand potential implications on operation.

response

*Noted*

The comment is not well understood.

The commentator is invited to consider including it in the agenda of the most relevant EASA Advisory Body for further consideration.

comment

24

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.AR.025/030

It is very much appreciated that the agency will take action on interoperability issues. Please note that this is not only an issue for ground systems but needs to be reflected also in air-ground operation.

response

*Noted*

The comment is well received.

comment

25

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.AR.A.030

Will EASA also issue equipment directives for equipment other than relevant for certification and declaration? And if so, how does EASA know about any unsafe condition?

response

*Accepted*

The answer is negative. The subject Directive will address the ATM/ANS equipment subject to EASA oversight.

comment

26

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.AR.055+060

both requirements ask for a "data sheet for continued suitability", what is that?

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

27

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.AR.065

Point (a) refers to Annex IV, which does not exist

response

*Accepted*

comment

28

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.AR.065

A.065 is titled to be the issue of DPO approvals. However it states that approval will be given if the requirements of Annex II or III are complied with. How does the DPO applicant know? These Annexes are about the activity to gain an equipment certificate or issue the declaration. I understood that Regulation "DPO approval" Appendix 1 to the NPA contains the relevant requirements for an organisation to obtain that approval. Article 4 of Regulation DPO (appendix 1) requires the DPO to demonstrate capability with the Annex to that Regulation. But not to obtain the approval? (See my comment on Article 4 to Appendix 1). The necessity to differ between this implementing act and the other delegated act creates a lot of confusion and potential inconsistency.

response

*Noted*

The commenter is kindly invited to note that in accordance with the proposed framework, the DPO will be responsible to specify, design and produce the equipment. The equipment will need to be certified or the DPO will declare that the equipment is compliant with the relevant essential requirements through the demonstration of compliance with the detailed specifications, depending on the type of equipment. For that purpose, the DPO should demonstrate its capability by holding an organisation approval (addressed in the Implementing Act) with certain privileges e.g. certification and/or issue of declarations (addressed in the draft Delegated Regulation on the ATM/ANS equipment conformity assessment).

comment

29

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.AR.B.015

point (d) requires to make the list of certificates and declarations according to point (b) available on request to competent authorities. Would it be possible that EASA rather publish a list of attested equipment on their website?

response

*Noted*

The answer is affirmative.

comment

30

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.CERT.005

The certificate is issued to the design organisation. It is not clear, whether this certificate allows the DPO to have produced and sell several products based on the certified model or whether each single product will need a certificate before it is being sold. In order to achieve

a harmonised system landscape and defragment local solutions a (each) product certificate does not promise the expected benefit.

response *Accepted*

The comment is considered in the Opinion.

comment 31

comment by: *DFS Deutsche Flugsicherung GmbH*

ATM/ANS.EQMT.CERT.035

Within the compliance check according to EQMT.CERT.025 the applicant is to perform also inspections and test. Point (b) requires to issue a statement of verification of the points listed in point (a). Point (d) requires to issue a statement of validation in accordance with point (b) in cases where the Agency has witnessed the test.

What does mean “in accordance with point (b)”? (b) requires a statement of verification, not validation. Is the participation of the Agency regarded as validation?

Point (d) (2) refers to a “statement of conformity provided for in point (b)”. A statement of compliance demonstration is required by EQMT.CERT.025. There is lot of confusion with statements in the two requirements (025+035). It is not clear when to issue what.

Furthermore, Regulation for the approval of DPOs (Appendix 1 of the NPA) requires a “declaration of design” and an “equipment declaration”. Both do not occur in this Regulation (Appendix 2).

This creates maximum confusion. Hopefully AMC/GM will clarify. A leaner IR could help, too.

response *Noted*

Taking into account the comments, the development of the associated AMC/GM is under consideration.

comment 45

comment by: *German NSA (BAF)*

page 54:

“Article 4

1. ATM/ANS equipment...”

Article 4 describes the ATM/ANS equipment very generally. Thoughts of NPA Section 2.3.1.2 page 16 and 17 should at least be in a short form content of recitals.

response *Noted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment

46

comment by: *German NSA (BAF)*

page 55:

*"Article 5  
1. ATM/ANS equipment..."*

see comment 45.

response

*Noted*

comment

47

comment by: *German NSA (BAF)*

page 55:

*"Question 8.2 #1"*

To be consistent and to keep interoperability in mind, sensors should be subject to declaration (also MET Sensors)

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

48

comment by: *German NSA (BAF)*

*"Article 6  
1. ATMN/ANS equipment..."*

see comment 40.

response

*Noted*

comment

49

comment by: *German NSA (BAF)*

page 56:  
*Article 7 (1) (c)*

See comment 33.

Content for SoC is missed and should be added. It should also be added which tasks NSA have when receiving SoC (could also be inserted in Regulation (EU) 2017/373).

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

50

comment by: *German NSA (BAF)*

page 56:

*"2. The Agency shall evaluate..."*

The evaluation procedure seems to produce unnecessary effort. It should be taken into account that the previous approach did not lead to unsafe conditions. Therefore, issued DoV and DoC/DsU should be valid until a manufacturer changes the equipment (e.g. evolutive maintenance) or the ANSP changes its systems/constituents. Then a SoC should be issued from the ANSP. The evaluation by EASA seems not to bring any advantages because both - DoV and SoC - are self-declarations of the ANSP. Therefore, EASA evaluation should be waived.

When detailed certification specifications and detailed declaration specifications will have been successively developed and published, the new produced equipment has to be certified/declared by/for EASA.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability' and 'Transitional provisions'.

comment

51

comment by: *German NSA (BAF)*

page 60:

*ATM/ANS.EQMT.AR.A.035 (a) (1)*

See comment 40.

response

*Noted*

comment

52

comment by: *German NSA (BAF)*

page 61:

*ATM/ANS.EQMT.AR.A.040*



See comment 40.

response *Noted*

comment 66

comment by: *ENAIRE*

**Original text:**

(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.

**Proposed amended text:**

(2) following the approval by the Agency of the proposal referred to in point (1), make available to all known users (**specially ANSPs**) of the equipment and, on request, to any person required to comply with the ATM/ANS equipment directive, appropriate descriptive data and accomplishment instructions.

**Comment/Rationale:**

ANSP should be mentioned specially.

response *Partially Accepted*

Taking into account the comment, associated GM is under consideration.

comment 104

comment by: *Thales Land and Air Systems*

Appendix 2/  
page 54

Article 4 - notion of criticality used in paragraph 2.3.1.2 is missing. The definition of ATM/ANS equipment subject to certification shall be based on the equipment criticality and be consistent with the regulation objective and expected benefits described in the NPA.  
Criticality levels could be defined based on the severity classification scheme defined in the SESAR SRM Accident and Incident Models.

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 105

comment by: *Thales Land and Air Systems*

Appendix 2/ page 54	Article 4 - Definition of equipment subject to certification can be subject to interpretation, in case of disagreement with regard the type of approval required for an equipment, who has the authority to decide whether the equipment is subject to certification or declaration?
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response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 106

comment by: *Thales Land and Air Systems*

Appendix 2/ page 55	Article 5 - The definition of ATM/ANS equipment subject to declaration shall be based on the equipment criticality, impact on interoperability and be consistent with the regulation objective and expected benefits described in the NPA. In paragraph 2.3.1.2 page 16 of the NPA 2022-09, criteria for identifying equipment subject to certification or declaration shall be based on its level of safety or interoperability criticality. This notion of safety or interoperability criticality is missing in definition provided in Article 5. Criticality levels could be defined based on the severity classification scheme defined in the SESAR SRM Accident and Incident Models.
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response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 107

comment by: *Thales Land and Air Systems*

Appendix 2/ page 55	Article 5 - ATM/ANS equipment subject to declaration of design compliance may not be subject to certification according to Article 6 and definition of equipment subject to certification in article 4 : why defining certain types of equipment for which no certification is sought, but declaration of design compliance to a technical standard would be required ? According to Article 6, 3 kind of exclusive approvals (certification by agency, declaration of design compliance, statement of compliance) with regards to recognized technical standards : what happens if there is no recognized technical standard for an ATM/ANS equipment ?
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response *Noted*

Please refer to topics ‘Categorisation of ATM/ANS equipment subject to conformity assessment’ and ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

comment 108

comment by: *Thales Land and Air Systems*

Appendix 2/ page 55	<p><b>Comment on question 8.2#1</b></p> <p>While NAVAIDS equipment are closely tight with the safety of operations and provide direct guidance to the aircraft and its crew; it is considered that, in Europe, surveillance sensors contribution to the provision of safe ATM/ANS services is more indirect. Indeed, data provided by one surveillance sensor are fed into a certified ATM system which consolidates those with at least one other surveillance source to provide to the operator (e.g air traffic controller) information on the air situation.</p> <p>On the other hand, compliance to interoperability requirements is key to the proper integration of surveillance sensors into an ATM system.</p> <p>Based on the above, we propose that surveillance sensors (for example PSR/SSR radars, ADS-B receivers or MLAT equipment) used for the provision of ATM/ANS services should be subject to Statement of Compliance under the responsibility of the ANSP supported by manufacturers.</p>
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response *Noted*

The comment is considered.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 109

comment by: *Thales Land and Air Systems*

Appendix 2/ page 55

Article 6 - reference to point (g)(3) ATM/ANS.OR.A.045 is incorrect.  
Article 6 - reference to point ATM/ANS.OR.A.050(e) is incorrect.

response *Accepted*

comment 110

comment by: *Thales Land and Air Systems*

Appendix  
2/ page 56

Article 7(1)(a) -

The use of "on a provisional basis" is confusing and could be interpreted as a provisional certificate being granted pending the Agency evaluation.  
To ease the understanding of Article 7(1)(a), it is proposed to remove "on a provisional basis" from the sentence.

ATM/ANS equipment which falls within the category of ATM/ANS equipment that requires certification in accordance with Article 4 of this Regulation shall 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;  
Same comment applies for 7(3)(a)

response *Not accepted*

Please refer to topic 'Transitional provisions'.

comment

111

comment by: *Thales Land and Air Systems*

Appendix 2/ page 56	<p>Article 7(1)(b) - The use of "on a provisional basis" is confusing and could be interpreted as a provisional certificate being granted pending the Agency evaluation. To ease the understanding of Article 7(1)(b), it is proposed to remove "on a provisional basis" from the sentence. 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; Same comment applies for 7(3)(b)</p>
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response

*Not accepted*

Please refer to topic 'Transitional provisions'.

comment

112

comment by: *Thales Land and Air Systems*

Appendix 2/ page 56	<p>Article 7 - "manufactured" needs to be defined and added in the definition. It is understood that a manufactured equipment is an equipment that has been through its design and production phase and that is ready to be installed.</p>
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response

*Partially accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

113

comment by: *Thales Land and Air Systems*

Appendix 2/ page 56	Article 7 - dates such as "13 Septembre 2028" or "12 Septembre 2030" should be removed from the regulation and replaced by either milestones such as: "X years after the date of entry into force of this regulation", "date of applicability of detailed specification"
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response *Note accepted*

Please refer to topic 'Transitional provisions'.

comment

114

comment by: *Thales Land and Air Systems*

Appendix 2/ page 56	article 7 - shall define the organisation responsible for the action plan definition and implementation.
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response *Noted*

Please refer to topic 'Transitional provisions'.

Taking into account the comment, the development of the associated GM is under consideration.

comment

115

comment by: *Thales Land and Air Systems*

Appendix 2/ page 57	Article (7)(3) - This sub-section is not understood, explanation is needed on why ATM/ANS equipment manufactured from date of entry in force until 12 september 2028 shall be subject to statement of compliance, since Article 6 mentions that equipment that falls in the category of article (5) or (6) do not require a statement of compliance.
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response *Noted*

Please refer to topic 'Transitional provisions'.

comment 116

comment by: *Thales Land and Air Systems*

Appendix  
2/ page 57

Article 7 - this transition phase shall ensure the continuity of ATM/ANS equipment design, production and delivery to the ANSPs.  
Taking into consideration that detailed specifications are developed in a step by step approach, it is acknowledged that ATM/ANS equipments subject to certification or declaration will not all have applicable detailed specifications available at the time this regulation enters into force.

The situation where an equipment design starts before the end of the transition phase for a planned transition into operation after the end of the transition phase (e.g 2031) needs to be considered. As detailed specifications will be developed in a step by step approach, detailed specifications applicable to this equipment may not be available at the time this equipment is being designed, as a result a declaration or certification baseline cannot be defined for this equipment.

With the incremental development of detailed specifications, applicable detailed specifications may become available for this equipment before the equipment enters into operations.

To ensure the continuity of ATM/ANS equipment design, production and delivery, it is proposed to add a notion of transition phase for equipment certification and declaration starting from the date of availability of the applicable detailed specifications. This transition phase shall allow time for the DPO to adapt their equipment to the newly available detailed specifications.

It is proposed to

- add in Article 7:

4. The following transitional provisions shall apply to ATM/ANS equipment that has been manufactured by an ATM/ANS provider before the availability of applicable detailed specifications :

- (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, be deemed to have been issued with a certificate in accordance with Article 4 of this Regulation unless the Agency determines, ...
- (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, be deemed to have been issued with a declaration of compliance in accordance with Article 5 of this Regulation unless the Agency

	<p>determines,...</p> <p>- add in ATM/ANS.EQMT.AR.A.040 that for each detailed specification, a date of applicability which is equal to X years after its date of publication shall be defined.</p>
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response

*Not accepted*

The comment is considered.

The Agency believes that the concern is addressed in 'Transitional provisions'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or in another forum.

comment

117

comment by: *Thales Land and Air Systems*

<p>Appendix 2/Subpart A/ page 58</p>	<p>ATM/ANS.EQMT.AR.A.005 It is understood that Declarations are provided to the EASA by the approved DPO. "acceptance" should be replaced by "verification of declarations for ATM/ANS equipment and acceptance of non-compliance;" Is it also proposed to define a delay framing EASA feedback upon Declaration reception.</p>
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response

*Partially accepted*

The text is amended to address the notion.

comment

118

comment by: *Thales Land and Air Systems*

<p>Appendix 2/ page 60</p>	<p>ATM/ANS.EQMT.AR.A.035 - Item (b) mentions "The inclusion of additional features, characteristics or functions not initially included in the certification basis shall be agreed by the Agency" : this may often happen since technical</p>
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	specifications will probably not cover all possible functions of an ATM/ANS equipment and result in difficulties in implementing such requirement. Moreover, what are the cases for which the Agency would not agree on additional features, as soon as item (c) is respected ?
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response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

119

comment by: *Thales Land and Air Systems*

Appendix 2/Subpart A/ page 61	ATM/ANS.EQMT.AR.A.035 error in the reference: ATM/ANS.EQMT.AR.A.040 should be ATM/ANS.EQMT.AR.A.045
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response

*Accepted*

comment

120

comment by: *Thales Land and Air Systems*

Appendix 2/Subpart A/ page 61	ATM/ANS.EQMT.AR.A.040 When developing the detailed specification, EASA shall ensure that the detailed specifications used as certification and declaration baseline are consistent with the safety assessments required by 2017/373 from the ATS providers, as a result an item (c) shall be added in ATM/ANS.EQMT.AR.A.040: We propose to add: (c) The detailed specifications referred to in point (a) shall ensure compliance to safety requirements resulting from service providers safety analysis, as required by (EU)2017/373 AMC.ATS.OR.205(a) (2)
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response

*Noted*

In addition to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability', the comment will be considered during the activities of RMT.0161 Subtask 3.

comment

121

comment by: *Thales Land and Air Systems*

Appendix 2/Subpart A/ page 61	ATM/ANS.EQMT.AR.A.040 As already raised to EASA, the successful integration of certified and declared ATM/ANS equipment into an ATM/ANS system and its associated safety analysis requires the development of harmonised severity definitions and associated safety objectives across Europe. It is paramount that compliance to detailed specifications, including safety requirements guarantees compliance to service provider safety requirements
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response

*Noted*

In addition to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability', the comment will be considered during the activities of RMT.0161 Subtask 3.

comment

122

comment by: *Thales Land and Air Systems*

Appendix 2/ page 61	ATM/ANS.EQMT.AR.A.040 - The wording is ambiguous since establishment of detailed technical specifications sounds to be done when an organisation apply for a certificate, a declaration of compliance or a statement of compliance. What happen if no organisation apply ? Are they allowed to not apply for one of those 3 kind of approvals if an ATM/ANS equipment is put in operation ? Or on the contrary, is it a race to the first organisation applying for a certificate will publish its technical specification, then other organisation should follow with the same features, characteristics or functions ?
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response

*Noted*

The comment is considered.

The Agency believes that the concerns are addressed in topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or in another forum.

comment

123

comment by: *Thales Land and Air Systems*

Appendix 2/Subpart A/ page 62	ATM/ANS.EQMT.AR.A.050 Level of Involvement not understood : to be discussed ensure it is limited to equipments subject to certification, not for equipment subject to declaration
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response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The answer is affirmative that this provision would apply in the case of ATM/ANS equipment subject to certification.

comment

124

comment by: *Thales Land and Air Systems*

Appendix 2/Subpart A/ page 63	ATM/ANS.EQMT.AR.A.065 should be moved to the Draft Commission implementing regulation .../... laying down technical requirements and administrative procedures for approval of organisation involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents
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response

*Not accepted*

The requirements laid down in the commented provision apply to the Agency acting as competent authority.

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

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

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

In conclusion, the commenter is invited to note that the split and allocation of the various provisions between delegated versus implementing acts are stipulated in the EASA Basic Regulation (EU) 2018/1139.

comment

125

comment by: *Thales Land and Air Systems*

Appendix  
2/Subpart B/  
page 65

ATM/ANS.EQMT.AR.B.005 :  
Level of delegation from the agency to the qualified entity shall be defined. Is the qualified entity providing technical assistance or does it have full delegation of responsibilities for the certification of equipment?

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

126

comment by: *Thales Land and Air Systems*

Appendix  
2/Subpart B/  
page 65

ATM/ANS.EQMT.AR.B.005 :  
A full delegation of responsibility for the certification of equipment creates a risk of heterogeneity in the certification process implementation and may lead to unlevelled playing field in ATM/ANS industry.

response

*Noted*

The comment is considered.

The Agency believes that the concerns are addressed in topic 'Roles and responsibilities of the different actors' as well as in topic 'Impact assessment', in particular 'Level playing field and benefits'.

comment

127

comment by: *Thales Land and Air Systems*

Appendix  
2/Subpart B/  
page 65

ATM/ANS.EQMT.AR.B.005 :  
Delegation related to continuing oversight of organisations (DPO) shall be removed as relying on different entities to oversight DPOs may lead to unlevelled playing field in ATM/ANS industry

response

*Not accepted*

It should be noted that at the end the final responsibility on the continuous oversight is within the Agency's scope.

comment

128

comment by: *Thales Land and Air Systems*

Appendix  
2/Appendix 1/  
page 71

This Appendix 1, shall be moved as an appendix to Draft Commission implementing regulation .../... laying down technical requirements and administrative procedures for approval of organisation involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents

response

*Not accepted*

If the commenter refers to Annex I to the draft Implementing act, it should be noted that the referenced Annex lays down the detailed requirements for organisations involved in the design and/or production of ATM/ANS equipment, which is the core of the Regulation in question.

comment

129

comment by: *Thales Land and Air Systems*

Appendix  
2/AnnexII/  
page 72

ATM/ANS.EQMT.CERT.015 (b)(2)(vi) this item is not understood?  
Clarification is required on the intent of this item with regards to unidentified non-compliance with certification-basis requirements.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

130

comment by: *Thales Land and Air Systems*

Appendix  
2/AnnexII/ page  
73

ATM/ANS.EQMT.CERT.015 (e)(2) error in the references to  
ATM/ANS.EQMT.AR.A.030, reference should be to  
ATM/ANS.EQMT.AR.A.035

response

*Accepted*

comment

131

comment by: *Thales Land and Air Systems*

Appendix  
2/AnnexII/  
page 73

ATM/ANS.EQMT.CERT.020 privileges should be provided to approved DPO based on its ability to manage and characterise changes to an equipment. The possibility should be given for the DPO to propose criteria defining different levels of change. The certification requirements applied to a change should be commensurate to the change undertaking, e.g. definition of major and minor changes.  
It is understood that major and minor changes will not be defined in the hard law, nevertheless the hard law should provide the opportunity to tailor the certification program requirements to the level of changes.

response

*Noted*

Following the order of the comments:

- Point DPO.OR.A.025 'Duration, continued validity and privileges of an organisation approval' of the draft Implementing Regulation addresses the subject.

- In addition to DPO.OR.B.005 ‘Change management’ of the draft Implementing Regulation, the concept of major/minor changes will be further illustrated at AMC level under the scope of RMT.0161 Subtask 3.
- The comment is duly considered.

comment 132

comment by: *Thales Land and Air Systems*

<p>Appendix 2/AnnexII/ page 73</p>	<p>ATM/ANS.EQMT.CERT.025 (b)  The certification baseline shall be defined at submission of the certification program based on ATM/ANS.EQMT.AR.A.035 and agreed between the DPO and the Agency. Once accepted by the EASA, the certification baseline should not be updated during the certification program except in specific situation where equipment directive issued by EASA requires update of the agreed certification baseline.</p>
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response *Noted*

It should be noted that ‘ATM/ANS equipment directive’ means a document issued by the Agency that is responsible for the oversight of ATM/ANS equipment subject to certification issued in accordance with Article 4 or subject to declaration declared in accordance with Article 5, which mandates actions to be performed by ATM/ANS providers on ATM/ANS equipment to address an unsafe and/or insecure condition that has been identified and restore the performance and interoperability of that ATM/ANS equipment when evidence shows that the safety, security, performance or interoperability of that particular equipment may otherwise be compromised.

That means that the directive is issued after the equipment is already deployed, i.e. the certification is completed and the declaration is registered.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 133

comment by: *Thales Land and Air Systems*



Appendix 2/Annex II/ page 74	ATM/ANS.EQMT.CERT.035 - Point (a) (1) (iii) is impossible to comply with when ATM/ANS equipment is based on COTS hardware such as laptops or market computers; there will be no manufacturing processes, construction and assembly complying to those specified in the equipment design.
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response *Noted*

The subject could be considered, but would require a deeper discussion, analysis and evaluation of the possible impacts. Therefore, the commenter is kindly invited also to consider whether a more detailed rulemaking proposal on the issue would be possible during the development of the associated AMC/GM as part of the activities of RMT.0161 Subtask 3.

comment 134

comment by: *Thales Land and Air Systems*

Appendix 2/Annex II/ page 76	<p>ATM/ANS.EQMT.CERT.055 - Point (b) With regard to point(a), point(b) is not clear.</p> <p>It is understood that approved DPO will have the privilege to approve minor changes, where major changes will require to be aproved by the Agency.</p> <p>ATM/ANS.EQMT.CERT.055 shall be reworded to ensure clarity on the management of changes to a certified equipment.</p>
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response *Partially accepted*

It is considered that point DPO.OR.A.025 'Duration, continued validity and privileges of an organisation approval' addresses the subject.

Furthermore, the stakeholder is invited to consider putting forward a proposal during the development of the associated AMC/GM as part of the activities of RMT.0161 Subtask 3.

comment 135

comment by: *Thales Land and Air Systems*

Appendix 2/Annex III/ page 77	ATM/ANS.EQMT.DEC.015 - "In this case, the changed equipment shall keep its original part number." : Do you mean that a change to the design that is within the scope of the approved organisation's privileges does not affect its part number ?
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response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The answer to the question is that, depending on the significance of the change, it does. Point (a) refers to 'minor' change, while 'point (b) addresses 'major' changes.

comment 137

comment by: DSNA

**#1** - Reference: 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.*

Comment: Same comments as on paragraph 2.3.1.2. ATM/ANS equipment concerned by certification or declaration are not clearly defined, creating ambiguity and difficulties for organizations to assess if they should become DPO or not.

Proposal: The list of ATM/ANS equipment for certification and declaration should be defined.

**#2** - 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.*

Comment: CNS equipment are already defined by ICAO standards. So it does not seem necessary to certify them. Declarations by DPO should be enough.

**#3** - Article 7  
*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;*

Comment: same comment as 2.3.1.2

Comment: In a worse case scenario, an ANSP may have to replace all or most of its ATM equipment if EASA decides so, which would be economically prohibitive.

Proposal: A real grandfathering process shall be in place in order to avoid unacceptable costs for ANSP whereas current operational systems do meet the applicable essential requirements of the Basic Regulation and the corresponding delegated and implementing acts.

response

*Partially accepted*

Following the order of the comments:

- Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.
- In addition to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’, please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.
- Please refer to topic ‘Transitional provisions’. In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

171

comment by: COULON FR SAA

*Article 3*

*competent authority*

*Article 5 of this Regulation shall be the Agency pursuant to Article 80*

the case of mil competent authorities has to be clarifies specifically.

response

*Noted*

The proposal establishes the framework on the basis of the EASA Basic Regulation (EU) 2018/1139, i.e. it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military. However, Member States should ensure that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

comment

179

comment by: Prof. Filippo Tomasello

Question 8.1 #2 it would be safer if the declaration would be backed by an attestation issued by an accredited and independent third party, such as Conformity Assessment (alias Notified) Bodies based on Regulation 765/2008 or Qualified Entity based on Art, 69 of 2018/1139.

response

*Noted*

The commenter is invited to note that Regulation (EC) No 552/2004 is repealed with effect from 11 September 2018. However, Articles 4, 5, 6, 6a and 7 of that Regulation and Annexes III and IV thereto continue to apply until the date of application of the new framework. In this context, Article 8 on Notified bodies does not apply since the referenced date.

As regards the qualified entities, the proposed framework addresses the subject; please refer to point ATM/ANS.EQMT.AR.B.005 Allocation of tasks to qualified entities of the draft Delegated Regulation.

comment

180

comment by: *Prof. Filippo Tomasello*

Art. 6.1 may add 'if applicable' to 'listed in the detailed specifications', since otherwise industry development may be hampered by lack of EASA guidance, while in that case industry standards might be available.

response

*Not accepted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

181

comment by: *Prof. Filippo Tomasello*

Add point (3) to Article 6: The statement of compliance may be based on verification of conformity based on Regulation 765/2008.

response

*Partially accepted*

The comment will be considered during the development of the associated AMC/GM under RMT.0161 Subtask 3.

comment

230

comment by: *CANSO*

Reference: 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.

Comment: Same comments as on paragraph 2.3.1.2.

ATM/CNS equipment concerned by certification or declaration are not clearly defined, creating ambiguity and difficulties for organizations to assess if they should become DPO or not.

Proposal: The list of ATM/CNS equipment for certification and declaration should be defined.

response *Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 231

comment by: *CANSO*

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.

Comment: CNS equipment are already defined by ICAO standards. So it does not seem necessary to certify them.

Declarations by DPO should be enough.

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 232

comment by: *CANSO*

Article 7

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;

Comment: same comment as 2.3.1.2

Comment: In a worst case scenario, an ANSP may have to replace all or most of its ATM equipment if EASA decides so, which would be economically prohibitive.

Proposal: A real grandfathering process shall be in place in order to avoid unacceptable costs for ANSP whereas current operational systems do meet the applicable essential requirements of the Basic Regulation and the corresponding delegated and implementing acts.

response

*Noted*

Please refer to topic 'Transitional provisions'. In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

244

comment by: *DFS Deutsche Flugsicherung GmbH*

Article 5 1.  
substitutue "... as specified in Annex II to this..." by "Annex III".

response

*Accepted*

The text is amended accordingly.

comment

255

comment by: *Romanian CAA*

Related to Question 8.2#1, we believe that SUR sensors may be dealt with in a similar way to NAV equipement as the rationale behind this decision may apply to SUR as well.

response

*Noted*

Please refer to the topic 'Categorisation of ATM/ANS equipment'.

comment

269

comment by: *CANSO*

8.2 Article 4

Must be much clearer regarding which Ground Equipment that is covered.

response

*Accepted*

Please refer to the topic 'Categorisation of ATM/ANS equipment'.

comment

272

comment by: *CANSO*

ATM/ANS.EQMT.AR.A.050

If the Agency has established the detailed technical specification is there really any alternative that the Agency takes the lead in verification and validation activities? Otherwise many ANSPs have to interpret a detailed technical specification which they have not written themselves, and try to figure out how verification and validation should best be performed. That is quite a difficult job when your organisation has not written the specification itself.

response

*Noted*

Please refer to topics 'Roles and responsibilities of the different actors' and 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

273

comment by: *CANSO*

ATM/ANS.EQMT.AR.A.045

Who is going to make the decision that a system has unusual design, unconventional use or that similar systems has newly identified risks (which are applicable to a specific ATM/ANS system in an approval process)? As design of a complex system is a spectrum of subparts and possible solutions it is neigh impossible to draw a line where something is unusual or not, or whether it is of unconventional use. The decision on unusual design, unconventional use will be influenced by the experience of the person managing the application, which could lead to different requirements for different applications depending on which person is managing the application.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

274

comment by: *CANSO*

ATM/ANS.EQMT.AR.C.020 (g)

What will happen to an actual operational ATM/ANS-system if the certificate for the manufacturer or system is revoked? Will the ANSP be able to continue with their operations using the system?

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment	281	comment by: <i>CANSO</i>
	<p>ATM/ANS.EQMT.CERT.015 (b)(2)(i)  The detailed description of the design (including configurations) can be a substantial amount of information, and not known to the DPO before delivery to an ANSP. Different ANSPs can have different configurations of the same ATM/ANS equipment.</p>	
response	<p><i>Noted</i></p> <p>Please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.</p>	

comment	282	comment by: <i>CANSO</i>
	<p>ATM/ANS.EQMT.CERT.020  How will DPOs know beforehand what type of changes in the design could be found as extensive by the Agency? There should be some criteria or definition of “extensive” so that DPOs will not be surprised by having to apply for certificate.</p>	
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>	

comment	283	comment by: <i>CANSO</i>
	<p>ATM/ANS.EQMT.DEC.025  Will EASA allow all languages in manuals?</p>	
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>	

comment	297	comment by: <i>CANSO</i>
	<p>General comment: in order to achieve the specific objectives as outlined in Section 2.2 of this NPA, it is important that no additional national regulations complicate market access, create additional administrative burden, and ultimately disadvantage the ATM/ANS providers.</p>	
response	<p><i>Noted</i></p>	



The comment is agreed.

comment

298

comment by: *CANSO*

Article 5

Question 8.2 #1:

The NAV perspective:

an ILS may be well specified and produced and declared compliant with all provisions. However, when erected at the wrong place of the aerodrome, it is useless or worst case produces harm. This is the ultimate responsibility of the ANSP, that no declaration can take over.

The SUR perspective:

Performance of surveillance sensors is heavily dependent on the surrounding environment. Even functionality and interoperability may be influenced by environmental or temporal conditions. The knowledge of these dependencies lies within the operating organization. Therefore, this organization will usually develop or propose acceptance tests specific to the given environment. A declaration by an approved ATM/ANS equipment manufacturer will cover general functionalities. Testing and tuning to achieve the required performance and ensure coverage and interoperability is a site specific task to be carried out with the ATM/ANS provider.

This thought also applies to the coverage of VHF (COM) stations.

In addition, while a lot of functionalities of surveillance sensors may be required for all installations, some specific functions may be required for certain site installations. These additional functions will also need specific testing.

A declaration by an approved ATM/ANS equipment manufacturer shall state conformance with certain functionalities documented in generally accepted standards for that equipment. However, experience shows that

- on site testing will be required to ensure interoperability and appropriate performance after installation
- manufacturers may implement not all items addressed in the related standards or implement them only partially.

General conclusion:

The effort of the ANSP will not evidently reduce compared to the additional cost that the DPO approval bears. Declaration of those products is though deemed meaningful, however the need and benefit to hold that DPO approval by their manufacturers is not visible, especially since the danger to have non-professionals selling such equipment AND professionals buying it is very low.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Categorisation of ATM/ANS equipment subject to conformity assessment’;
- ‘Roles and responsibilities of the different actors’; and
- ‘Access to the market’.

In case CANSO sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between CANSO and the Agency or it could be included in the agenda of the most relevant EASA Advisory Body.

comment 299

comment by: CANSO

Article 6

Statement of Compliance is made against detailed specifications adopted by EASA. It ceases to be valid if (in accordance with point 2. a)) the equipment no longer complies with the essential requirements.

Many detailed specifications, however, do not apply on some essential requirements. Wouldn't it be more consistent to indicate "no longer complies with the detailed specifications adopted by the Agency..." ?

**CANSO understands that the intention expressed in this NPA is that the ATM/ANS provider is no longer obliged to show compliance with the essential requirements.**

**The given regulatory framework does not clarify how essential requirements have to be handle by ANSPs which could lead to national differences.**

response *Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment 332

comment by: Nils PALMQVIST

8.2 Article 4

Must be much clearer regarding which Ground Equipment that is covered.

response *Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

333

comment by: *Nils PALMQVIST*

8.2 Article 5

Regarding Question 8.2 #1.

Sensors can be used in different ways. Tracks can be used directly from a sensor, or the sensor provides plots to a tracker which in turn produce the tracks. Either way LFVs position is that sensors shall not be subject to declaration by approved design.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

334

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.AR.A.040

To what level of detail will the Agency establish detailed technical specifications? As an ANSP it is difficult to believe that these specifications can be so detailed that they reduce the work for ANSPs and DPOs with specification. It is suspected that the specifications from the Agency will be either too generic to be of practical use, or contain too detailed solutions which are not what is needed or preferred by ANSPs and DPOs.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

335

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.AR.A.045

Who is going to make the decision that a system has unusual design, unconventional use or that similar systems has newly identified risks (which are applicable to a specific ATM/ANS system in an approval process)? As design of a complex system is a spectrum of subparts and possible solutions it is neigh impossible to draw a line where something is unusual or not, or whether it is of unconventional use. The decision on unusual design, unconventional use will be influenced by the experience of the person managing the application, which could lead to different requirements for different applications depending on which person is managing the application.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 336

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.AR.A.050

If the Agency has established the detailed technical specification is there really any alternative that the Agency takes the lead in verification and validation activities? Otherwise many ANSPs have to interpret a detailed technical specification which they have not written themselves, and try to figure out how verification and validation should best be performed. That is quite a difficult job when your organisation has not written the specification itself.

response *Noted*

Please refer to topics 'Roles and responsibilities of the different actors' and 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 337

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.AR.A.055 (a)(3)

At this stage no ANSP has been involved and this means that a DPO has to know how existing and future customers intend to configure and use the equipment.

response *Noted*

comment 338

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.AR.C.020 (g)

What will happen to an actual operational ATM/ANS-system if the certificate for the manufacturer or system is revoked? Will the ANSP be able to continue with their operations using the system?

response *Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

339

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.CERT.015 (b)(2)(i)

The detailed description of the design (including configurations) can be a substantial amount of information, and not known to the DPO before delivery to an ANSP. Different ANSPs can have different configurations of the same ATM/ANS equipment.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

340

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.CERT.020

How will DPOs know beforehand what type of changes in the design could be found as extensive by the Agency? There should be some criteria or definition of "extensive" so that DPOs will not be surprised by having to apply for certificate.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

341

comment by: *Nils PALMQVIST*

ATM/ANS.EQMT.DEC.025

Will EASA allow all languages in manuals?

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

352

comment by: *DAC-LU*

**- Article 4 (1)**

A closed list of systems that must be issued with a certified is needed to avoid diverging interpretations on which equipment falls under Article 4(1).

A list of systems requiring a certificate or a more detailed description of the principle for

deciding what equipment requires certification would be needed to avoid issues with interpretation, an AMC on this could be a way forward.

E.g.1: If an ANSP used radar data to provide separation, would that radar need to be certified?

- The radar processes radar detections to provide radar tracks, which could be delivered to ATC directly.

E.g.2: Direction Finders process and deliver data, which could be used by ATC for the tasks described in this article.

**- Article 5 (1)**

A closed list of systems that are subject to declaration of design compliance is needed to avoid diverging interpretations on which equipment falls under Article 5(1).

**- Question 8.2 #1**

ANSPs of all sizes depend on the support of DPOs for compliance verifications. It would be logic to place this verification with the DPO.

The correct functioning of surveillance sensors is essential to ensure the systems using this information are safe and stable (e.g. SDPS, Safety nets), as well as to avoid overall loss of detection due to issues such as over-interrogation.

The rationale why essential constituents of the surveillance chain like PSR/SSR radars, ADS-B receivers or MLAT equipment should be excluded from the certification performed by EASA, when other surveillance components are subject to EASA certification cannot be identified.

**- ATM/ANS.EQMT.AR.A.025 c)**

Notification to CAAs is specifically mentioned "when joint action is required". However, it is needed for CAAs to always be notified (see the newly proposed requirement ATM/ANS.AR.C.005(a)(4)). This would in any case be covered by requirement ATM/ANS.EQMT.AR.A.015 (a) and the need to include this specific text here is therefore not clearly understood.

**- ATM/ANS.EQMT.AR.A.030 c)(2)**

Information shall also be made available to CAAs in order to enable performing the task describe in ATM/ANS.AR.C.005(a)(4).

response *Accepted*

Following the order of the comments:

- As regards Article 4 and Article 5, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.
- As regards compliance verification issue, please refer to topic 'Roles and responsibilities of the different actors'.

- As regards point ATM/ANS.EQMT.AR.A.025, it should be pointed out that it refers to ‘Immediate reaction to a safety problem’ e.g. via means of ATM/ANS equipment directive, while ATM/ANS.EQMT.AR.A.015 covers the oversight activities.
- It should be noted that the commented provision does not address continuous oversight, but an action performed 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.

comment

354

comment by: *ENAIRE*

It should be address in the regulation, in ANNEX II, ATM/ANS EQUIPMENT CERTIFICATES, (Part-ATM/ANS.EQMT.CERT) how to deal with the non compliance with the requirements detected by the service provider (ANSP) during the testing of the system, for the integration and commissioning. This situation could affect not only to the service provider performing the testing but for the rest of the ANSPs, that could be using the system certified either by EASA or the Approved design organization.

response

*Noted*

Please refer to topic ‘Roles and responsibilities of the different actors’.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

The commenter is also invited to refer to ATM/ANS.OR.A.065 (c).

comment

361

comment by: *LEONARDO*

Question 8.2 #1: For surveillance system (e.g. PSR) Leonardo is in favour of “DECLARATION”

response

*Noted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment

362

comment by: *LEONARDO*

(p.77) Article 7: Do EASA confirm that the systems that are today in operation will have to be reassessed again through certification/declaration/SoC?

response

*Noted*

The answer is negative. For further details, please refer to topic 'Transitional provisions'.

comment

382 ❖

comment by: *Tern Systems*

**Single competent authority is a risk for overall safety, innovation and a business risk for DPOs**

The NPA proposes EASA as the single competent authority for all DPOs and the provided equipment: This creates a single point of failure and bottleneck in the production of future ATM/ANS equipment.

If the EASA infrastructure is not sufficient, this will delay delivery of equipment. This can influence safety of operations and can hinder DPOs to fulfil their contracts with ANSPs. Neither Appendix 1 or 2 of the NPA define any restrictions for the duration of the process of obtaining approval for a DPO or certification and declaration of compliance for equipment.

ATM/ANS.EQMT.CERT.015 Application for an ATM/ANS equipment certificate (d): "An application for the issue of an ATM/ANS equipment certificate shall be valid for 5 years" could indicate processing times of several years. For a software DPO, development cycles of several years are unrealistic and not supportive of innovation.

Were other options considered to achieve consistent regulation of ATM/ANS equipment throughout Europe by the national regulators? Guidance by EASA to the national regulators for example? Using the existing infrastructure of national regulators allows for distributing the load of approval/certification/ ... Could the competence issue be solved by better knowledge distribution and sharing of EASA expertise? These questions have to be addressed also internally at EASA to ensure consistent evaluation of all DPOs and equipment.

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

409

comment by: *Civil Aviation Authority the Netherlands*

Page 54, Art. 4(1)

In our opinion, it should be completely clear which ATM/ANS equipment is liable for certification. Otherwise, States do not know to which package they are supposed to agree.

For this reason, the details of this should in our opinion not be elaborated on at a later stage by an AMC (as set by the EASA-ED), but should be set right away (possibly by way of an annex to the proposed regulation) at IR-level.



Could EASA indicate if it could agree to this line of thinking (and if not, why not)?

Could EASA elaborate on this?

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

410

comment by: *Civil Aviation Authority the Netherlands*

Page 54, Art. 4(1)

Manufacturers of equipment may not be willing or available to apply for a certificate, e.g. standard computer manufacturers, writers of open source software like Linux. What is foreseen in this regulation for this kind of vital equipment?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

411

comment by: *Civil Aviation Authority the Netherlands*

Page 54, Art. 4(2)

First question: could you please describe what would happen with the equipment that is used by one or several service providers if its manufacturer loses its organizational approval? Would the certification of this equipment then automatically become 'null and void'? And could you describe what this would mean for the involved service providers if this equipment turns out to be essential for the service providers' operations?

Second question: how could the certificate holder (the manufacturer) ensure the continuous compliance with the certification-basis? Should it set up its own oversight-schedule for all the service providers that use the equipment for which it is the certificate holder?

response

*Noted*

Following the order of the questions:

- Please refer to topic 'DPO approval discontinuation'.
- Taking into account the comment, the development of the associated GM is under consideration.

comment

417

comment by: *Civil Aviation Authority the Netherlands*

Page 55, Art. 5(1)

In our opinion, the focus of this article should not also be on safety, as this is already sufficiently covered by the requirements of (EU)2017/373 (see also our general comment on this issue). Instead, the focus should in our opinion be limited to ensuring interoperable air navigation.

response

*Accepted*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

418

comment by: *Civil Aviation Authority the Netherlands*

Page 55, Art. 5(1)

In our opinion, the focus of this article should not also be on safety, as this is already sufficiently covered by the requirements of (EU)2017/373 (see also our general comment on this issue). Instead, the focus should in our opinion be limited to ensuring interoperable air navigation.

In our opinion, it should be completely clear which ATM/ANS equipment is liable for declaration (new style). Otherwise, States do not know to which package they are supposed to agree.

For this reason, the details of this should in our opinion not be elaborated on at a later stage by an AMC (as set by the EASA-ED), but should be set right away (possibly by way of an annex to the proposed regulation) at IR-level.

Could EASA indicate if it could agree to this line of thinking (and if not, why not)?

Article 45, first paragraph, of the BR gives the possibility for an obligation for providers to make a declaration. Only the last part of second paragraph of article 45 BR introduces the possibility that, by way of derogation from the first paragraph, manufacturers may be permitted to make declarations.

Furthermore, BR article 47, first paragraph under (e) clearly points to the providers as making the declarations.

It would therefore be logical if this would lead to a system at IR-level, where declaration by a provider is the standard-situation and where only in certain instances, for valid reasons to be set at IR-level, declarations by manufacturers are allowed (and not compulsory).

However, article 5 of this regulation gives no possibility whatsoever for declarations by providers and makes declarations by manufacturers compulsory (instead of permitted). This actually seems to put the situation as prescribed by the BR upside down.

Could you elaborate on why the situation as prescribed by the BR (and in an earlier stage negotiated by Council and parliament) has not been followed in the NPA on this subject?

response *Accepted*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 419 ❖

comment by: *Tern Systems*

**Unclear requirements on DPOs after 12th of September 2023 - transition period not sufficiently defined**

This even ignores the unclear situation after September 2023. It is doubtful that within less than a year from now the following that is promised can be achieved: *"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"*. Even EASA acknowledges that *"EASA will issue an opinion during 2023/Q3"*.

What is expected of DPOs that provide equipment after the 12th of September 2023 until the new regulatory ATM/ANS equipment framework is in place? DPOs need to be given time to implement the framework, to seek approval from EASA, to apply for certificates etc.. As of now, the framework is not even yet completely specified.

response *Noted*

Please refer to topic 'Transitional provisions'.

In addition, it should be noted that the referenced NPA will propose the associated AMC/GM/DSs to the proposed regulatory framework.

The new framework, to be in place as from 13 September 2023, anticipates 5-year transition period within which the DPO should become an approved DPO if their product would be subject to certification and/or declaration.

comment

424

comment by: *Civil Aviation Authority the Netherlands*

Page 56, Art. 7(1) and (3)

As is stated in our comment on page 54, Art. 4(1) it should in our opinion be completely clear which ATM/ANS equipment is liable for certification. Otherwise, States do not know to which package they are supposed to agree.

For this reason, the details of this should in our opinion not be elaborated on at a later stage by an AMC (as set by the EASA-ED), but should be set right away (possibly by way of an annex to the proposed regulation) at IR-level.

response

*Accepted*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

425

comment by: *Civil Aviation Authority the Netherlands*

Page 58, Annex I Requirements for the Agency

The requirements for the Agency for the certification of DPOs should be moved from this regulation to the implementing act on DPO approval:

ATM/ANS.EQMT.AR.A.005(a) and (c)

ATM/ANS.EQMT.AR.A.010

ATM/ANS.EQMT.AR.A.015(a)

ATM/ANS.EQMT.AR.A.020

ATM/ANS.EQMT.AR.A.025

ATM/ANS.EQMT.AR.A.050(a)(1) and (b)

ATM/ANS.EQMT.AR.A.065

ATM/ANS.EQMT.AR.B.001

ATM/ANS.EQMT.AR.B.005

ATM/ANS.EQMT.AR.B.010

ATM/ANS.EQMT.AR.B.015

ATM/ANS.EQMT.AR.C.001

ATM/ANS.EQMT.AR.C.005

ATM/ANS.EQMT.AR.C.010

ATM/ANS.EQMT.AR.C.020

response

*Not accepted*

The requirements laid down in the commented provision apply to the Agency acting as competent authority.

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

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

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

In conclusion, the commenter is invited to note that the split and allocation of the various provisions between delegated versus implementing acts are stipulated in the EASA Basic Regulation (EU) 2018/1139.

Page 59, ATM/ANS.EQMT.AR.A.020

“The Agency shall evaluate all AltMoC proposed by an organisation involved in the design and/or production of ATM/ANS equipment”

It is proposed that EASA will be the CA for certification, declarations and AMCs. Therefore, there would not be a separation between making regulations and oversight on these regulations if EASA would also decide on AltMoCs proposed by DPOs. Furthermore, EASA would then in the end oversee the AltMoCs that it has decided on.

Could you please elaborate on how this could be solved?

response

*Noted*

The Agency acknowledges the need for clear separation of the activities in question. This separation has already been established and implemented in all other aviation domains, including ATM/ANS provision and will be deployed in this specific case as well. It should be highlighted that the Agency’s competence is clearly regulated in the EASA Basic Regulation (EU) 2018/1139.

comment

428

comment by: *Civil Aviation Authority the Netherlands*

Page 59-60, ATM/ANS.EQMT.AR.A.030

In how far does the Agency in your opinion have the legal powers to issue any equipment directives regarding underperformance and/or interoperability? Article 76 of the BR establishes the powers for the Agency to act immediately in case of an identified safety problem.

There actually seems to be no basis in the BR for the issuing of directives that goes beyond powers within the framework of safety. This is quite logical, as for example situations involving ‘underperformance’ actually seem to be rather arbitrary and are, as long as they do not concern safety, for either the provider to decide, and/or the State(s) for which it provides its services within the framework of the designation act (perhaps in a dialogue with the Network Manager).

Could you please elaborate on this if in your opinion the elaborated powers for the Agency within this framework are there AND should be there?

response

*Noted*

The commenter is kindly invited to note that the ATM/ANS equipment directive is only one of the means for immediate reaction to a safety problem. The empowerment of the Agency is provided in Article 76(6)(a) of Regulation (EU) 2018/1139.

comment

429

comment by: *Civil Aviation Authority the Netherlands*

Page 61, ATM/ANS.EQMT.AR.A.040(a)

“The Agency, in accordance with Article 76(3) of Regulation (EU) 2018/1139, shall establish and make available detailed technical specifications”

According to (EU)2018/1139 Art. 76(3) EASA may issue detailed specifications related to certification. Technical detailed specifications are established by organisations like Eurocae.

In our opinion issuing detailed specifications implies publication. Establishing on the other hand includes deciding on the contents: definitions, standards etc. This regulation should only make EASA responsible for publication and not setting standards.

response

*Noted*

The Agency is acting within its remit as established in accordance with Regulation (EU) 2018/1139.

In addition to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’, the commenter is kindly invited to refer to Management Board Decision No 01-2022 of 2 May 2022 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’) as referred to in Article 76(1) and (3) of the Basic Regulation. This procedure aims at transparency to the Member States, to other affected and interested parties, to the EASA Advisory Bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation, and to the public on how EASA develops regulatory material.

Moreover, as stated in Opinion No 01/2023, during the committee procedure for the adoption of the implementing and delegated acts proposed, EASA will continue the work with the preparation of a decision with the related acceptable means of compliance (AMC) and guidance material (GM) and detailed specifications (DSs), which can be used by the affected parties to demonstrate compliance. Before the publication of such decision, the related proposed AMC/GM/DSs will be publicly consulted through a dedicated NPA (as defined for Subtask 3 of RMT.0161).

comment

430

comment by: *Civil Aviation Authority the Netherlands*

Page 61, ATM/ANS.EQMT.AR.A.045

Prescribing additional requirements ‘that the Agency deems necessary’ in case that ‘related applicable specifications are not deemed adequate’ in an ad hoc manner seems to be quite arbitrary and especially not in line with the principle of legal certainty.

Seen the above, it may be necessary to develop an alternative set-up for this article, which is more in line with this very important principle? Could you elaborate on your opinion regarding this matter?

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

431

comment by: *Civil Aviation Authority the Netherlands*

Page 69, ATM/ANS.EQMT.AR.C.020

In paragraph (a) and (b) of this proposal, possible findings and enforcement measures are directed against certificates and declarations. However, when this is elaborated for level 1 findings in paragraph (c), it all of a sudden concerns organisations' approvals (so it concerns manufacturers).

Could you elaborate on how the abovementioned paragraphs should be read in conjunction with each other?

response

*Noted*

The prerequisite for an ATM/ANS equipment certificate is the applicant to be also an approved DPO, which demonstrates the capability of the organisation to design and/or produce certain ATM/ANS equipment. If Level 1 findings would be raised, the capability of the organisation is under question.

Taking into account the comments, the development of the associated AMC/GM is under consideration.

comment

432

comment by: *Civil Aviation Authority the Netherlands*

Page 72, ATM/ANS.EQMT.CERT.015(b)(2)(i)

"a detailed description of the design, including all the configurations to be certified;"

Configurations differ significantly per implementation or site and performance is changed when settings are altered. How should this requirement be fulfilled?

response

*Noted*



Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

435

comment by: *Civil Aviation Authority the Netherlands*

Page 72-73, ATM/ANS.EQMT.CERT.015(b)(2)(vi)

What would be the reason for the situation that the applicant needs to issue a proposal for the Agency's involvement of the verification (...)? Shouldn't this be something that the authority is responsible for itself?

And what would be the reason for having to address the likelihood of an unidentified non-compliance? Shouldn't the issue be that the applicant is, also based on its SMS, convinced that it actually does comply?

response

*Noted*

Taking into account the comment and questions, the development of the associated AMC/GM is under consideration.

comment

436

comment by: *Civil Aviation Authority the Netherlands*

Page 73, ATM/ANS.EQMT.CERT.020

Could you elaborate on how this process would work in practice in conjunction with the service provider(s) that make use of the equipment in question?

In how far would it be workable and efficient in practice if any change in the operation of the service providers' equipment first has to be proposed to the manufacturer by the provider, after which the manufacturer needs to propose this in its turn to the Agency which would need to decide on it?

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that most of your general concerns are addressed in topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a

dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

Furthermore, taking into account the comment and questions, the development of the associated AMC/GM is under consideration.

comment

437

comment by: *Civil Aviation Authority the Netherlands*

Page 76, ATM/ANS.EQMT.CERT.060(a)

Could you elaborate on how this system would work if EASA would want to audit equipment that is in active use? If this is the case, this equipment would be at the facilities of a service provider and not at the facilities of the manufacturer that holds the certificate. However, this article introduces auditing-requirements to the manufacturer, not to the service provider.

response

*Noted*

It should be noted that the certification/declaration of the ATM/ANS equipment will take place before that equipment is deployed.

Therefore, the commented requirements are on the manufacturer's side.

comment

440

comment by: *Civil Aviation Authority the Netherlands*

Page 54, Art. 4(1)

The scope of equipment includes also MET, AIS and FPD which is too extensive for the objectives of this regulation.

response

*Accepted*

The comment is considered in the Opinion.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

444

comment by: *Tern Systems*

**No time constraints for processing of applications for attestation**

The NPA does not contain any guarantees on the processing time of applications. Thus, attestation can introduce unforeseeable delays in the delivery of equipment. DPOs' business success will depend upon staffing and prioritisation at EASA.

Additionally, to apply for an equipment certificate, the DPO, amongst other documents, has to provide a “certification programme” including “a project schedule including the major milestones” (ATM/ANS.EQMT.CERT.015 Application for an ATM/ANS equipment certificate). Without any guaranteed processing times of applications, a DPO cannot create a reliable schedule.

The following statements are too vague:

“without undue delay” - ATM/ANS.EQMT.AR.A.020 Means of compliance (d);

“plan the availability of personnel in order to ensure the proper completion of all related tasks;” - ATM/ANS.EQMT.AR.B.001 Management system (a)(2)

response

Noted

The proposed certification scheme is already used in other aviation domains and experience shows that it is effective and reasonable.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

445 ❖

comment by: Tern Systems

**Several times in the NPA leaves the impression that EASA believes that equipment can be defined as safe or unsafe - but if equipment is safe depends on its usage**

If equipment is safe or unsafe depends on its operation, the concept of operations and the operational environment it is used in. A DPO and also EASA cannot reasonably judge if it is safe to use a certain equipment in a certain environment. However, the service provider using the equipment can. DPOs can provide information on the characteristics of the equipment, for example, possible failure modes that help a service provider build the argument.

Examples where the impression is created that the DPO is supposed to demonstrate the safety of equipment:

- DPO.OR.A.015 Organisation exposition: “shall establish and maintain an exposition, which provides the following information: ... (8) the procedure(s) for the verification and demonstration that the design of ATM/ANS equipment, or changes to it ... has no unsafe features”
- DPO.OR.B.001 Management system (d): “The management system shall be proportionate ... taking into account the hazards and associated risks inherent in those activities.”
- 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: ... (3) no feature or characteristic has been identified that may render the equipment unsafe for the intended use.”

There might be more instances.

It seems ATM/ANS.EQMT.AR.A.055 (b) is supposed to address this *“The ATM/ANS equipment certificate shall include the operating limitations ... and any other conditions or limitations prescribed for the product”*. Will this result in certificates adapted to certain ANSP’s operational environments?

response

*Noted*

The comments are considered.

In response to the question, the general answer is negative but this depends depending on the circumstances.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

446

comment by: *Tern Systems*

**What happens to equipment in operations if approval/certificate is revoked?**

EASA can revoke approvals and certificates (ATM/ANS.EQMT.AR.C.020 Findings, corrective actions, and enforcement measures (b)). This instrument needs clearer definition under which conditions it is applicable and how safe operations can be ensured.

response

*Noted*

Please refer to topic ‘DPO approval discontinuation’.

comment

449 ❖

comment by: *Tern Systems*

**For which changes of the quality management system or the equipment does EASA need to be informed - when is re-attestation necessary?**

This question remains unanswered but has huge effects on the estimated costs for DPOs and the ability of DPOs to react to the need for change, for example, to fix bugs, to address necessary updates of software for example to address security issues. Innovation and improvement of the DPO’s management system and products is hindered and made expensive.

*“DPO.OR.B.005 Change management (a) ... any change to the management system **that is significant** for the demonstration of compliance shall be approved by the Agency before it is implemented.* - that is significant is too vague.

*(b) **Each change made to the ATM/ANS equipment shall be notified to the Agency ...”** - this will slow down reaction to security issues for example and generally reduce innovation due to the increased bureaucracy.*

response	<p><i>Noted</i></p> <p>Taking into account the comment, the text is amended to promote clarity.</p>
comment	<p>456 <span style="float: right;">comment by: NAV Portugal E.P.E</span></p> <p><b>#1 - Reference: Article 4 Certification of ATM/ANS equipment</b></p> <p>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 aircrafts and the prevention of collisions, shall be issued with a certificate by the Agency as specified in Annex II to this Regulation.</p> <p><b>Comment:</b> ATM/CNS equipment concerned by certification or declaration are not clearly defined, creating ambiguity and difficulties for organizations for becoming DPO or not.</p> <p><b>Proposal:</b> The list of ATM/CNS equipment for certification and declaration should be defined.</p>
response	<p><i>Accepted</i></p> <p>Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.</p>
comment	<p>472 <span style="float: right;">comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</span></p> <p><b>General 8.2, page 53</b> Will EASA notify CA when a EQMT is certified/declared?</p>
response	<p><i>Noted</i></p> <p>There are no notification requirements as such.</p> <p>However, the same approach, as for the approved by EASA ATM/ANS provider, will apply. The list with certified/declared ATM/ANS equipment will be publicly available.</p>
comment	<p>473 <span style="float: right;">comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</span></p> <p><b>General 8.2, page 53</b> What is the detail level of entity regarding certification/declaration? Do parts sum up to a whole? Is there certification on screws and bolts?</p>

response

*Noted*

The proposed framework provides flexibility in this context.

The proposal does not prevent different modules/products as part of complete system form being certified/declared. This will be further illustrated by the respective detailed specifications.

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

474

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**General 8.2, page 53**

Will there be a list of all certified /declared equipment shared between EASA, CA's and ANSP's?

response

*Noted*

There are no notification requirements as such.

However, the same approach, as for the approved by EASA ATM/ANS provider, will apply. The list with certified/declared ATM/ANS equipment will be publicly available.

comment

475

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen,  
Luftfartsavdelningen)*

**8.2 , Article 4, page 54**

What if the DPO with the certified equipment closes down. What will be the lifelength of equipment?

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

476

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

**8.2 , Article 4, 2, page 54**

When do the responsibility change from the DPO to the ANSP? It could be difficult hold the DPO responsible for the equipments continuous compliance when integrated to functional system and under the influence of ANSP.

response *Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

comment

477 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**8.2, Article 5, page 55**

What if the DPO with the declared equipment closes down. What will be the lifelength of equipment?

response *Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

478 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Question 8.2 #1, page 55**

Yes. The design and the production organisations should declare sensors used for surveillance.

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment'.

comment

479 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**8.2, Article 6, page 55**

Could you explain? If at oversight of the ANSP, a non-compliance in any area of (EU) 2017/373 is detected, will it give the consequence of the withdrawals of statements of compliance for all equipment used by this ANSP?

response *Noted*

The commenter is invited to note that the SoC is subject to oversight and any non-compliance would not lead to being withdrawn by the ATM/ANS provider, but rather to enforcement measures by the competent authority requiring corrective actions and mitigation measures.

comment

480

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**8.2, Article 7, page 56**

During transitional period the CA will be subject of additional workload. Is the equipment already in use to be handled with grandfathers rights?

response

*Noted*

The answer is affirmative on a provisional basis.

For further details, please refer to topic 'Transitional provisions'.

comment

481

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**8.2, Article 7, page 56**

Could you explain? What information will EASA need from CA to facilitate the evaluation?

response

*Noted*

Please refer to topic 'Transitional provisions'.

In addition, the development of the associated AMC/GM is under consideration.

comment

485

comment by: *DGAC (French CAA)*

Reference: Article 4(1) of the EQMT DR

Comment: certification requirements for ATM/ANS ground equipment does not seem to be a proportionate approach with regards to the safety risks associated to the operation of any ATM/ANS system. Most ATM/ANS ground systems are well known and mastered by ATM/ANS providers. The same approach used for avionics in the airworthiness domain is not considered to be strictly necessary for every ATM/ANS ground equipment.

Proposal: restrict the scope of ATM/ANS GE subject to certification to the ones that directly contribute to aircraft separation and collision avoidance, as explained in the explanatory parts of the NPA, that is to say the ones that really are safety critical. The present wording of article 4.1 of the EQMT DR is way too broad when mentioning "...*for the purpose of the provision of ATM, including...*". This could be interpreted to concern all the systems involved in an ATM function whatever their safety criticality or their interoperability impact. ATM includes ASM



and ATFM and those last two, while of great use for the interoperability of the EATMN, are not yet safety critical.

*“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.”*

response *Partially accepted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

comment 489

comment by: DGAC (French CAA)

Reference: Draft EQMT DR, article 1, point 1.

Comment: it is article 45 of Regulation 2018/1139 that introduces the notion of ATM/ANS GE certification and declaration.

Proposal: shouldn't a reference to article 45 be mentioned in the EQMT DR?

response *Partially accepted*

It is agreed that Article 45 stipulates the requirements on ATM/ANS systems and ATM/ANS constituents. However, it should be noted that Article 47 refers to Article 45, and empowers the Commission to adopt delegated acts, in accordance with Article 128 of Regulation (EU) 2018/1139.

comment 490

comment by: DGAC (French CAA)

Reference: Question 8.2#1

CAA comment: sensors (for example, PSR/SSR radars, ADS-B receivers or MLAT equipment) used for surveillance should indeed be subject to declaration by approved design and/or production organisations because such sensors fall under the scope of article 5.1 *“ATM/ANS equipment which generates, receives, and transmits data and/or signals in space for the purpose of ensuring safe and interoperable air navigation”*.

Such sensors are by the way well covered by internationally recognized standards such as ICAO's and do not need to enter the proposed certification process.

NSA comment : disregarding the definition in Article 4 which could include radar and ADS B systems as these systems process and provide data for the purpose of ATM provision: surveillance sensors and radio receivers/transmitters are essential components for interoperability with aircraft and for ensuring proper and safe air traffic management. They are also one of the most shared components between suppliers and the most stable in terms of design. Hence declaration at least is suitable.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

512

comment by: *Deutscher Wetterdienst*

The clear limitation of "safety relevance" mentioned several times in the explanatory text and to equipment used in the EATMN cannot be found in the draft delegated regulation.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

Furthermore, the definition on EATNM is introduced in Article 2 of the draft Delegated Regulation.

comment

517

comment by: *Belgian NSA*

Article 6 page 55: replace "revoked by the Agency", and indicate that the certificate refers to article 6 from Regulation 2017/373. Indeed, not all 2017/373 certificates are issued by the Agency.

There should be an Annex IV describing the content for the declaration of compliance

response

*Partially accepted*

The text is amended accordingly.

comment

521

comment by: *Belgian NSA*

Question 8.2 page 55: if navigation systems are subject to declaration, it seems logic to make surveillance systems subject to declaration: those systems are manufactured in sufficient

quantities, and are well described in ICAO Annex 10. However, it may be desirable to start only with navigation in a first step to test the scheme.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

533

comment by: *Copenhagen Airports*

Regarding

Question

8.2

Sensors should be subject to declaration. We consider the mentioned constituents critical in regards to safety-related systems. Deep technical knowledge of the system lies with the equipment manufacturer, hence the DPO is best equipped to submit a declaration. This will provide the ATM/ANS-providers flexibility and better options for choosing preferred equipment.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

536 ❖

comment by: *Copenhagen Airports*

What is the definition of "airborne". Does that mean "during flight" or does it mean "in the airplane"?  
Phrase "excluding airborne constituents" is used, but what about other "mobiles" such as VLT/vehicles?

response

*Noted*

According to Article 3(7) of Regulation (EU) 2018/1139, 'ATM/ANS system' means the aggregation of airborne and ground-based constituents, as well as space-based equipment, that provides support for air navigation services for all phases of flight.

In this context, airborne constituents are excluded from the scope of the proposal.

comment

555

comment by: *Austro Control*

**Comment: Article 5, 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.

**Proposed Change:**

We welcome the certification of ATS- related components (Air/Ground radios, NAVaids, SUR sensors). It is expected to ease/replace the present procurement process itself. But we shall finally expect higher invest cost.

**Classification:**

Major/conceptual

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

556

comment by: *Austro Control*

**Comment: Article 7**

For ATM/ANS equipment for which a certificate or declaration is required and which was placed in service before the regulation came into force, it is intended that a certificate or declaration is deemed to have been issued on a provisional basis as long as EASA (within 5 years of the regulation coming into force) does not determine in an evaluation that a level of safety, performance and interoperability is not met. This creates legal uncertainty. After all, we are dealing with certified ANSPs and NCAs are involved in the processes. There was no such provision in Implementing Regulation (EC) No 552/2004 either.

In addition the date of production is foreseen as the reference for the transitional provisions between the entry into force of the Regulation and September 13, 2023. Here, too, legal uncertainty is created, since a significant period of time can pass between the signing of the contract and the "production". And in the case of software development, the production date is difficult to identify anyway. Here, as in Implementing Regulation (EC) No 552/2004, the contract date should be used. A subsequent review by EASA (until 2030) is foreseen, which again leads to legal uncertainty.

**Proposed Change:**

In general, all implementing dates should not be based on the entry into force of the regulation, but on the date on which all required supporting documents are available (AMC, GM, DS).

**Classification:**

Major/conceptual

response

*Noted*

Please refer to topics 'Detailed certification/declaration/SoC (technical) specifications and their development/availability' and 'Transitional provisions'.

comment

629

comment by: *Austro Control*

**Comment: Page 54**

Art. 4(1): The scope of equipment is much too wide. It covers even MET, AIS or FPD systems etc.

**Proposed Change:**

Restrict the scope to systems that have an immediate impact on safety of ATM provision. Rephrase Art. 4(1) to ATM/ANS equipment that processes and **directly** delivers data for the purpose of the provision of ATM **and that has an immediate and direct impact on the safety of ATM provision**, 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.

**Classification:**

Major/conceptual

response

*Partially accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

630

comment by: *Austro Control*

**Comment: Page 54**

Art.4(2)(a) Why would a certified and thus compliant equipment lose its certificate when the DPO no longer has an approval? As long as the equipment is not changed it must continue to be considered compliant.

What happens to the deployed equipment in this case?

**Proposed Change:**

Please explain and correct. Equipment must not lose its certificate if the DPO no longer has an approval. That could constitute a major economic burden, e.g. if a DPO goes out of business.

**Classification:**

Major/conceptual

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment 632

comment by: *Austro Control*

**Comment: Page 55**

Art.5(2)(b) Why would compliant equipment lose the validity of the declaration when the DPO no longer has an approval? As long as the equipment is not changed it must continue to be considered compliant.

What happens to the deployed equipment in this case?

**Proposed Change:**

Please explain and correct. Equipment must not lose the validity of its declaration if the DPO no longer has an approval. That could constitute a major economic burden, e.g. if a DPO goes out of business.

**Classification:**

Major/conceptual

response *Noted*

Please refer to topic 'DPO approval discontinuation'.

comment 633

comment by: *Austro Control*

**Comment: Page 55**

Art.6(1) Which equipment would remain for this article given the broad definitions in Art. 4 and 5.

**Proposed Change:**

Please explain

**Classification:**

Major/conceptual

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 634

comment by: *Austro Control*

Comment: Page 56  
Appendix 2, Article 7

A transition period of 5 years seems too short and, in this respect, unrealistic. It is clear that legacy systems must be adapted to the new standards over time. If this is imposed in too short a period, it can lead to premature depreciation and thus sunk costs.

Proposed Change:

In the interests of renewing the European air traffic control infrastructure, the reduction of residual costs by replacing legacy systems must be regulated throughout Europe and financed in a route charges-neutral manner. This must also be taken into account in the performance and charging scheme for RP 4.

Classification:

Major/conceptual

response

*Noted*

Please refer to topic 'Transitional provisions'.

comment

635

comment by: *Finnish Meteorological Institute (FMI) - MET SP*

**Article 4**

Certification requirement shall be limited only to most safety critical systems used for ATM provision.

Due do that, not even applicable for any MET systems.

**Justification:**

According to explanatory text of this NPA "classification" of systems shall be based on impacts on aviation safety (and interoperability).

No MET system has such nor any direct impact on aviation safety. MET services shall be treated only as support information to ATM.

\*\*\*\*\*

**Article 5**

No MET equipment should require 'declaration of design compliance'

**Justification:**

Justifications are provided in the FMI's general comments and also for item Article 4 of this drafted delegated regulation.

Notable is, that most MET systems are in place just to provide services only for flight-planning purposes

\*\*\*\*\*

**Article 6**

All those MET equipment, that are in the scope of this delegated regulation, should fall into this category (including AWOS).

**Justification:**

Provided in the FMI's general comments and also for items Article 4 and 5 of this drafted delegated regulation.

Most MET systems are in place just to provide services only for flight-planning purposes.

**Additional comment concerning AWOS:**

If it will be, for some reason, deemed crucial during the rulemaking process and/or based on received comments to require declaration for AWOS systems, all such systems designed and manufactured by a certified MET SP and used only by itself nationally and not available in markets, shall definitely be excluded and treated nationally by local CA.

\*\*\*\*\*

**Article 8**

Applicability date cannot be same as 'entry into force', as there will be significant impact and totally new requirements for both DPOs and ATM/ANS providers.

Maybe even up to 2 years is needed, especially for ATM/ANS equipment, requiring either declaration or certification.

Applicability date needs to be defined and added for Article 8. See e.g. time schedules set for future Part-IS regulation.

**Justification:**

Planned scope of ANS systems and ANS providers affected by forthcoming regulation is significantly larger than in (EU) 552/2004. E.g. MET systems have typically not been in the scope.

response

*Partially accepted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Transitional provisions'.

comment

637

comment by: *Austro Control*

**Comment: Page 56**

Art.7(2) The CA can only provide the documentation as required by Regulation (EU) 552/2004 to EASA.

**Proposed Change:**



Rephrase to "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 **that they have received iaw Art. 6 and Annex IV of Regulation (EU) 552/2004** to facilitate this evaluation."

**Classification:**

Major/conceptual

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

673

comment by: NATS

Article 4  
(1)

Page 54

We do not think it is possible to use this definition to consistently determine whether a particular piece of equipment would need certifying because it is still open to interpretation, and it is likely that some equipment could be argued either way / it may vary depending on the operational context

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

674

comment by: NATS

Article 4  
(2) (a)

Page 54

This suggests that ANSPs can procure certified equipment, put it into service, and then find themselves unexpectedly having to withdraw it from service if the organisation that originally produced it ceases to trade / has their approval suspended etc. This could be very problematic; ANSPs must be able to continue using certified equipment regardless of the DPO approval status.

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

675

comment by: *NATS*

**Question 8.2 #1**

*Page 55*

If this question is asking whether it should be certified instead, or excluded then given their relatively "generic" nature and robust set of standards, sensors feel like one of the few pieces of ATM/ANS equipment which could benefit from centralised certification.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

677

comment by: *NATS*

**Article 6  
(1)**

*Page 55*

Given the requirement above detailing which equipment would need to be subject to a declaration (i.e. anything which does anything with data for ATM/ANS purposes, noting that almost all operational systems contribute in some way to the safety/efficiency of the service), and that a statement of compliance can only be written for equipment which is not subject to certification or declaration, it is not clear what equipment is expected to fall into this category.

What if an ANSP needs to use equipment which doesn't meet these standards (e.g. for legacy reasons) or there is an otherwise acceptable discrepancy?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In response to the question, there are various means for demonstration of compliance and all the instruments available will provide enough flexibility in the proposed harmonised and mutually recognised framework.

comment 678

comment by: NATS

Article 7  
(1)  
Page 56

There are seemingly no provisions for equipment not yet in service, but which have already been procured under binding contracts.

response *Noted*

Please refer to topic 'Transitional provisions'.

comment 679

comment by: NATS

Article 7  
(1) (a)  
Page 56

What exactly is expected to happen if some equipment is deemed not sufficiently compliant?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 680

comment by: NATS

Article 7  
(2)

Page 56

This is a potentially monumental task and, given that the equipment to be evaluated is already in service (and assessed as sufficiently compliant by the relevant NSA), it is not clear what this aims to achieve... Effort may be better spent focusing on new equipment.

response *Noted*

The associated AMC/GM will be developed to support the implementation, further illustrate the intent of the provisions, and provide means of compliance.

comment 681

comment by: NATS

Article 7  
(3) (c)

Page 57

The intent of this sentence is not clear: is "until" the correct word?  
Could this be clarified

response *Accepted*

The text is amended to promote clarity.

comment 682

comment by: NATS

**ATM/ANS.EQMT.AR.A.015**  
(b)

Page 58

It is not clear if this is oversight of the ANSP or the DPO, presumably the company being audited will need to pay for this joint oversight? Is it possible to make a cleaner split in responsibilities to minimise oversight costs?

response *Noted*

The commented provision addresses the oversight of the DPO.

For further details, please refer to topic 'Roles and responsibilities of the different actors'.

comment 683

comment by: NATS

**ATM/ANS.EQMT.AR.A.020**  
(a)

Page 59

It is not clear if these AMC will contain the requirements to be implemented (e.g. functional behaviour, message formats, etc.) and/or the testing to be performed (i.e. the means of assessing the conformity with a specification)... in the case of many IRs, it is the conformity assessment material which is currently lacking (and again this is not an issue with the current framework; it is a deficiency in the standards / means of compliance).

response *Noted*

‘Acceptable means of compliance (AMC)’ means non-binding standards issued by EASA which may be used by persons and organisations to demonstrate compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof, or with the related certification specifications and detailed specifications.

For further details, please refer to the EASA website:

[Acceptable Means of Compliance \(AMC\) and Alternative Means of Compliance \(AltMoC\) | EASA \(europa.eu\)](#)

comment 684

comment by: NATS

**ATM/ANS.EQMT.AR.A.020**

(c)

Page 59

Is the AltMoC being proposed by the DPO or the ANSP, and what would such an inspection aim to determine, especially noting that such AltMoC needs to be approved before being implemented?

response *Noted*

The purpose of a possible inspection of the organisation is to evaluate if the AltMoC is/are in compliance with Regulation (EU) 2018/1139 and this Regulation.

For further details, please refer to EASA website:

[Acceptable Means of Compliance \(AMC\) and Alternative Means of Compliance \(AltMoC\) | EASA \(europa.eu\)](#)

comment 685

comment by: NATS

**ATM/ANS.EQMT.AR.A.025**

(b)

Page 59

this includes an incorrect reference

response *Accepted*

comment 686

comment by: *NATS*

**ATM/ANS.EQMT.AR.A.030**

( a )

Page 59

Care must be taken here, as the operational context of the equipment may vary between ANSPs; will there be a mechanism for an ANSP to "object to" / challenge a directive?

response *Noted*

The comment will be further considered during the development of the associated AMC/GM as part of the activities of RMT.0161 Subtask 3.

comment 687

comment by: *NATS*

**ATM/ANS.EQMT.AR.A.030**

( b ) ( 1 )

Page 60

Such a deficiency may involve an interface between two Constituents, and this may be as a result of an ambiguity in the specification, such that both manufacturers can legitimately claim compliance; the proposal lacks detail on how to deal with a deficiency in the specifications / AMC / etc.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 688

comment by: *NATS*

**ATM/ANS.EQMT.AR.A.035**

( b )

Page 61

The scope of these additional features is unclear; is this referring to functionality etc. which cannot demonstrably meet point (c)?

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

689

comment by: NATS

**ATM/ANS.EQMT.AR.A.040**

(b)

Page 61

Note that design specifications alone are normally not sufficient to enable robust conformity assessment; what is needed is a set of tests which - if passed - should confirm that the specification has been correctly implemented

response

*Noted*

The comment is agreed and considered in the Opinion.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

690

comment by: NATS

**ATM/ANS.EQMT.AR.A.050**

(a)

Page 62

The implication of this is that EASA certification does not ensure any given requirement is met, or that any particular testing has taken place, etc. is this the intention?

response

*Noted*

The purpose of the provision is to define the depth of the Agency's evaluation in the verification of compliance demonstration and data required to be provided by the applicant for the issue of a certificate or for changes to it.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

691

comment by: NATS

**ATM/ANS.EQMT.AR.A.055**

(3)

Page 63

Safety depends on the intended use/environment/etc. and a product may thus be safe for some uses but not others; as this equipment certification is meant to be ANSP-agnostic, how is the intended use to be accounted for?

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

692

comment by: NATS

**ATM/ANS.EQMT.AR.A.055**

Page 63

Capturing robust yet flexible conditions of use can be challenging, especially as we move to software-only products which may e.g. be executed on a virtual machine, and noting the sometimes complex interactions between hardware/firmware/OS/software/etc.

Manufacturers often need to work with ANSPs to ensure the Conditions of Use on their Declaration are appropriate; if EASA are taking responsibility for determining these then they need to be careful to ensure they are necessary and sufficient to meet the needs of both the ANSP and DPO.

response

*Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

693

comment by: NATS

**ATM/ANS.EQMT.AR.A.060**

( d)

Page 63

There does not appear to be a provision to allow ANSPs or NSAs to make use of this register



response

*Noted*

It should be noted that the list of declared ATM/ANS equipment will be made available in the same way as the list of approved ATM/ANS organisations under the oversight of EASA.

comment

694

comment by: *NATS*

**ATM/ANS.EQMT.AR.A.065**

( a )

Page 63

There is no Annex IV?

response

*Accepted*

The reference is corrected.

comment

695

comment by: *NATS*

**ATM/ANS.EQMT.AR.B.001**

( a ) ( 4 )

Page 64

Are these requirements on the Management System?

response

*Noted*

The answer is affirmative.

comment

696

comment by: *NATS*

**ATM/ANS.EQMT.AR.B.015**

( a ) ( 1 )

Page 65

This seems to be missing an obligation to ensure the data is stored securely (protected against damage, alteration & theft).

response

*Accepted*

Taking into account the comment, the text is amended accordingly.

comment

697

comment by: NATS

**ATM/ANS.EQMT.AR.C.010  
( a ) ( 8 )**

**Page 68**

Noting that DPO approval must be held to obtain product certification / make a declaration, and that ANSPs cannot deploy products which do not have such approval, the implication of this legislation for non-EU suppliers of ATM/ANS products is not clear; how will auditing be done worldwide (noting that e.g. management systems etc. may be written in any language)?

response

*Noted*

Please refer to topic 'Access to the market'.

In addition, based on the advice from the NPA 2022-09 consultation, Article 7 'Third-country organisations involved in the design and/or production of ATM/ANS equipment' is introduced with the aim of allowing an organisation whose principal place of business is in a third country to demonstrate its capability by holding a certificate issued by that third country that covers the ATM/ANS equipment for the certification of which that organisation applies to the Agency, provided that the Agency has determined that the system of that third country includes the same independent level of checking of compliance as provided for by the implementing act on the approval of organisations involved in the design and/or production of ATM/ANS equipment, either through an equivalent system of approvals of organisations or through the direct involvement of the competent authority(ies) of that third country. In such case, that organisation shall be considered as a design organisation approval holder.

comment

698

comment by: NATS

**ATM/ANS.EQMT.AR.C.020  
( b )**

Page 69

This may be difficult to ascertain without liaison with all of the ANSPs deploying that product.

What is the implication of revocation of an approval to the ANSPs that have deployed the product?

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment 699

comment by: NATS

**ATM/ANS.EQMT.CERT.035**

( d ) ( 2 )

Page 75

Is this suggesting that EASA could require testing to be repeated, rather than witnessing the planned testing?

This needs clarification

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 700

comment by: NATS

**ATM/ANS.EQMT.CERT.055**

( a )

Page 76

These terms need further defining to ensure some consistency, although the implication of a minor vs major change is also not clear. Further, point (b) refers to "other changes", but it is not clear if this means changes which are neither minor or major, or something else?

response *Partially accepted*

Taking into account the comment, the text is amended to promote clarity.

comment 710

comment by: IAA Aviation Regulator

Article 4 (1) - "1. ATM/ANS equipment that processes and delivers data for the purpose of the provision of ATM, [...]"

It is noted that the term 'ATM' is not defined in EASA Basic Regulation (BR) or this draft CDR.

Rather the term 'ATM' is defined in point (10) of Article 2 of Regulation (EC) No 549/2004 as – "[...] the aggregation of the airborne and ground-based functions (air traffic services, airspace management and air traffic flow management) required to ensure the safe and efficient movement of aircraft during all phases of operations;".

It is further noted that the BR uses the term 'ATM/ANS' and the definition incorporates ATM as defined in 549/2004.

Suggest clarification be provided in appropriate section.

response

*Noted*

The comment is considered.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

711

comment by: IAA Aviation Regulator

Article 4 (2)(b) - *"the certificate holder ensures the continuous compliance of the ATM/ANS equipment with its certification basis;"*

Suggest rewording to state - "the certificate holder ensures the continuous demonstration of compliance of the ATM/ANS equipment with its certification basis, in accordance with point ATM/ANS.EQMT.CERT.025".

response

*Accepted*

comment

712

comment by: IAA Aviation Regulator

Article 5 (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"*

Draft CDR; Annex II is in relation to *"ATM/ANS Equipment Certificates"* .

Suggest rewording in Article 5 (1) as follows to refer to Draft CDR; Annex III which is in relation to *"Declaration of compliance of the ATM/ANS Equipment Design"* -

*"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 III to this Regulation"*

response

*Accepted*

comment

713

comment by: IAA Aviation Regulator

Article 5(1) - *"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."*

It is suggested that EASA establishes a 'Technical Committee' to further address and agree on what types of ATM/ANS equipment should be subject to certification / declaration, to include manufacturers, ANSPs and National CAs.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment', which will be complemented by the associated DSs and AMC/GM.

comment

714

comment by: IAA Aviation Regulator

Article 5 (2)(a) - *"the ATM/ANS equipment no longer complies with the applicable technical specifications against which the declaration has been made; [...]"*

It is noted that ATM/ANS.EQMT.AR.A.040 identifies that *"detailed technical specifications which organisations may use to demonstrate compliance with the relevant essential requirements set out in Annex VIII [...]"*.

Therefore, it is considered that conformance with the 'detailed technical specifications' will ensure compliance with the relevant ERs.

As such suggest changing wording in this section to "the ATM/ANS equipment no longer conforms with the applicable technical specifications against which the declaration has been made" and review of other instances in the document that refers to compliance with technical standards (e.g. Art.6(1)).

response

*Accepted*

comment

715

comment by: IAA Aviation Regulator

Article 6 (2)(d) - *"[...] taken in accordance with point ATM/ANS.AR.A.050(e)."*

This appears to be an editorial as neither extant Regulation (EU) 2017/373 or proposed amendment include a point ATM/ANS.AR.A.050(e).

Suggest update to refer to point ATM/ANS.AR.C.050(e).

response *Accepted*

comment 716 comment by: IAA Aviation Regulator

Article 7 (1)(a)(b) & 3(a)(b) - "[...] 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;"

Suggest insertion of 'security' to align with objective set out in NPA;Section 2.2 and with BR;Annex VIII; Section 3.3.1 "Systems and constituents shall be designed to meet applicable safety and security requirements".

Suggest the following text for the above instances in Article 7 -  
"[...] that such ATM/ANS equipment does not ensure a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation;"

response *Accepted*

comment 717 comment by: IAA Aviation Regulator

Article 7 (2) & (3)(c) - "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."

Suggest insertion of 'security' to align with objective set out in NPA; Section 2.2 and with BR; Annex VIII; Section 3.3.1 "Systems and constituents shall be designed to meet applicable safety and security requirements".

Suggest the following text for the above instances in Article 7 -  
"The objective of that evaluation shall be to determine that the particular ATM/ANS equipment ensures a level of safety, security, performance and interoperability equivalent to that required by Regulation (EU) 2018/1139 and this Regulation;"

response *Accepted*

comment 718 comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.005 (b) - "the acceptance of declarations for ATM/ANS equipment;"

It is considered that ATM/ANS.EQMT.AR.A.005 'Scope' should also address requirements for the administration and management systems of the Agency to address scenarios where an ATM/ANS equipment declaration needs to be deregistered due to scenarios set out in Art.5 (2).

response *Noted*

The deregistration is one of the enforcement measures related to the declarable ATM/ANS equipment and part of the oversight activities. Therefore, it is not considered essential to be mentioned separately.

comment

719

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.015 (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."*

While provision for such coordination between EASA and the National Competent Authority (CA) is welcome and supported, it is not clear on what type of event/scenario/request would initiate the coordination of *"a product-focused investigation and oversight of the ATM/ANS equipment designed and produced in accordance with this Regulation"* and what role the National CA would undertake, in instances where the ATM/ANS equipment is subject to certification / declaration of design compliance where EASA is the designated CA.

Suggest that this is addressed as part of the planned AMC and if applicable GM, that support Subtask 1 deliverables.

response *Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration as specified in RMT.0161 Subtask 3.

comment

720

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.020 (c) - *"[...] if considered necessary, conducting an inspection of the ATM/ANS provider."*

The basis for EASA to conduct an oversight inspection of the ATM/ANS provider in instances where they have not been assigned the role of CA and without reference to engagement with the National CA is unclear.

It is understood that Article 4(1) of Implementing Regulation (EU) 2017/373 identifies the role of the National CA.

Additionally, it is understood that EASA BR Art.80(1)(b)/(c) states that EASA shall be responsible for the tasks related to certification, oversight and enforcement w.r.t organisations that are "involved in the design, production or maintenance of ATM/ANS systems and ATM/ANS constituents, including where they contribute to Single European Sky ATM Research (SESAR) implementation, used in the provision of the services" where such services are provided by ATM/ANS providers on a "pan-European ATM/ANS basis".

Suggest clarification is provided regarding National CA role in the referenced EASA inspection of the ATM/ANS provider, where EASA has not been assigned the role of CA of the ATM/ANS provider.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

In addition, please refer to topic 'EASA acting as competent authority for all DPOs'.

comment

721

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.020 (d) - "When the Agency finds that the AltMoC proposed by an applicant [...]"

Suggest reword to align with scope of points (b) & (c) and CIR (EU) 2017/373; ATM/ANS.AR.A.015(d) -

"When the Agency finds that the AltMoC proposed by an organisation involved in the design and/or production of ATM/ANS equipment is/are sufficient [...]"

response

*Not accepted*

comment

722

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.025 "Immediate reaction to a safety and interoperability problem"

Suggest inclusion of 'security' to align with objective set out in NPA; Section 2.2 and EASA BR; Annex VIII; Section 3.3.1.



Suggest revision of text to remove the 'and' function to align with point (b) text which states 'and/or'.

Proposed text for consideration in ATM/ANS.EQMT.AR.A.025 header - "*Immediate reaction to a safety/security/interoperability problem*" and to align text in point (b) accordingly.

response *Partially accepted*

comment 723

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.025 (b) - "[...] including the issue of ATM/ANS equipment directives in accordance with point ATM/ANS.EQMT.AR.A.025"

Noted that reference is to 'ATM/ANS.EQMT.AR.A.025'

It would appear that reference should be to 'ATM/ANS.EQMT.AR.A.030' which addresses "ATM/ANS equipment directives".

response *Accepted*

comment 724

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.030 (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 [...]"

Clarification if this action taken by the Agency is limited to ATM/ANS providers, where EASA acts as the competent authority to align with BR; Article 76 (6)(a).

Suggest further text in this section to address how EASA will communicate with the associated National CAs as per BR; Article 76 (6)(b).

response *Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 725

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.030 - "[...] 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"

Suggest inclusion of security to align with objective set out in NPA; Section 2.2. and EASA BR; Annex VIII; Section 3.3.1 requirement.

Proposed text - "[...] and restore the performance and interoperability of that ATM/ANS equipment when evidence shows that the safety, security, performance or interoperability of that particular equipment may otherwise be compromised"

response *Accepted*

comment 726 comment by: IAA Aviation Regulator

ATM/ANS.EQMT.AR.A.030 (b)(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;"

Suggest inclusion of insecure to align with objective set out in NPA; Section 2.2. and EASA BR; Annex VIII; Section 3.3.1 requirement -

Proposed text - "an unsafe, insecure, underperformance or non-interoperability condition has been determined by the Agency to exist in the equipment as a result of a deficiency in the equipment;"

response *Accepted*

comment 727 comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.035 (a)(1) - "[...] point ATM/ANS.EQMT.AR.A.035 [...]"

Clarification if the above intended reference is to ATM/ANS.EQMT.AR.A.040 "Detailed specifications for the equipment design compliance"

response *Accepted*

Taking into account the comment, the reference is corrected.

comment 728 comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.A.040 - "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."

It is imperative that the referenced detailed technical specifications provide design standards that meet both safety and security applicable requirements, to align with objective set out in NPA; Section 2.2. and EASA BR; Annex VIII; Section 3.3.1 requirement.

The onus on ensuring that the overall design of the ATM/ANS equipment (incl. use of any COTS software (Operating systems, third-party software used as part of the system design, etc as part of the system design) is secure and that a "security by design" approach has been incorporated, should be with the approved DPO.

It is understood that DPOs for ATM/ANS equipment are not captured within the scope of the separate CIR/CDR associated with "management of information security risks with a potential impact on aviation safety".

response *Accepted*

Taking into account the comment, the Agency is complementing the proposal submitted for consultation with NPA 2022-09 by:

- introducing the relevant Part-IS provisions for organisations involved in the design and/or production of ATM/ANS equipment and the Agency acting as competent authority; and
- adding a new article intended to amend the scope of the Part-IS Regulation.

comment 729

comment by: *IAA Aviation Regulator*

Annex I; ATM/ANS.EQMT.AR.A.050 (a)(2)(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"

Suggest inclusion of security to align with objective set out in NPA; Section 2.2 and BR; Annex VIII; Section 3.3.1.

Proposed text - "(iii) criticality of the design or the technology, the related safety, security or service-compliance risks and the functioning of the ATM/ANS equipment, including those identified on similar designs; [...]"

response *Accepted*

comment

730

comment by: *IAA Aviation Regulator*

Annex I; SUBPART C - OVERSIGHT, CERTIFICATION AND ENFORCEMENT (ATM/ANS.EQMT.AR.C)

It is noted that points 'ATM/ANS.EQMT.AR.C.001', 'ATM/ANS.EQMT.AR.C.005' and 'ATM/ANS.EQMT.AR.C.015' all focus on the 'Declaration of compliance' attestation method.

Suggest that "Subpart C - Oversight, certification and enforcement (ATM/ANS.EQMT.AR.C)" be updated to also address appropriate EASA oversight, certification and enforcement measures, in relation to Art. 4 and Annex II 'ATM/ANS Equipment Certificates' attestation method.

response

*Accepted*

comment

731

comment by: *IAA Aviation Regulator*

Annex I; 'ATM/ANS.EQMT.AR.C.010' Oversight programme -

Clarification should be provided if the scope of the audits undertaken as part of the EASA oversight programme, will also cover a review of ATM/ANS equipment design demonstration of compliance and DPO management of same, to ensure that the current configuration of the ATM/ANS equipment at the time of audit, continues to meet all appropriate section(s) of the applicable technical specifications and that this is satisfactorily demonstrated.

response

*Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

732

comment by: *IAA Aviation Regulator*

Annex I; ATM/ANS.EQMT.AR.C.010 (a)(1) - "(1) cover all the areas of potential concern, with a focus on those areas where problems have been identified in the past;"

In advance of such audits, will EASA engage and seek feedback from applicable National Competent Authorities regarding any areas of potential concern that have been identified with the ATM/ANS equipment design following its introduction into operational use, so that it may be addressed as part of the audit with the approved DPO?

It is noted that ATM/ANS.EQMT.AR.B.001(c) addresses "mutual exchange of all the necessary information with any other competent authority(ies) [...] and provide them with assistance [...]" but this appears to be set out from the point of view to provide the national competent authorities with assistance and not to provide EASA with assistance as part of their oversight activities.

response *Accepted*

comment 733

comment by: *IAA Aviation Regulator*

Annex I; ATM/ANS.EQMT.AR.C.010 (a)(5)(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*" -

Reference to point ATM/ANS.EQMT.AR.C.010 regarding extension of CAP is noted but point ATM/ANS.EQMNT.AR.C.010 does not appear to address CAP extensions.

Should this be a reference to ATM/ANS.EQMT.AR.C.020?

response *Accepted*

comment 734

comment by: *IAA Aviation Regulator*

ATM/ANS.EQMT.AR.C.015 (a) -  
"Upon receiving a notification of changes in accordance with point ATM/ANS.EQMT.DEC.015, [...]"

It is noted that referenced point 'ATM/ANS.EQMT.DEC.015' does not require the approved DPO to submit a notification of change to EASA.

Suggest amendment to text to also capture reference to requirement for approved DPOs to notify EASA of planned changes to the design of their ATM/ANS equipment.

response *Noted*

It should be noted that the commented provision refers to '(b) Any change to the design that is within the scope of the approved organisation's privileges (...)', which itself refers to DPO.OR.B.005 Change management that requires 'Each change to ATM/ANS equipment shall be notified to and approved by the Agency before being implemented unless such a change is managed in accordance with a change management procedure approved by the Agency, defining the classification of the changes to the ATM/ANS equipment and describing how such changes will be notified and managed'.

For further details, please refer to topic 'ATM/ANS equipment change management'.

comment

735

comment by: IAA Aviation Regulator

Annex I; ATM/ANS.EQMT.AR.C.020 (g)(6) - "[...] a credible threat to the safety, performance or interoperability of ATM/ANS equipment;"

Suggest inclusion of security to align with objective set out in NPA; Section 2.2 and BR; Annex VIII; Section 3.3.1.

Proposed text "[...] a credible threat to the safety, security, performance or interoperability of ATM/ANS equipment;"

response

*Accepted*

comment

736

comment by: IAA Aviation Regulator

Annex II; 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."

The scope of point ATM/ANS.EQMT.CERT.001 suggests that it is not limited to ATM/ANS equipment that processes and delivers data for the purpose of the provision of ATM.

Suggest update Annex II; ATM/ANS.EQMT.CERT.001 'Scope' text to align with Art.4 (1).

response

*Accepted*

comment

737

comment by: IAA Aviation Regulator

Annex II; ATM/ANS.EQMT.CERT.015 (b)(2)(i) - "a detailed description of the design, including all the configurations to be certified;"

**and**

Annex III; ATM/ANS.EQMT.DEC.010 (a) - "description of the design, including all the configurations"

It is proposed that reference to "*all the configurations*" should incorporate use of any COTS software (Operating systems, third-party software used as part of the system design, etc as part of the system design) that is used as part of the ATM/ANS equipment design and required for its correct operation.

Suggest that this is addressed as part of the planned AMC and if applicable GM, that support Subtask 1 deliverables.

response

*Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration under the activities of RMT.0161 Subtask 3.

comment

738

comment by: *IAA Aviation Regulator*

Annex II; ATM/ANS.EQMT.CERT.025 (c) - "[...] ATM/ANS.EQPT.CERT.015(a)(2)(vi) [...]" -

Editorial, as point 'ATM/ANS.EQPT.CERT.015(a)(2)(vi)' does not exist.

Appears to be an intended reference to 'ATM/ANS.EQMT.CERT.015(b)(2)(vi)'

response

*Accepted*

comment

739

comment by: *IAA Aviation Regulator*

Annex III; ATM/ANS.EQMT.DEC.010 (d) - "*reference to relevant test reports;*" -

In addition to the above "*relevant test reports*", suggest that the Declaration of compliance should be accompanied with supporting evidence to demonstrate that the ATM/ANS equipment meets all applicable section(s) of the appropriate technical specifications.

An example of one possible option available to an approved DPO to achieve this could be use of traceability matrices where justifications are provided as necessary.

response

*Accepted*

comment

751

comment by: *POL CAA LOZ-4*

The "equipment directive" regulations appear to be duplicated with the "safety directive" regulations. Is there really separate treatment of the equipment directive? It seems that the general regulations can be easily applied to the "equipment directive", and only the regulations treating strictly technical issues can be implemented.

response

*Partially accepted*

Taking into account the comment, the text is amended accordingly.

comment	753	comment by: <i>POL CAA LOZ-4</i>
	Ref. to ATM/ANS.EQMT.AR.A.020 Means of compliance. Will EASA also explicitly notify the DPO organization in the case of an AltMoC that is "insufficient to establish compliance with the applicable requirements"?	
response	<i>Noted</i> The answer is affirmative.	

comment	754	comment by: <i>POL CAA LOZ-4</i>
	Ref. to ATM/ANS.EQMT.AR.B.010 Changes in the management system. Reference to EU Regulation 376/2014 I think by mistake. It seems there should be a reference to EU Regulation 2017/373.	
response	<i>Noted</i> The reference is correct.	

comment	772	comment by: <i>CAA-Denmark</i>
	In the transitional provisions in Article 7 (2) and Article 7 (3) (c) it is stated that the competent authorities responsible for the certification and oversight of the ATM/ANS providers shall provide the Agency with the relevant information to facilitate the evaluation of the ATM/ANS equipment. It is unclear what this task encompasses. What is "relevant information"? Would it be an option to impose this task on the ATM/ANS providers instead?.	
response	<i>Noted</i> Please refer to topic 'Transitional provisions'. In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.	

comment	787	comment by: <i>EUROCONTROL</i>
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Subpart ATM/ANS.EQMT.AR refers to “investigation”  
This wording needs to be clarified to avoid any confusion with the terms in EU.996/2010  
Proposed action:  
Use other term (assessment? Review?)

response *Not accepted*

The referenced term is not only used in the context of occurrence investigations.

comment 788

comment by: *EUROCONTROL*

ATM/ANS.EQMT.AR.A.030(a) : this is not a requirement but a definition.

Proposed action:  
Move to the definition section

response *Not accepted*

As the commented provision is developed based on well-established and known similar provisions in other aviation domains, it is concluded that the text does not require to be amended as proposed.

comment 789

comment by: *EUROCONTROL*

ATM/ANS.EQMT.AR.A.030(c) : this is not a requirement for the Agency.  
ATM/ANS.EQMT.AR.A.030(e) : this is not a requirement for the Agency  
ATM/ANS.EQMT.AR.A.035(c) : this is not a requirement for the Agency

Those requirements that are not for the Agency but for DPOs or National CAs

Proposed action:  
Move to the relevant place or modify completely the structure of the Part - ATM/ANS.EQMT.AR to reflect that some requirements apply to other bodies/entities or separate the two sets of requirements

response *Accepted*

The text is amended accordingly.

comment 790

comment by: *EUROCONTROL*

ATM/ANS.EQMT.AR.A.045(b) : the text is unclear. Syntax error? Verb missing?

Proposed action:  
Correct sentence, add missing text.

response *Accepted*

comment 791

comment by: *EUROCONTROL*

ATM/ANS.EQMT.AR.A.040 and ATM/ANS.EQMT.AR.A.045

Those articles (non exhaustive list) use terms as “state of the art”, “best practice”, “not deemed adequate”: those words are extremely subjective and would lead to different interpretation.

To ensure harmonization, those terms have to be clearly and unambiguously defined.

Proposed action:

Define in an unambiguous way the terms "state of the art", "best practice", "deemed", "adequate".

response *Accepted*

comment 793

comment by: *EUROCONTROL*

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

There is no reference made to “security management system” by the Agency. For example, how should be handles access restriction, protection of documents provided by DPOs, SPs and CAs and of document issued by EASA.

Proposed action:

Clarify security management aspects for the new requirements introduced in the proposed regulation.

response *Accepted*

Taking into account the feedback received, the Agency is complementing the proposal submitted for consultation with NPA 2022-09 by:

- introducing the relevant Part-IS provisions for organisations involved in the design and/or production of ATM/ANS equipment and the Agency acting as competent authority; and
- adding a new article intended to amend the scope of the Part-IS Regulation.

comment

794

comment by: *EUROCONTROL*

ATM/ANS.EQMT.CERT.015 and 025 refer to “certification basis” that is not defined and not available.

Any statement on the maturity, credibility of this NPA and the subsequent regulatory framework depend on the availability of those documents.

Proposed action:

Define certification basis.

response

*Noted*

The commenter is invited to note point ATM/ANS.EQMT.AR.A.035 ATM/ANS equipment certification basis of the proposed Delegated Regulation.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

796

comment by: *EUROCONTROL*

ATM/ANS.EQMT.CERT.020 refers to “changes ... so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.”  
“so extensive” is subjective.

To ensure harmonization, those terms have to be clearly and unambiguously defined.

Proposed action:

Provide unambiguous definition of the term "so extensive"

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

799

comment by: *EUROCONTROL*

ATM/ANS.EQMT.CERT.020 refers to “... the scope of the changes to ATM/ANS equipment as ‘minor’ and ‘major’.”

‘minor’ and ‘major’ need to be defined;

“minor” and “major” concept created confusion in the previous regulation(s) such as 1035 and are subjective.

To ensure harmonization, those terms have to be clearly and unambiguously defined.

Proposed action:

The legislation should to not use 'minor' and 'major' terminology.

response

*Not accepted*

However, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

802

comment by: *EUROCONTROL*

The scope of this regulation is very unclear notably when it comes to digital services which will need more and more certification. Even though this regulation targets future digital services which will be supported primarily by software deliverables based on clouds infrastructure, the current text refers to equipment more of a hardware nature. Therefore, the term equipment does not appear to be the most appropriate term. Moreover, reliance on digital systems and constituents on Non-EU manufacturers should be clearly addressed, since such certification scheme has no other equivalent worldwide.

Another missing element is the approach for ATM/ANS constituents that are COTS products or COTS services. We expect that the industry will move away from vertically integrated ATM products to portable applications. Components that used to be embedded in ATM constituents (e.g. communication middleware, platform layer, orchestration) become stand-alone constituents or external services, purchased by ATM/ANS service providers from general IT companies. Do these components need to be certified or originate from an approved DPO?

Proposed actions:

Adapt the term equipment to the digital context.

Digital products should be made clearer in the proposal notably when relying on non-EU manufacturers.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

803

comment by: *EUROCONTROL*

**Appendix 2 Article 6 Statement of compliance:** ... ATM/ANS equipment complies with the technical standards established by recognised EU standardisation bodies and listed in detailed

specifications adopted by the Agency in accordance with Article 76(3) of Regulation (EU) 2018/1139.

Due to the missing information of the “to be defined” detailed specifications we expect that the currently EASA recognised standardisation bodies will remain unchanged (CEN/CENELEC/ETSI , ICAO, ISO, ITU , EUROCONTROL, EUROCAE/RTCA, AEEC, ISOC, etc.).

Proposed actions:

Ensure that the detailed specifications do not limit the recognised standardisation bodies.

response *Noted*

Please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

comment 804

comment by: *EUROCONTROL*

**Appendix 2 Article 4 to 6:** As this regulation will apply to all digital products which are designed and/or produced, how is artificial intelligence being addressed knowing that it is of a transversal nature to any system or constituent? As such AI can be introduced in a critical or non-safety critical operational system or equipment, could you clarify in which category AI would fall? Article 4, 5 or 6?

Proposed action:

Clarify how AI fits into this new framework and if a certification / Declaration would be required or not even when to be used in non-safety critical systems.

response *Noted*

Please refer to topic ‘Detailed certification/declaration/SoC (technical) specifications and their development/availability’.

comment 805

comment by: *EUROCONTROL*

**Appendix 2 – Article 6:**

The scope of the current conformity assessment is limited to 8 systems. In this NPA the definition is so broad that it could encompass any ATM/ANS system or constituent. Therefore, it could lead to a number of tools (“equipment”) that are currently not considered within the scope of Reg No 552 falling within the scope of this new regulation but have, currently, no standards or DoV/DSU.

One specific example is MET: (EC) 552/2004 considers “8. Systems and procedures for the use of meteorological information” as the BR refers to “(h) Meteorological services”. The associated equipment will be subject to compliance with the new rule (even if only as part of ‘Statement of Compliance’).

Proposed actions:  
Clarify the extent of systems and constituents that fall under this regulation. Clarify if a constituent has currently no standard, such standard would need to be developed. Provide an estimate of the cost and standardization that is required for those constituents and the associated transition practicalities.

response

*Accepted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

806

comment by: *EUROCONTROL*

**Appendix 2 Article 4, 5 and 6:**

As it would not affect interoperability nor the performance of the operational systems, tools used for testing (conformance verification) equipment or for monitoring equipment should fall outside the scope of this regulation.

Proposed action:

Add following text in the scope definition (Articles 4, 5 and 6):" This regulation does not apply to testing or monitoring equipment."

response

*Not accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

807

comment by: *ENAIRE*

Regarding Question 8.2#1, from ENAIRE side we believe that sensors used for surveillance (such as PSR/SSR radars, ADSB receivers or MLAT equipment) should also be subject to Declaration by DPOs.

We do not understand why surveillance sensors should be different from other sensors/equipment such as equipment used for communications or navigation. That is, if communications or navigation equipment must have a Declaration, then surveillance equipment should also need a Declaration by a DPO.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 808

comment by: EUROCONTROL

**Appendix 2 Article 4, 5 and 6:**

A number of tools (i.e. SAFIRE, MICA, NAMS, AMC, PEGASUS) unique purpose is to provide support for the configuration of the ATM/ANS systems prior to operation. Therefore, they should clearly be excluded from the scope of the proposed regulation.

Proposed action:

Add following text in the scope definition (Article 4, 5 and 6):" This regulation does not apply to equipment providing support for the configuration of the ATM/ANS systems prior to operation."

response *Not accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 809

comment by: EUROCONTROL

**Part-ATM/ANS.EQMT.AR :**

In the IOP framework the DoV was attached to systems made of constituents that should have DSU or DoC.

In the proposed regulation, since ATM/ANS equipment considers globally systems and constituents it is not clear if a system that will have to be certified will require that all its constituents will have to be certified or not.

Proposed actions:

Clarify if all constituents of a system have to be certified / qualified separately or not  
Provide in the impact assessment the cost associated to it.

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 810

comment by: EUROCONTROL

**Appendix 2 Article 4, 5 and 6:**

A system / constituent that provides predictions should be clearly excluded from scope when not directly connected to an operational system.

Add following text in the scope definition (Article 4, 5 and 6) :” This regulation does not apply to prediction systems/constituents when not connected to an operational system

response *Not accepted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 811

comment by: EUROCONTROL

**Appendix 2 Article 4:**

Commercial Service providers such as telecommunication services providers which are not certified as air navigation service provider in accordance with Article 7 of the service regulation are currently exempted from conformity assessment tasks.

This is the case for the New PENS service provider which delivers managed network services relying on ‘Market standard (not specific to ATM/ATS)’ IP telecommunication equipment which are not ATM/ANS end systems/equipment/constituents.

Such telecommunication equipment is already subject to stringent telecommunication standard, therefore this regulation should not apply to them.

On the other hand, it would make sense that ATM/ANS end system interfacing with IP telco equipment demonstrate interoperability with telco standards.

In case the current exemption is withdrawn by the new proposed regulation and the communication service provider must become a DPO with certified equipment, the cost impact on New PENS for the network could be significant, whereas the benefit is unclear if any. Moreover, there is no guarantee that the current or future service providers would accept to adapt to the new regulation, there is therefore a risk in the disruption of the service for the network.



Proposed action:

For market standard IP telecommunication equipment exemption to the certification scheme for communication service providers should be retained.  
Cost benefit assessment should be provided.  
Interoperability of ATM/ANS end system and telco standard should be demonstrated.

response

*Noted*

The comment is considered.

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Impact assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

813

comment by: EUROCONTROL

**Article 7 Transitional provisions:**

Systems that were not issued with DoVs but fall due to the scope of this regulation under Article 4 are not mentioned. EASA should clarify transitional measures for such cases.

As proposed in this regulation, EASA will have 5 years to evaluate ATM equipment and decide if they confirm the allocation under article 4, 5 or 6. But there is no provision in terms of time for the equipment manufacturer and or ANSP / NM to conform to any new decision from EASA nor to DPOs.

Transitional arrangements that were applied for Regulation 552/2004 gave 7 years (March 2004 to April 2011) for legacy systems to demonstrate compliance to the essential requirements. The transition measures were making a difference between systems which are to be putting into service and those which are already in service. Details of such arrangements are recalled below and should be used as a source of inspiration for this new regulation:

*1. Starting from 20 October 2005, the essential requirements shall apply to the putting into service of systems and constituents of the EATMN, if not otherwise specified by the relevant implementing rules for interoperability.*

*2. Compliance with the essential requirements shall be required for all systems and constituents of the EATMN currently in operation by 20 April 2011, if not otherwise specified by the relevant implementing rules for interoperability.*

*3. Where systems of the EATMN have been ordered or binding contracts to that effect have been signed*

*— before the date of entry into force of this Regulation, or, where appropriate,*

— before the date of entry into force of one or more relevant implementing rules for interoperability,  
so that compliance with the essential requirements and/or the relevant implementing rules for interoperability cannot be guaranteed within the time limit mentioned in paragraph 1, the Member State concerned shall communicate to the Commission detailed information on the essential requirements and/or implementing rules for interoperability where uncertainty of compliance has been identified. The Commission shall enter into consultation with the parties concerned, after which it shall take a decision in accordance with the procedure referred to in Article 5(3) of the framework Regulation.”

As there is no safety issue identified in this NPA but just the change of regulation framework, which will have significant budget implications including resources management, a transitional measure of a minimum of 7 years should be proposed to conform with the Agency new evaluation.

Additional transitional measures should be proposed for DPOs when they cannot guarantee to be approved when this regulation will be in force. For example, in order to avoid disruption of services due to unexpected decision from EASA, a DPO could be offered the possibility to propose a list of equipment which it believes to be concerned by the regulation, and an associated time plan to comply with the proposed regulation.

Proposed actions:

Clarify the transitional measures for equipment that had no DoV but will fall now in the scope of this new regulation?

Introduce transitional measure of a minimum of 10 years to conform with the new reassessment of the ATM/ANS equipment done by EASA.

The following transitional measures for service providers and DPOs should be introduced:

Starting from March 2024, the new regulation on conformity assessment of ATM/ANS equipment shall apply to new equipment only, especially where this equipment is part of a larger system which aggregates several constituents or systems.

Compliance with the proposed regulation shall be required for all ATM/ANS equipment (systems and constituents) of the EATMN by Sept 2030.

Starting from Sept 2023 manufacturers can send their application form as DPO to EASA and could suggest equipment that it believes could be regulated under this proposed regulation

*Where ATM/ANS equipment of the EATMN have been ordered or binding contracts to that effect have been signed before the date of entry into force of this Regulation, so that compliance with this regulation cannot be guaranteed within the time limit mentioned in paragraph 1, the Member State concerned shall communicate to the Agency detailed information on the essential requirements and/or implementing rules for interoperability where uncertainty of compliance has been identified. The Agency shall enter into consultation with the parties concerned, after which it shall take a decision.*

Practical considerations should be taken into account during the transition period for existing equipment.

response

*Noted*

Please refer to topic 'Transitional provisions'.

comment

817

comment by: *EUROCONTROL*

**Appendix 2 – Article 4, 5 and 6:**

The proposed regulation aims at responding to the ATM digitalisation. However, there is no specific element in this respect. Hence the impact on existing or foreseen "common services" unclear and open for interpretation:

EAD; systems and software used appear to be in scope

PENS; systems and software used appear to be in scope

SWIM Registry; systems and software used appear to be in scope

EACP (PKI); systems and software used appear to be in scope

EATM-CERT; systems and software used appear to be in scope

**While the indicated common services are mostly based on systems and software provided by industry suppliers, some elements of these services are developed by EUROCONTROL.**

Could EASA clarify how they will address common services and exclude any common service that is not safety critical from the scope of the DPO?

To continue to deliver these common services EUROCONTROL, would have to follow two parallel tracks: one as service provider (as today but with additional requirements) and one as manufacturer for Common Services. This will negatively impact all our operational stakeholders as well as the Network Manager cost efficiency target, due to extra workload, and lead to delays on iNM timelines as applicability date coincides with transition/migration activities to iNM

The alternative could be that EUROCONTROL supports only the role of service provider, where its suppliers are considered manufacturers? Such option would add new risks on the Common Services as current contracts could have to be modified or suspended by contractors not accepting to change their terms and conditions. Moreover, there is no certainty that the certificate will be obtained by those new manufacturers.

Therefore, to address proportionality and avoid duplication and excess of regulatory requirements, ATM/ANS service providers and the NM which are both service providers and manufacturers shall be offered a derogation to article 4 of the proposed regulation.

Moreover, a derogation should be given to all ATM/ANS equipment that are supporting ATM/ANS services at the time the regulation shall enter into force.

Proposed actions:

Could EASA clarify how they will address common services and exclude any common service that is not safety critical from the scope of the DPO?

To address proportionality and avoid duplication and excess of regulatory requirements, Air navigation service providers which are both service providers and manufacturers shall be offered a derogation to article 4 of the proposed regulation.

A derogation should be given to all ATM/ANS equipment that are supporting ATM/ANS services at the time the regulation shall enter into force.

response

*Noted*

The comment is considered.

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

819

comment by: *EUROCONTROL*

**Part ATM/ANS.EQMT.CERT**

For the equipment (constituents) part it should be clear what type of changes require a re-certification.

Proposed action:

Clarify the type of changes that are required for a re-certification.

response

*Noted*

Please refer to topic 'ATM/ANS equipment change management'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration as regards the concept of 'major/minor changes'.

comment

820

comment by: *EUROCONTROL*

**Part ATM/ANS.EQMT.CERT**

Digital services certification

Although the proposal mentions historical systems such as ILS CNS equipment, it does not provide any hint regarding how digital services which should be at the heart of this regulation and their systems and constituents could be certified under this new regulation. These services come with their specificities and none of them are mentioned.

Will EASA be certifying non-EU cloud platforms as a constituent of our future system supporting our digital services. Moreover, how will the detailed spec be developed to reflect service-oriented certification as opposed to mere 'individual components'? (example: the reliability of a single Amazon AWS hard disk vs hard disks in our ATM data centre is ridiculous, but because they spread the risk on million servers, the overall reliability is way above any on-premise data centre)

Proposed actions:

EASA should clarify how modern technology which require a move from certification based on individual components, to certification based on product/service will be addressed

Regarding digital services, the proposed regulation should exclude explicitly public IT architectures providing Infrastructure as a service (IaaS, i.e. virtualisation) and industry standard IP network infrastructure and services'

Additional provision should be added regarding the certification of digital services notably for systems and constituents of non-EU manufacturers serving any worldwide company or citizen.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

824

comment by: *EUROCONTROL*

**Question 8.2 p.55:**

For all CNS equipment, ANSP follow a process with first a factory acceptance test (FAT) followed by a site acceptance test (SAT). The FAT can have several stages and will include demonstration of compliance to Annex 10 and EUROCAE or other standards, as well as any additional ANSP requirements and interface specifications. More rigorous ANSP also review the design assurance documents.

There is no evidence that these processes are not sufficiently safe, so it is not clear what benefit could be claimed to regulate them by EASA (local CAA oversight seems to work). Certainly, navigation systems have a very impressive safety record.

What would be needed is write down these processes as this is not available anywhere. Such guidance would make sure that all ANSP (also the smaller, more fragmented ones we have

today) know what they should be doing. Therefore, even the declaration by a DPO is considered to be too costly for the expected benefits.

Proposed action:

EASA to reconsider the types of CNS equipment that justify the high cost of a declaration by a DPO.

response

*Noted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Impact assessment', in particular 'Certification costs and impacts on the market'.

comment

892

comment by: ENAV

Reference: 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.

Comment: Same comments as on paragraph 2.3.1.2. ATM/CNS equipment concerned by certification or declaration are not clearly defined, creating ambiguity and difficulties for organizations to assess if they should become DPO or not.

Proposal: The list of ATM/CNS equipment for certification and declaration should be defined.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

893

comment by: ENAV

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.

Comment: CNS equipment are already defined by ICAO standards. So it does not seem necessary to certify them. Declarations by DPO should be enough.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

894

comment by: *ENAV*

Article 7

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;

Comment: same comment as 2.3.1.2

Comment: In a worst-case scenario, an ANSP may have to replace all or most of its ATM equipment if EASA decides so, which would be economically prohibitive.

Proposal: A real grandfathering process shall be in place in order to avoid unacceptable costs for ANSP whereas current operational systems do meet the applicable essential requirements of the Basic Regulation and the corresponding delegated and implementing acts.

response

*Noted*

Please refer to topic 'Transitional provisions'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

895

comment by: *ENAV*

8.2 Article 4

Must be much clearer regarding which Ground Equipment that is covered.

response

*Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

896

comment by: *ENAV*

ATM/ANS.EQMT.AR.A.050

If the Agency has established the detailed technical specification is there really any alternative that the Agency takes the lead in verification and validation activities? Otherwise many ANSPs have to interpret a detailed technical specification which they have not written themselves, and try to figure out how verification and validation should best be performed. That is quite a difficult job when your organisation has not written the specification itself.

response *Noted*

Please refer to topics 'Roles and responsibilities of the different actors' and 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 897

comment by: ENAV

ATM/ANS.EQMT.AR.A.045

Who is going to make the decision that a system has unusual design, unconventional use or that similar systems has newly identified risks (which are applicable to a specific ATM/ANS system in an approval process)? As design of a complex system is a spectrum of subparts and possible solutions it is neigh impossible to draw a line where something is unusual or not, or whether it is of unconventional use. The decision on unusual design, unconventional use will be influenced by the experience of the person managing the application, which could lead to different requirements for different applications depending on which person is managing the application.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 898

comment by: ENAV

ATM/ANS.EQMT.AR.C.020 (g)

What will happen to an actual operational ATM/ANS-system if the certificate for the manufacturer or system is revoked? Will the ANSP be able to continue with their operations using the system?

response *Noted*

Please refer to topic 'DPO approval discontinuation'.



comment	899	comment by: ENAV
	<p>ATM/ANS.EQMT.CERT.015 (b)(2)(i)  The detailed description of the design (including configurations) can be a substantial amount of information, and not known to the DPO before delivery to an ANSP. Different ANSPs can have different configurations of the same ATM/ANS equipment.</p>	
response	<p><i>Noted</i></p> <p>Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.</p>	

comment	900	comment by: ENAV
	<p>ATM/ANS.EQMT.CERT.020  How will DPOs know beforehand what type of changes in the design could be found as extensive by the Agency? There should be some criteria or definition of "extensive" so that DPOs will not be surprised by having to apply for certificate.</p>	
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>	

comment	901	comment by: ENAV
	<p>ATM/ANS.EQMT.DEC.025  Will EASA allow all languages in manuals?</p>	
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>	

comment	902	comment by: ENAV
	<p>General comment: in order to achieve the specific objectives as outlined in Section 2.2 of this NPA, it is important that no additional national regulations complicate market access, create additional administrative burden, and ultimately disadvantage the ATM/ANS providers.</p>	

response

*Noted*

The comment is agreed.

comment

903

comment by: ENAV

Article 5

Question 8.2 #1:

The NAV perspective:

an ILS may be well specified and produced and declared compliant with all provisions. However, when erected at the wrong place of the aerodrome, it is useless or worst case produces harm. This is the ultimate responsibility of the ANSP, that no declaration can take over.

The SUR perspective:

Performance of surveillance sensors is heavily dependent on the surrounding environment. Even functionality and interoperability may be influenced by environmental or temporal conditions. The knowledge of these dependencies lies within the operating organization.

Therefore, this organization will usually develop or propose acceptance tests specific to the given

environment. A declaration by an approved ATM/ANS equipment manufacturer will cover general functionalities.

Testing and tuning to achieve the required performance and ensure coverage and interoperability is a site specific task to be carried out with the ATM/ANS provider.

This thought also applies to the coverage of VHF (COM) stations.

In addition, while a lot of functionalities of surveillance sensors may be required for all installations, some specific functions may be required for certain site installations.

These additional functions will also need specific testing.

A declaration by an approved ATM/ANS equipment manufacturer shall state conformance with certain functionalities documented in generally accepted standards for that equipment. However, experience shows that on site testing will be required to ensure interoperability and appropriate performance after installation

manufacturers may implement not all items addressed in the related standards or implement them only partially.

General conclusion:

The effort of the ANSP will not evidently reduce compared to the additional cost that the DPO approval bears. Declaration of those products is though deemed meaningful, however the need and benefit to hold that DPO approval by their manufacturers is not visible, especially since the danger to have non-professionals

selling such equipment AND professionals buying it is very low.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- ‘Categorisation of ATM/ANS equipment subject to conformity assessment’;
- ‘Roles and responsibilities of the different actors’; and
- ‘Access to the market’.

In case ENAV sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally between ENAV and the Agency or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

904

comment by: ENAV

Article 6

Statement of Compliance is made against detailed specifications adopted by EASA. It ceases to be valid if (in accordance with point 2. a)) the equipment no longer complies with the essential requirements.

Many detailed specifications, however, do not apply on some essential requirements. Wouldn't it be more

consistent to indicate "no longer complies with the detailed specifications adopted by the Agency..." ?

ENAV understands that the intention expressed prior to NPA is that the ATM/ANS provider is no longer obliged to show compliance with the essential requirements.

The given regulatory framework does not clarify how essential requirements have to be handled by ANSPs which could lead to national differences.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

906

comment by: FOCA Switzerland

The Statement of Compliance (SoC) is introduced by the draft article 6, to replace the DoV (that was introduced by regulation 552/2004). This article does not contain the necessary information for proper implementation. In our opinion, it would be essential to give clear indications on the content of such a declaration, at least in the AMC/GM. This would also allow for a homogeneous application between the different States concerned.

Furthermore, it is unclear for us if NSAs have to examine SoCs. If SoCs have to be examined by the authority, then the criteria should be described.

response

*Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

It should be noted that the SoC will be subject to oversight by the competent authorities.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

946

comment by: *EUROCONTROL*

Article 7 is mentioning that "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)". That means that all legacy systems which are not compliant with the EASA BR needs to be certified by EASA.

**Recommendation:** The certification of legacy systems shall not subject of any certification by EASA.

**Rationale :** A legacy system should not be certified and updated to be compliant to requirements which have not been existent during the put-into-operation time.

response

*Partially accepted*

Please refer to topic 'Transitional provisions'.

comment

947

comment by: *EUROCONTROL*

Article 3 is giving the Agency the mandate to conduct 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.

**Recommendation:** This mandate shall be limited to organisations involved in the design, and/or production of ATM/ANS equipment for pan-European service Provider as defined in the current EASA BR.

The explanation given by EASA on page 13 that it is impossible to determine upfront how a ATM/ANS equipment will be used afterwards shall not draw conclusions from it that ALL equipment's will be used by pan-European Service Provider.

**Rationale:** According to EASA BR art. 80(1)(b) and art. 80(1)(c) the Agency is only responsible for the tasks related to certification, oversight and enforcement in accordance with Article 62(2) with respect to:

(a) the certificates for the ATM/ANS providers referred to in Article 41, where those providers have their principal place of business located outside the territories for which Member States are responsible under the Chicago Convention and they are responsible for providing ATM/ANS in the airspace above the territory to which the Treaties apply;

(b) the certificates for the ATM/ANS providers referred to in Article 41, where those providers provide pan-European ATM/ANS;

(c) the certificates for and the declarations made by the organisations referred to in Article 42, where those organisations are involved in the design, production or maintenance of ATM/ANS systems and ATM/ANS constituents, including where they contribute to Single European Sky ATM Research (SESAR) implementation, used in the provision of the services referred to in point (b) of this paragraph;

response *Not accepted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

comment 961

comment by: AESA

In page 53, Article 1 d), why does the proposal not include an annex regarding to the statement of compliance (SoC), in the same way as it has been proposed with the certification/declaration [content of the statement of compliance (technical file,...); updates; changes; failures, malfunctions and defects; manuals; ...], in addition to what is stated in article 6? It should be specified in the requirements, even if referring to a requirement of another regulation (Regulation (EU) 2017/373, ...).

response *Noted*

As the ATM/ANS providers will be responsible for the issue of statement of compliance, Regulation (EU) 2017/373 is considered as a better placeholder.

comment 962

comment by: AESA

In page 53 Article 1.1 c) and page 63 ATM/ANS.EQMT.AR.A.065 c), what is the concept of "privileges"? Which set of privileges can an approved organization exercise?

response

*Noted*

Taking into account the comment, point DPO.OR.A.025 Duration, continued validity and privileges of an organisation approval of the draft Implementing Regulation on DPO approval is amended.

comment

963

comment by: AESA

Regarding page 54, Article 2, it is necessary to include the definitions of ""recurrent maintenance"" (as it is named in page 11, 2.3.1.1) / ""routine maintenance"" (as it is named in page 21, 2.3.2) and ""evolutive maintenance"" (as it is named in page 11, 2.3.1.1) / ""equipment upgrade"" (as it is named in page 21, 2.3.2), as well as a unique nomenclature. It would also be appropriate to include them in the Annex I — Part-Definitions to Regulation (EU) 2017/373).

response

*Partially accepted*

Taking into account the comment, a recital to the draft Implementing Regulation on DPO approval is introduced. In addition, the development of the associated GM is under consideration.

comment

964

comment by: AESA

In page 54, Article 4, regarding "ATM/ANS equipment that processes and delivers data", does it include VOICE COM G/A? It should be considered

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

965

comment by: AESA

In page 54, Article 4, risk Performance should be considered (such as in article 5.c): "the ATM/ANS equipment has proved to give rise to unacceptable risk or unacceptable performance in service;"

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment	<p>966</p> <p style="text-align: right;">comment by: AESA</p> <p>In page 54, Article 2, it would be appropriate to include the definition of design and production organisation (DPO), organisation involved in the design and/or production of ATM/ANS equipment, as well as a unique nomenclature.</p>
response	<p><i>Not accepted</i></p> <p>The purpose of the definitions is to define a specific term, while it is considered that the DPO is well described in the regulatory text itself, e.g. please refer to point (c) of DPO.OR.A.025 Duration, continued validity and privileges of an organisation approval</p>

comment	<p>967</p> <p style="text-align: right;">comment by: AESA</p> <p>In page 54, Article 2, it would be appropriate to include the definition of ATM/ANS equipment directive, that only appears in the requirement ATM/ANS.EQMT.AR.A.030 ATM/ANS equipment directives, letter a).</p>
response	<p><i>Not accepted</i></p> <p>The purpose of the definitions is to define a specific term, while it is considered that the directive is well defined in point (a) of the commented provision itself.</p>

comment	<p>968</p> <p style="text-align: right;">comment by: AESA</p> <p>Regarding page 54, Article 4, 5, 6, in 2.3.1.2 it is stated: ""[...]the interoperability Regulation had identified a list of systems, their constituents, and associated procedures, to which the interoperability framework applied[...]"".</p> <p>Are systems for the FPD service subject to certification, declaration or statement of compliance? This is not explicitly included in the proposal.</p>
response	<p><i>Noted</i></p> <p>Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.</p>

comment	<p>969</p> <p style="text-align: right;">comment by: AESA</p> <p>In page 54, Articles 4 and 5, communications equipments are not considered to be attested through a certification/declaration?</p>
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response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

970

comment by: AESA

Regarding page 54, Article 4.1, will there be AMC(s) detailing the equipments subject to certification?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, established and issued detailed (technical) specifications for the various categories of ATM/ANS equipment will be available.

comment

971

comment by: AESA

Regarding page 54, Article 4.2, what happens to the certificate if the design and production organisation (organisation involved in the design and/or production of ATM/ANS equipment) loses its DPO approval?

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

972

comment by: AESA

Regarding page 54, Article 4.2, what happens to the certificate in case of failures, malfunctions and defects (DPO.OR.A.040) that, in the end, are not fixed by the DPO?

response

*Noted*

There are various tools and means to address the issue, e.g. applying enforcement measures to DPO approval holders and issue an ATM/ANS equipment directive.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.



comment	973	comment by: AESA
	In page 54, Article 4.2, what should the ATM/ANS provider that uses the equipment do if that equipment loses its certificate?	
response	<i>Noted</i>	
	Please refer to topic 'DPO approval discontinuation'.	
comment	974	comment by: AESA
	In page 55, Article 5.1, there is an error in the reference to "Annex II". It should be referenced to "Annex III".	
response	<i>Accepted</i>	
comment	975	comment by: AESA
	Regarding page 55, Article 5.1, will there be AMC(s) detailing the equipments subject to declaration?	
response	<i>Noted</i>	
	Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.	
comment	976	comment by: AESA
	Regarding page 55, Article 5.2, what happens to the declaration if the design and production organisation (organisation involved in the design and/or production of ATM/ANS equipment) loses its DPO approval?	
response	<i>Noted</i>	
	Please refer to topic 'DPO approval discontinuation'.	
comment	977	comment by: AESA

Regarding page 55, Article 5.2, in addition to letter c), what happens to the declaration in case of failures, malfunctions and defects (DPO.OR.A.040) that, in the end, are not fixed by the DPO?

response

*Noted*

There are various tools and means to address the issue, e.g. applying enforcement measures to DPO approval holders and issue an ATM/ANS equipment directive.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

978

comment by: AESA

Regarding page 55, Article 5.2, what should the ATM/ANS provider that uses the equipment do if that equipment loses its declaration?

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

979

comment by: AESA

Regarding page 55, Article 6.1, as well as page 12 point 2.3.1.1, it is unclear which will be the aim of a statement of compliance. Manufacturers are responsible for design and production while the national competent authority of the ATM/ANS provider is responsible for integration and entry into service. This is different from the current approach of proceeding with DoVs (design+production+integration+entry into service), so the SoC will focus only on the integration and entry into service part?

response

*Noted*

The statement of compliance is the third means of conformity assessment of ATM/ANS equipment.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

980

comment by: AESA

Regarding page 55, Article 6.1, will there be AMC(s) detailing the equipments subject to statement of compliance (SoC)?

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

981

comment by: AESA

In page 55, Article 6.1, it is unclear which documents should the ATM/ANS provider submit to the Competent Authority (e.g. a technical file).

response

*Noted*

The text referenced to Regulation (EU) 2017/373 is amended to promote clarity.

comment

982

comment by: AESA

In page 55, Article 6.2, it is established: ""A statement of compliance for ATM/ANS equipment shall be issued for an unlimited duration. It shall remain valid unless [...]"".

The Competent Authority role is not established, but should be. Is it the same as for current DoVs? Clarification needed.

response

*Noted*

The commentator is invited to refer to Article 3 defining which the competent authority is for the various means of conformity assessment.

comment

983

comment by: AESA

Regarding page 55, Article 5 2)a), what about if the ATM/ANS equipment still complies with the technical specifications against which the declaration was made, but new technical specifications arise and the ATM/ANS equipment does not comply with them yet? Maybe this case should be considered. Perhaps a new declaration of design compliance should be issued.

response

*Noted*

The draft Delegated Regulation specifies that the certification basis consists amongst others of detailed specifications issued by the Agency, which are applicable to the ATM/ANS equipment on the date of submission of the application for that certificate, unless the applicant chooses to comply or is required to comply with a detailed certification specification, which became applicable after the date of the submission of the application.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 984

comment by: AESA

In page 56, Article 7.1 c), it would be appropriate, analogously to what is established in a) and b), that "[...] shall be deemed to a statement of compliance pursuant to Article 6 of this Regulation" unless the Competent Authority determines, following the supervision activities, 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.

It seems that Competent Authorities don't have to re-oversight the content of the DoV. Competent Authorities should have the possibility to oversight DoVs issued before the implementation of this Regulation, in order to verify the compliance with this Regulation and the ammended Regulation (EU) 2017/373 when they enter into force.

response *Noted*

Please refer to topic 'Transitional provisions'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 985

comment by: AESA

In page 56, Article 7.2, who initiates the process for each equipment? Competent Authorities? The Agency? Further information on the process and coordinations needed.

response *Noted*

Please refer to topic 'Transitional provisions'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 986

comment by: AESA

In page 56, Article 7.2 and 7.3.c), "the competent authorities responsible for the certification and oversight of the ATM/ANS providers [...] shall provide the Agency with the relevant information to facilitate this evaluation".

Need for clarification about which information is considered relevant to perform this task.

response

*Noted*

Please refer to topic 'Transitional provisions'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

987

comment by: AESA

In page 56-57, Article 7.2 and art. 7.3.c), it is stated: "[...] the competent authorities [...] shall provide the Agency with the relevant information to facilitate this evaluation [...]."

Wouldn't it be more efficient if the ATM/ANS providers sent this relevant information directly to the Agency? This would also allow testing the communication channels for future certifications/declarations.

response

*Noted*

Please refer to topic 'Transitional provisions'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

988

comment by: AESA

In page 56, Article 7.2, "... The objective of that evaluation shall be to determine that the particular ATM/ANS equipment ensures a level of safety,..."

What happens if the result of that evaluation is that the ATM/ANS equipment is not safe? A safety directive is issued? Maybe some clarification is needed."

response

*Noted*

Please refer to topic 'Transitional provisions'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

In response to the question, the answer is affirmative that one of the means is an issue of ATM/ANS equipment directive, but it is not the only means.

comment

989

comment by: AESA

In page 56, regarding article 7.3, ATM/ANS equipment that is subject to certification or a declaration 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. Who will carry out the oversight of this SoC during the period indicated above?

response

*Noted*

The competent authority responsible for the oversight of the statements of compliance issued by an ATM/ANS provider in accordance with Article 6 of the draft Regulation should 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.

comment

990

comment by: AESA

In page 56, Article 7.3, the Agency shall evaluate the ATM/ANS equipment referred to in point 3(a) and (b) until [12 September 2030]. Point 3(a) and(b) are referred only to ATM/ANS equipment subject to certification/declaration.

When the competent authorities, responsible for the certification and oversight of the ATM/ANS providers that use a ATM/ANS equipment subject to statement of compliance (SoC), will carry out the oversight?"

response

*Noted*

The answer is affirmative; the competent authority responsible for the oversight of the statements of compliance issued by an ATM/ANS provider in accordance with Article 6 of the draft Regulation should 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.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

991

comment by: AESA

In page 56, Article 7.3, regarding the transitional provisions: clarification is needed on how to proceed and manage changes in a system, as well as the update of the technical file, during the transition period.

response

*Noted*

Please refer to topic 'Transitional provisions'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

992

comment by: AESA

In page 56, Article 7.3, regarding the transitional provisions, for those systems/equipments subject to a certification or declaration:

- It is unclear what happens to the provisional ATM/ANS equipment certification/declaration if the manufacturer finally is not recognized as a DPO.
- During this period of 5 years, have the SoCs issued for ATM/ANS equipments that are subject of certification/declaration to comply the correspondent requirements of the respective Annexes?
- During this period of 5 years, it's not stated that this Transitional Provisiones do not apply anymore to a approved DPO.

response

*Noted*

The comment is duly considered in the Opinion.

The Agency believes that most of your general concerns are addressed in the following topics, which have been duly considered in the Opinion:

- 'Transitional provisions';
- 'Roles and responsibilities of the different actors';
- 'DPO approval discontinuation'.

In case the commenter sees that there are aspects in the comments which have not been answered by the CRD or by the respective Opinion, the Agency proposes to organise a dedicated session to discuss these matters. This could take place bilaterally or it could be included in the agenda of the most relevant EASA Advisory Body.

comment

993

comment by: AESA

Regarding page 58, ANNEX I. REQUIREMENTS FOR THE AGENCY, will there be any requirements for national CAs?

response

*Noted*

Please refer to topic 'EASA acting as competent authority for all DPOs'.

In addition, it should be noted that the requirements for the competent authorities as regards the SoC are laid down in Regulation (EU) 2017/373.

comment

994

comment by: AESA

In page 58, ATM/ANS.EQMT.AR.A.005 "Scope", for consistency, the numbering of this requirement should start at "001".

response *Accepted*

comment 995

comment by: AESA

Regarding page 58, ATM/ANS.EQMT.AR.A.015, how will the exchange of information and the coordination take place?

Will there be any common procedure for how these coordinations are carried out between the Agency and the national competent authorities? Or, will there be a particular procedure for each competent authority?

Will it be specified in the AMCs?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under development.

comment 996

comment by: AESA

In page 58, ATM/ANS.EQMT.AR.A.015 (b), in which cases will joint audits between EASA and the competent authority of the Member State be carried out?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 997

comment by: AESA

In page 59, ATM/ANS.EQMT.AR.A.025, regarding point (a):

Will the Agency implement new notification channels for events related to safety and interoperability problems?

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The Agency will make best use of already existing best practice(s) on the subject.



comment	998	comment by: AESA
	In point 59, ATM/ANS.EQMT.AR.A.025 (b), there is an error in the reference to point "ATM/ANS.EQMT.AR.A.025". The correct reference should be to the point " <b>ATM/ANS.EQMT.AR.A.030</b> ", which is related to equipment directives.	
response	<i>Accepted</i>	

comment	999	comment by: AESA
	In page 59, ATM/ANS.EQMT.AR.A.025, in letter c) it is said "When joint action is required, the competent authorities of the ATM/ANS providers concerned shall also be notified". Why are the measures taken related to safety and/or interoperability problems not always notified to the Competent Authorities of the ATM/ANS provider concerned?	
response	<i>Noted</i>  Taking into account the comment, the development of the associated AMC/GM is under consideration.	

comment	1000	comment by: AESA
	In page 59, ATM/ANS.EQMT.AR.A.020 (d), when an AltMoC is considered sufficient, the Agency notifies the applicant. Are Member States notified about these?"	
response	<i>Noted</i>  They will be notified if that organisation is subject also to oversight by the national competent authority.  For further details, please refer to: <a href="https://www.easa.europa.eu/en/document-library/acceptable-means-compliance-amcs-and-alternative-means-compliance-altmocs">https://www.easa.europa.eu/en/document-library/acceptable-means-compliance-amcs-and-alternative-means-compliance-altmocs</a> .	

comment	1001	comment by: AESA
	In page 60, ATM/ANS.EQMT.AR.A.030, in letter c), why notification to competent authorities of the ATM/ANS providers that use the affected ATM/ANS equipment is not considered, if in letter e) is established that they are in charge of verifying the compliance with the applicable ATM/ANS equipment directives?	
response	<i>Accepted</i>	

Taking into account the comment, the text is amended accordingly.

comment	1002	comment by: AESA
	In page 60, ATM/ANS.EQMT.AR.A.030, a reference to Regulation 2018/1139, Article 76 (6)(b) may be appropriate.	
response	<i>Not accepted</i>	

comment	1003	comment by: AESA
	In page 60, ATM/ANS.EQMT.AR.A.035 (a) (1), it would be useful to clarify the content of these paragraphs in letter a) point 1):	
	"(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);"	
response	<i>Noted</i>	
	Taking into account the comment, the development of the associated AMC/GM is under consideration.	

comment	1004	comment by: AESA
	In page 61, ATM/ANS.EQMT.AR.A.040 (a)(3), we suggest to use the complete reference ATM/ANS.OR.A.045(g)(3), because it is where reference to statement of compliance is made."	
response	<i>Accepted</i>	

comment	1005	comment by: AESA
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In page 62, ATM/ANS.EQMT.AR.A.050, regarding "**Level of involvement**", which is the aim of this concept?

response *Noted*

The purpose of the provision is to define the depth of the Agency's evaluation in the verification of compliance demonstration and data required to be provided by the applicant for the issue of a certificate or for changes to it.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment *1006* comment by: AESA

In page 63, ATM/ANS.EQMT.AR.A.065 (a), there is an error. The referenced Annex IV does not exist in the document.

response *Accepted*

comment *1007* comment by: AESA

Regarding page 63, ATM/ANS.EQMT.AR.A.055 (b) and ATM/ANS.EQMT.AR.A.060 (b), what is the data sheet for continued suitability? A clarification about data sheet would be welcomed.

response *Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment *1008* comment by: AESA

Regarding page 63, ATM/ANS.EQMT.AR.A.065, shouldn't this whole requirement be on the IR in page 42 dealing with the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents?

response *Noted*

For ATM/ANS systems and ATM/ANS constituents, the Commission is empowered under Article 47(1) of Regulation (EU) 2018/1139 to adopt delegated acts, in accordance with Article 128 of the same Regulation, laying down detailed rules with regard to:

- the conditions for establishing and notifying to an applicant the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents for the purposes of certification in accordance with Article 45(2) of the same Regulation;
- the conditions for issuing, maintaining, amending, limiting, suspending or revoking the certificates referred to in Article 45(2) of Regulation (EU) 2018/1139, and for the situations in which, with a view to achieving the objectives set out in Article 1 and while taking account of the nature and risk of the particular activity concerned, such certificates are to be required or declarations are to be permitted, as applicable;
- the privileges and responsibilities of the holders of certificates referred to in Article 45(2) of Regulation (EU) 2018/1139;
- the privileges and responsibilities of the organisations issuing declarations in accordance with Article 45(1) and (2) of Regulation (EU) 2018/1139;
- the conditions and procedures for the declaration by ATM/ANS providers, in accordance with Article 45(1) of Regulation (EU) 2018/1139, and for the situations in which, with a view to achieving the objectives set out in Article 1 and while taking account of the nature and risk of the particular activity concerned such declarations are to be required; and

the conditions for establishing the detailed specifications applicable to ATM/ANS systems and ATM/ANS constituents which are subject to a declaration in accordance with Article 45(1) and (2) of Regulation (EU) 2018/1139.

Consequently, the commented provision should be placed in the delegated act.

comment

1009

comment by: AESA

In page 64, ATM/ANS.EQMT.AR.A.065 (c), the duration of that approval is already covered by DPO.OR.A.020.

response

*Noted*

The commenter is invited to note that one of the provisions addresses the EASA responsibilities, while the other one the organisation requirements.

comment

1010

comment by: AESA

In page 65, ATM/ANS.EQMT.AR.B.005 (b), there is an error in the reference to point "ATM/ANS.EQMT.AR.B.001(a)(4)". The correct reference should be to the point "ATM/ANS.EQMT.AR.B.001(a)(5)", which is related to the establishment of an internal audit process and a safety risk management process by The Agency.

response

*Accepted*

comment	1011	comment by: AESA
	<p>In page 66, ATM/ANS.EQMT.AR.B.015, in letter c), it is established that "all the records [...] shall be kept for a minimum period of 5 years [...], subject to the applicable data protection law". However, all the information related to the certification/declaration of a ATM/ANS equipment should be kept during the whole lifecycle of the equipment.</p>	
response	<p><i>Accepted</i></p> <p>The text is amended accordingly.</p>	

comment	1012	comment by: AESA
	<p>In page 66, ATM/ANS.EQMT.AR.B.015, in letter d), in relation to the record-keeping system, it is established that this shall be made available upon request to the competent authorities. If competent authorities have to carry out supervision activities of the ATM/ANS equipments used by the ATM/ANS providers, why is upon request?</p>	
response	<p><i>Noted</i></p> <p>The criteria in which circumstances a reporting will be required will be further stipulated at AMC/GM level and the comment will be considered during the activities of RMT.0161 Subtask 3.</p>	

comment	1013	comment by: AESA
	<p>In page 67, ATM/ANS.EQMT.AR.C.001 (a)(3), it is stated: "[...] the Agency shall verify that [...] the declaration does not contain information that indicates a non-compliance with the applicable requirements of Annex III to this Regulation". Regarding that, it should be considered that there may be known issues or bugs in a ATM/ANS equipment, currently in operational use, that may imply a non-compliance with the applicable requirements contained in the Certification Basis when they entry in force.</p>	
response	<p><i>Noted</i></p> <p>The commenter is invited to note that the declarations to be issued by the ATM/ANS equipment manufacturers is an upfront activity, i.e. before ATM/ANS equipment is deployed, and it is not anticipated at the time of the declarations that any issues pertaining to the operational use will be known.</p>	

comment	1014	comment by: AESA
	In page 67, ATM/ANS.EQMT.AR.C.010, it would be appropriate to specify that the Agency's oversight programme covers the certificates and declarations.	
response	<i>Accepted</i>	
	Please refer to point (a)(2) of the commented provision.	

comment	1015	comment by: AESA
	In page 68, ATM/ANS.EQMT.AR.C.015, there is no mention to the declaration's change approval. Is it not required? Does the acknowledge receipt of the notification imply that change approval?	
response	<i>Noted</i>	
	The change is that the declarations should be performed in compliance with the point (b) of DPO.OR.B.005 Change management.	
	For further details, please refer to topic 'ATM/ANS equipment change management'.	
	In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.	

comment	1016	comment by: AESA
	Regarding page 72, ATM/ANS.EQMT.CERT.015 (b)(2)(vi), it is stated that the application shall include a proposal for the Agency's level of involvement. Guidance on how to propose the Agency's level of involvement is needed.	
response	<i>Accepted</i>	
	The proposal is well received. Please refer to RMT.0161 Subtask 3.	

comment	1017	comment by: AESA
	In page 73, ATM/ANS.EQMT.CERT.015 (c), replace ""(b)(i)"" by ""(b)(2)(i)""."	
response	<i>Accepted</i>	

comment

1018

comment by: AESA

In page 73, ATM/ANS.EQMT.CERT.015 (e)(2), it states that the applicant must propose a new date for the issue of the certificate. However, can the applicant propose a date for the certificate issue? Because in the previous paragraphs, such thing is not required. Besides, the applicant probably does not know how long will take the Agency to issue the certificate. He can estimate when he will be in condition to comply with certification basis, but for the issue of the certificate, the Agency is involved and the applicant does not control that part of the process.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1019

comment by: AESA

In page 73, ATM/ANS.EQMT.CERT.020, it is stated: "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 [...]".

How can the Agency find something related to a change if there is no requirement about the notification of the changes to certifications, as if there is about the changes to declarations [ATM/ANS.EQMT.AR.C.015]?

response

*Noted*

The change management is addressed in point DPO.OR.B.005 of the draft Implementing Regulation.

comment

1020

comment by: AESA

Regarding page 73, ATM/ANS.EQMT.CERT.025 (a), some requirements about the acceptance of the certification and the verification of the compliance with certification basis may be appropriate in Annex I.

response

*Noted*

The subject could be considered but would require further discussion and better understanding of the comment. Therefore, the commenter is kindly invited also to consider whether a more detailed rulemaking proposal on the issue would be possible.

comment

1021

comment by: AESA

In page 73, ATM/ANS.EQMT.CERT.025 (b), is the reference to ATM/ANS.EQMT.AR.A.015 at the end of point (b) correct? Because that requirement refers to the exchange of information between the competent authorities and the Agency, and has nothing to do with the content of this point (b).

response

*Accepted*

The reference is corrected.

comment

1022

comment by: AESA

In page 75, ATM/ANS.EQMT.CERT.040, no specific retention period is established. All the information related to the declaration of compliance of the ATM/ANS equipment design should be kept during the whole lifecycle of the equipment.

response

*Partially accepted.*

The comment is well received. It is considered that the phrase 'to ensure the continued compliance' implies 'whole lifecycle of the equipment'. In addition, taking into account the comment, the development of the associated AMC is under consideration.

comment

1023

comment by: AESA

Regarding page 75, ATM/ANS.EQMT.CERT.050, this requirement mentions that maintenance instructions shall be available on request to any other person that is required to comply with any of these maintenance instructions.

It would be useful to specify which "other person" could have access to the maintenance instructions, specially if it is related to a contracted activity of the ANSP.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1024

comment by: AESA

In page 76, ATM/ANS.EQMT.CERT.055 (a), for the identification of changes to ATM/ANS equipment as 'minor' and 'major', a definition for both types should be included.



response

*Partially accepted*

Further details on the concept 'major/minor' changes will be provided at AMC/GM level.

For further details, please refer to topic 'ATM/ANS equipment change management'.

comment

1025

comment by: AESA

In page 76, ATM/ANS.EQMT.CERT.055 (b), "All other changes shall be approved by the Agency...". According to (a), the changes are identified as minor or major, it seems there is no other type of change. So, which are "all other changes"?

response

*Noted*

Please refer to topic 'ATM/ANS equipment change management'.

The change management is addressed in point DPO.OR.B.005 of the draft Implementing Regulation.

comment

1026

comment by: AESA

In page 77, ANNEX III DECLARATION OF COMPLIANCE OF THE ATM/ANS EQUIPMENT DESIGN, there is a possible mistake in the title of the Annex, since the statement "Part-ATM/ANS.EQMT.DEC" is omitted.

response

*Accepted*

The text is amended accordingly.

comment

1027

comment by: AESA

In page 77, ATM/ANS.EQMT.DEC.010.(f), how are these "levels of compliance" defined or determined?

It is understood that until EASA issues the Decision detailing the "certification/declaration specifications" (CSs/DSs), it will not be possible to know what these levels of compliance refer to.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1028

comment by: AESA

In page 77, ATM/ANS.EQMT.DEC.010, what about other important information such the verification of compliance procedure/programme established by manufacturer; manufacturer's specifications, including installation and on-site tests; conditions of use (considering that are different from "deviation");... ?

response

*Noted*

The referenced information would be subject to the continuous oversight, while the commented provision lists only the essential information in order for the declaration to be registered.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1029

comment by: AESA

Regarding page 77, ATM/ANS.EQMT.DEC.015, it would be useful to clarify the content of this requirement.

With respect to the point (a):

What conditions must be met in the change to the equipment's design so that the original part number is kept? How it is determined if the change requires keeping the original part number or not?

With respect to the point (b):

Which changes to the design will require a substantially complete investigation by EASA and the assignment of a new model designation to the equipment?

It also would be necessary to identify a list of conditions of change applicable to each type of system, in order to identify what the manufacturer must do and what EASA must investigate.

response

*Noted*

Please refer to topic 'ATM/ANS equipment change management'.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1030

comment by: AESA

In page 77, ATM/ANS.EQMT.DEC.020, no specific retention period is established. All the information related to the declaration of compliance of the ATM/ANS equipment design should be kept during the whole lifecycle of the equipment.

response

*Partially accepted*

The comment is well received. It is considered that the phrase 'to ensure the continued compliance' implies 'whole lifecycle of the equipment'.

In addition, taking into account the comment, the development of the associated AMC is under consideration.

comment

1031

comment by: AESA

In page 77, ATM/ANS.EQMT.DEC.015 (b), clarification on the terms ""extensive enough"" and ""substantially complete"" would be appreciated."

response

*Noted*

Taking into account the comments, the development of the associated AMC/GM is under consideration.

comment

1032

comment by: Civil Aviation Authority the Netherlands

ATM/ANS.EQMT.AR.C.020

As a general observation, throughout the proposed article findings and enforcement measures regarding approvals, certificates and declarations seem to be mixed up. Whereas first measures regarding approvals seem to be described, all of a sudden the elaboration is on measures regarding certificates and declarations.

However, it is difficult to understand an elaboration of a certain subject if the basis for it is described concerning another subject.

Could you elaborate on how the mutual coherence between these different subject should be identified and in how far this seems to be legally sound?

response

*Noted*

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

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

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

In conclusion, the commenter is invited to note that the split and allocation of the various provisions between delegated versus implementing acts are stipulated in the EASA Basic Regulation (EU) 2018/1139.

comment 1034

comment by: *Civil Aviation Authority the Netherlands*

As a general observation, enforcement measures based upon this article regarding certificates and declarations shall be issued against the holders, which are in fact (based on the proposed regulatory structure) the manufacturers. This leads to three questions:

- Could you describe how findings regarding the certificates and declarations could be raised, as actually the involved equipment is not in use at the premises of the manufacturers, but at the premises of the service providers?
- Could you please describe what would happen with the equipment that is used by one or several service providers if its certificate (as held by the manufacturer) would be limited, suspended or revoked ? Could you describe what this would mean for the involved service providers if this equipment turns out to be essential for the service providers' operations?
- Could you describe what would happen if it turns out to be that the use of certified equipment by one service provider would lead to the conclusion that enforcement measures would be appropriate, however that the use of the same equipment by other service providers would not warrant such a conclusion?

response *Noted*

Following the order of the comments:

- The commenter is kindly invited to note that the enforcement measures will be against certification/declaration of design compliance, which would happen before the ATM/ANS equipment deployment.
- Please refer to topic 'DPO approval discontinuation'.
- There will be various measures to address certain conditions, e.g. ATM/ANS equipment directive, which is a document issued by the Agency or by the competent authority, 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, security, performance or interoperability of that particular equipment may otherwise be compromised.

comment *1035*

comment by: *FOCA Switzerland*

response *Noted*

comment *1036*

comment by: *Civil Aviation Authority the Netherlands*

Page 75, **ATM/ANS.EQMT.CERT.050**

Could you elaborate on what/where would be the border between the manuals for the equipment which the manufacturer, based on this article, is obliged to supply and the manuals that the providers that use the equipment may produce for their provider-specific situations?

Or would this article mean that only manuals of the manufacturer are allowed for the use of the equipment by service providers?

response

*Noted*

Taking into account the comment and questions, the development of the associated AMC/GM is under consideration.

The answer is negative. Furthermore, it should be noted that the issue on operations manuals at ATM/ANS level is addressed by ATM/ANS.OR.B.035 of Regulation (EU) 2017/373.

comment

1037

comment by: *Civil Aviation Authority the Netherlands*

Page 76, **ATM/ANS.EQMT.CERT.055**

Could you elaborate on how this process would work in practice in conjunction with the service provider(s) that make use of the equipment in question?

In how far would it be workable and efficient in practice if changes in the operation of the service providers' equipment first have to be proposed to the manufacturer by the provider, after which the manufacturer would need to issue them in its turn to the Agency which would need to approve them?

response

*Noted*

The commenter is invited to note that the certification/declaration of design compliance is to take place before the ATM/ANS equipment deployment activity. If the DPO would intend to change an already certified/declared ATM/ANS equipment design, it should be managed in accordance with the commented provision.

For further details, please refer to topic 'ATM/ANS equipment change management'.

Taking into account the comment and questions, the development of the associated AMC/GM is under consideration.

comment

1038

comment by: *Civil Aviation Authority the Netherlands*

Page 77, **ATM/ANS.EQMT.DEC.005**

Please see our comment on article 5, first paragraph (on the organisation that should issue the declarations). Please elaborate on why, seen article 45 and 47 of the BR, an article like this is not addressed to the service providers instead of the manufacturers.

response

*Noted*

The subject could be considered, but would require further discussion, analysis and evaluation. Therefore, the commenter is kindly invited also to consider whether a more detailed rulemaking proposal on the issue would be possible.

comment

1039

comment by: *Civil Aviation Authority the Netherlands*

Page 77, **ATM/ANS.EQMT.DEC.015**

Please elaborate on how this would work in practice, as the equipment in question will be used by service providers and not by the manufacturer that has issued the declaration.

response

*Noted*

The commenter is kindly invited to note that the certification/declaration is on the design compliance and these activities take place before the ATM/ANS equipment deployment.

Thus, the commented provision is on the manufacturer's side.

comment

1040

comment by: *Civil Aviation Authority the Netherlands*

Page 78, **ATM/ANS.EQMT.DEC.025**

Could you elaborate on what/where would be the border between the manuals for the equipment which the manufacturer, based on this article, is obliged to supply and the manuals that the providers that use the equipment may produce for their provider-specific situations? Or would this article mean that only manuals of the manufacturer are allowed for the use of the equipment by service providers?

response

*Noted*

Taking into account the comment and questions, the development of the associated AMC/GM is under consideration.

The answer is negative. Furthermore, it should be noted that the issue on operations manuals at ATM/ANS level is addressed by ATM/ANS.OR.B.035 of Regulation (EU) 2017/373.

comment

1041

comment by: *Civil Aviation Authority the Netherlands*

Page 78, **ATM/ANS.EQMT.DEC.035**

Could you elaborate on how this system would work if EASA would want to audit equipment that is in active use? If this is the case, this equipment would be at the facilities of a service

provider and not at the facilities of the manufacturer that has issued the declaration. However, this article introduces auditing-requirements to the manufacturer, not to the service provider.

response *Noted.*

It should be noted that the certification/declaration of the ATM/ANS equipment is on the design compliance and these activities take place before that equipment is deployed.

Therefore, the commented requirements are on manufacturer's side.

comment 1043

comment by: FOCA Switzerland

We would like to know if article 4, 1., includes the datalink providers (e.g. SITA and ARINC)

response *Noted*

The commenter is invited to note that the requirements for the providers of ATM/ANS are laid down in Regulation (EU) 2017/373, while the proposed framework addresses the conformity assessment of the ATM/ANS equipment enabling particular ATM/ANS.

For further details, please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 1051

comment by: Fintraffic Air Navigation Services

The systems/equipment requiring (or not requiring) certification shall be listed

response *Accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 1072

comment by: DGAC (French CAA)

Reference: Appendix 2 Article 6 Statement of compliance

Comment:

As defined, article 6 is covering all the equipment which do not fall in the definition of article 4 and 5. Whereas the definition supposes that a standard will systematically exist to support a statement of compliance, it is currently far to be true.



What is expected for all these systems in the absence of standard?  
Some systems (the least critical as regards safety and interoperability) should be subject to no particular regulatory requirement.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1073

comment by: DGAC (French CAA)

Reference: Appendix 2 Article 6 Statement of compliance

Comment :

What is expected from the ATM/ANS provider to make the statement of compliance ?

response

*Noted*

The answer is affirmative.

Article 6 of the Draft Delegated Act should be read in conjunction with the amendments of ATM/ANS.OR.A.045 (g).

For further details, please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Roles and responsibilities of the different actors'.

comment

1074

comment by: DGAC (French CAA)

Reference: Article 6 Statement of compliance

Comment : What if the equipment no longer complies with the technical standard mentioned in article 1, for example due to an update of such standards or any other reason ? It should be clarified. If not, we will keep the same issue we have with the former regulation 552/2004 and the evolution of CS (community specifications)

response

*Noted.*

The draft Delegated Regulation specifies that the certification basis consists amongst others of detailed specifications issued by the Agency, which are applicable to the ATM/ANS equipment on the date of submission of the application for that certificate, unless the applicant chooses to comply or is required to comply with a detailed certification specification, which became applicable after the date of the submission of the application.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 1075 comment by: DGAC (French CAA)

Reference: Article 6 Statement of compliance

Comment : Where will be such list of technical standards (detailed specification ?). It is not clear

response *Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment 1076 comment by: DGAC (French CAA)

Reference : Article 7 – 2)

Comment: EASA's intention is not clear as regards its expectations of the national authorities in charge of the certification of ANS/ATM providers. Since national authorities will not be involved in the DPOA and certification of equipment, the relevant information should be collected directly from the supplier/designer of the equipment to be certified according to EASA criteria (assuming that such criteria exist...). Proposal: Reword the article so that the relevant information is collected directly from the supplier of the equipment applying for certification (article 4). And clarify what kind of document would be expected to facilitate the task of EASA.

response *Noted*

Please refer to topic 'Transitional provisions'.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 1077 comment by: DGAC (French CAA)

Reference : Article 7 – 3)c)

Comment: It is not clear what type of relevant information EASA expects from the national authority responsible for the certification of ANS/ATM providers. Since national authorities will not be involved in the DPOA, the relevant information should be collected directly from

the DPOA applicant.  
Proposal: Reword the article so that the relevant information is collected directly from the equipment provider applying for declaration (article 5). And explicit what kind of document would be expected to ease EASA's task.

response

*Noted*

Please refer to topic 'Transitional provisions'.

Furthermore, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1078

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT.CERT.015

Comment: Considering that for an equipment, an approved design organisation and a separate approved production organisation could be involved, which organisation is the certificate holder? Is there any intent to deliver "design certificates" (like type-certificates) and "product certificates" (like certificates of airworthiness)?

Proposal: Clarify since for many systems, ATM/ANS providers are acting as production organisations when integrating system parts in wider systems (software deployment, network integration, etc.).

response

*Noted*

As correctly stated by the commenter, the ATM/ANS equipment certificate and the declaration result from the demonstration of design compliance with the applicable requirement, i.e. detailed specification.

comment

1079

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT.CERT.020

Comment: What does a "complete investigation" mean in this context? The DPOA holder may perfectly perform incremental compliance demonstration based on extensive impact analysis and thus not requiring a complete investigation. See Part-21 wording.

Moreover, issuance of a new ATM/ANS equipment certificate should not only be driven by the extent of the compliance demonstration but mainly by a significant change in the functionalities, architecture, technology or certification basis.

Proposal: Prefer Part-21 (Regulation (EU) No 748/2012 Annex I GM 21.A.91) wording: "where the extent of new substantiation data necessary to comply with the applicable certification

specifications and the degree to which the original substantiation data has to be re-assessed and re-evaluated is considerable".  
Add functional/performance and certification basis considerations in the criteria for issuing a new certificate.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM/DSs is under consideration.

comment

1080

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT.CERT.050 (b)

Comment: Does a change to maintenance instructions has to be considered as a change for the equipment? Shall it be notified to the Agency and shall it necessitate an update of the equipment certificate?

Proposal: Clarify.

response

*Noted*

The comment will be considered under RMT.0161 Subtask 3.

comment

1081

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT.CERT.050

Comment: Do "maintenance instructions" also include configuration manuals for end-users?

Proposal: Clarify.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM/DSs is under consideration.

comment

1082

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT.CERT.050

Comment: Depending on the kind of “maintenance instructions” they could either be issued by a design organisation (equipment configuration, diagnosis test, etc.) and/or by a production organisation (LRU replacement, preventive maintenance for hardware pieces, etc.). Considering that “concrete” equipment can only be provided by the production organisation, should maintenance instructions be completely endorsed by the production organisation, or should responsibilities be shared? How is it mentioned on the certificate?

Proposal: Clarify.

response

*Noted*

The comment will be considered under RMT.0161 Subtask 3.

comment

1083

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT.DEC.015 (b)

Comment: What does a “complete investigation” mean in this context? The DPOA holder may perfectly perform incremental compliance demonstration based on extensive impact analysis and thus not requiring a complete investigation. See Part-21 wording.

Proposal: Prefer Part-21 (Regulation (EU) No 748/2012 Annex I GM 21.A.91) wording: “where the extent of new substantiation data necessary to comply with the applicable certification specifications and the degree to which the original substantiation data has to be re-assessed and re-evaluated is considerable”.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1084

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT.DEC.030

Comment: Do “maintenance instructions” also include configuration manuals for end-users?

Proposal: Clarify.

response

*Noted*

The comment will be considered under RMT.0161 Subtask 3.

comment

1085

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT. DEC.030

Comment: Depending on the kind of “maintenance instructions” they could either be issued by a design organisation (equipment configuration, diagnosis test, etc.) and/or by a production organisation (LRU replacement, preventive maintenance for hardware pieces, etc.). Considering that “concrete” equipment can only be provided by the production organisation, should maintenance instructions be completely endorsed by the production organisation, or should responsibilities be shared? How is it mentioned on the declaration?

Proposal: Clarify.

response

*Noted*

The comment will be considered under RMT.0161 Subtask 3.

comment

1086

comment by: DGAC (French CAA)

Reference: ATM/ANS.EQMT. DEC.030 (b)

Comment: Does a change to maintenance instructions has to be considered as a change for the equipment? Shall it be notified to the Agency and shall it necessitate an update of the equipment declaration?

Proposal: Clarify.

response

*Noted*

The comment will be considered under RMT.0161 Subtask 3.

comment

1091

comment by: IAA Aviation Regulator

It is suggested that EASA host a workshop to include National CAs & potential DPOs, to further discuss how areas of potential concern and where problems have been identified in the past, can be raised by relevant parties and how they will be addressed as part of the proposed Agency oversight programme, as set out in ATM/ANS.EQMT.AR.C.010.

response

*Noted*

The Agency welcomes the proposal and will consider the organisation of such workshop on the subject.

comment

1113

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art. 4(1): The scope of equipment is much too wide. It covers even MET, AIS or FPD systems etc.

Restrict the scope to systems that have an immediate impact on safety of ATM provision. Rephrase Art. 4(1) to "ATM/ANS equipment that processes and **directly** delivers data for the purpose of the provision of ATM **and that has an immediate and direct impact on the safety of ATM provision**, 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."

response

*Partially accepted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1116

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art.4(2)(a) Why would a certified and thus compliant equipment lose its certificate when the DPO no longer has an approval? As long as the equipment is not changed it must continue to be considered compliant.

Please explain and correct. Equipment must not lose its certificate if the DPO no longer has an approval. That could constitute a major economic burden, e.g. if a DPO goes out of business.

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

1117

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art.5(2)(b) Why would compliant equipment lose the validity of the declaration when the DPO no longer has an approval? As long as the equipment is not changed it must continue to be considered compliant.

Please explain and correct. Equipment must not lose the validity of its declaration if the DPO no longer has an approval. That could constitute a major economic burden, e.g. if a DPO goes out of business.

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment 1118 comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art.6(1) Please explain which equipment would fall under this article given the broad definitions in Art. 4 and 5.

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment 1119 comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art.7(2) The CA can only provide the documentation as required by Regulation (EU) 552/2004 to EASA.

Rephrase to "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 **that they have received iaw Art. 6 and Annex IV of Regulation (EU) 552/2004** to facilitate this evaluation."

response *Noted*

Please refer to topic 'Transitional provisions'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 1121 comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art. 7:

A transition period of 5 years seems too short and, in this respect, unrealistic. It is clear that legacy systems must be adapted to the new standards over time. If this is imposed in too short a period, it can lead to premature depreciation and thus sunk costs.

In the interest of renewing the European air traffic control infrastructure, the reduction of residual costs by replacing legacy systems must be regulated throughout Europe and financed in a route charges-neutral manner. This must also be taken into account in the performance and charging scheme for RP 4

response *Noted*

comment 1122 comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*



ATM/ANS.EQMT.CERT.015 Shall all possible configurations of a system be certified? Currently systems offer a multitude of configuration options - it seems impossible to certify them all. Please explain and revise.

response

*Noted*

The answer is affirmative provided that changes to an item of ATM/ANS equipment are to be done under the control of the DPO responsible for its certificate/declaration and oversight. This does not prevent those certain changes (e.g. under maintenance instruction, in the frame of configurable elements) from being implemented by the user (ANSP), but always under the conditions prescribed by the DPO in the relevant manuals.

comment

1136

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

ATM/ANS.EQMT.AR.A.035 (b)

This could constitute an obstacle to innovation as new features would have to be disclosed. Please revise in conjunction with (c) such that only the demonstration of non-interference is required without detailing the feature as such.

response

*Noted*

The comment will be further considered during the activity of RMT.0161 Subtask 3.

comment

1140

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art. 7: Equipment that holds an EC DoV: It is very unlikely that legacy equipment will be able to fulfil newly drawn-up requirements. What would happen in the case a system is not considered compliant by EASA? What if the manufacturer does not exist any more? Please also clarify what EASA considers an appropriate action in case a non-compliance is identified.

If equipment must be depreciated prematurely due to this regulation, this will produce sunk costs on the hand and major investments for new equipment on the other hand, both with negative effects on the unit rate. Furthermore, as the assessment by EASA will take place amidst RP4, these issues cannot be reflected in the Performance Plan for RP4, which has to be submitted in 2024 already!

response

*Noted*

Please refer to topic 'Transitional provisions'.

In addition, taking into account the consultation feedback, the development of the associated AMC/GM is under consideration.

comment

1152

comment by: AESA

In page 55, regarding Article 5 and answering **Question 8.2#1**.  
Radar sensor design may be considered to be subject to certification.  
AESA does not have a definitive opinion on this on this subject. However, it could be advisable to think of an analogy to the on-board transponder certification scheme.

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1153

comment by: AESA

In page 55, regarding Article 5 and answering **Question 8.2#1**.  
Regarding GNSS, GBAS and radio navigation aids, AESA does not have a definitive opinion on this subject.

response

*Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment

1155

comment by: FOCA Switzerland

Regarding art. 7 (transitional provisions), it is foreseen that the competent national authorities shall provide the Agency with relevant information during a periode of 5 years. We fear that this provision will produce an unnecessary additionnal burden for the national authorities with only little benefice.

response

*Noted*

Please refer to topic 'Transitional provisions'.

comment

1164

comment by: Deutscher Wetterdienst

Art. 4 (1.) ATM/ANS equipment by current definition only includes systems and procedures for the use of meteorological information. MET is not part of ATM. Meteorological data and/or information may be considered "data for the purpose of provision of ATM". Since the equipment operated by the MET-P is not considered ATM/ANS equipment, this may refer to systems operated by e.g. an ATS-P to process and/or deliver MET data to specific units. See (EU) 2017/373, Annex IV, ATS.OR.500 and following for the related requirements. If that is

understood correctly then it is consistent with the rationale that equipment subject to certification will mainly/only apply to ATS.

response *Noted*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

comment *1165*

comment by: *Deutscher Wetterdienst*

Art. 4 (2.) & (3.) If the certificate holder surrenders the certificate for specific equipment or the certificate is revoked, what happens to the equipment already installed and in operation?

response *Noted*

Please refer to topic 'DPO approval discontinuation'.

comment *1166*

comment by: *Deutscher Wetterdienst*

Art. 6 (1.) Assumes that there are / will be technical standards for the respective ATM/ANS equipment which are (both) established by recognized standardization bodies and listed in a DS.

What about in-house developments of equipment?

response *Noted*

Please refer to topic 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment *1190*

comment by: *Juan L. Diz*

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

These qualified entities should be described completely, clearly identify and define the roles, competencies, responsibilities of the '*qualified entities*' as well as the associated EASA oversight and the given level of delegation.

response *Accepted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

8

comment by: *Civil Aviation Directorate of the Republic of Serbia*

When this regulation enters into force, changes to functional systems can be undergoing for some time, as procurement procedures can last several years. Also, when this regulation comes into force and ATM/ANS provider wants to purchase or replace some equipment, they have to check if particular equipment is subject to certification or declaration. And if it is, the set of rules must be ready and certification/declaration process finished. It takes some time and this regulation should not stop necessary changes. So, the transitional provisions will be necessary.

response

*Noted*

Please refer to topic 'Transitional provisions'.

comment

32

comment by: *DFS Deutsche Flugsicherung GmbH*

General comment:

The described need to amend the IR (EU) 2017/373 is strongly supported.

It is recommended to re-visit in this amendment also the definition of Terms in Annex 1, point (56), the term "functional system". It will be essential to have European wide the same interpretation of the scope of the functional system to avoid confusion on the subjects addressed in this NPA, namely the ATM/ANS equipment.

We understand that ATM/ANS equipment according to this NPA (if so purchased by an ANSP) will always become part of a functional system according to IR (EU) 2017/373. As IR (EU) 2017/373 includes hard- and software explicitly, we need to define more specifically what this means in modern IT-architectures like data centre and cloud infrastructure. We believe the beforementioned IT architectures will play an increasingly significant role in the ATM/ANS equipment as they provide enormous potential for cost efficiency, availability, harmonisation, interoperability and timely implementation of ATM/ANS services and functions.

We also understand that explicitly such basic IT architectures, which have no specific function within the context of ATM/ANS and ATM networks, are excluded from the new framework.

Instead they are providing the necessary IT platform based on IT industry standards. The main relevant characteristic of such platforms for ATM/ANS is the required availability for the functional system which may even vary concerning the criticality of the ATM/ANS function and be finally provided and verified by the ATM/ANS provider. The ATM/ANS function (i.e. the functional system) is in such architectures only the software application including some platform services which provide the specific ATM/ANS function.

In consequence, we see also need to reflect the scope of functional systems in this regard:  
Our proposal for the amendment of IR (EU) 2017/373 would read as follows:  
(56) 'functional system' means a combination of procedures, human resources and equipment, including ATM/ANS **specific** hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions; and add a clause for hardware also in GM1 (56) and add, "e.g. in all other cases (especially in IT architectures providing Infrastructure as a service (IaaS, i.e. virtualisation) and Container as a service (CaaS)) the functional system includes only the ATM/ANS specific software application and platform services".

response *Noted*

The subject could be considered, but would require further discussion, analysis and evaluation.

Therefore, the comment will be further analysed as part of the activities of RMT.0719.

comment 53

comment by: *German NSA (BAF)*

page 80:  
*Amendment to Implementing Regulation (EU) 2017/373, Annex II 2(a) (4)*

The reference seems to be not correct. Instead of ATM/ANS-EQMT.AR.A.025 probably ATM/ANS.EQT.AR.A30 is meant.

response *Accepted*

comment 54

comment by: *German NSA (BAF)*

page 81:  
*"(f) where the competent..."*

The actual text leaves it open how a competent authority can detect that ATM/ANS equipment is not integrated into the ATM/ANS functional system. The principle of the task how a missed integration can be detected should be added.

response *Noted*

The comment will be considered under RMT.0161 Subtask 3.

comment	55	comment by: <i>German NSA (BAF)</i>
	<p>page 82:  <i>"4 (g) (3) by way of derogation ..."</i></p> <p>It is not clear whether NSAs have to check the SoC and against which requirements. It is proposed to describe such requirements more in detail.</p>	
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>	

comment	56	comment by: <i>German NSA (BAF)</i>
	<p>page 82:  <i>"4 (g) (4) in particular ATM/ANS equipment..."</i></p> <p>This paragraph is essential and therefore fully supported. The wording should describe the requirements for ANSP and authority more in detail.</p>	
response	<p><i>Noted</i></p> <p>Taking into account the comment, the development of the associated AMC/GM is under consideration.</p>	

comment	57	comment by: <i>German NSA (BAF)</i>
	<p>page 82:  <i>"4 (h) When the ATM/ANS provider..."</i></p> <p>ANSPs shall ensure that ATM/ANS equipment is deployed according to the conditions of use. Further explanations seem necessary. Especially, tests should be required to verify that the conditions for use are fulfilled.</p>	
response	<p><i>Noted</i></p> <p>Please refer to the draft point (g)(5) of ATM/ANS.OR.A.045.</p>	

comment	103	comment by: <i>Thales Land and Air Systems</i>
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Appendix 3/ page 82	<p>ATM/ANS.AR.C.050 (g) is a missing scenario to be considered, being the ATM/ANS equipment integration into the ATM/ANS functional system without applicable technical standard established in accordance with Article (6), meaning no technical standards established by recognised standardisation bodies and listed in detailed specifications adopted by the Agency.</p> <p>It is proposed to reword 4.(g)(3) and (4) as follow  (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]; <del>and</del> or  (4) when no applicable technical standard is established, the particular ATM/ANS equipment has been verified to comply with the equipment manufacturer’s specifications, including installation and on-site test(s).</p>
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response *Partially accepted*

comment 256

comment by: *Romanian CAA*

We believe that the text in Article 1, section 4, letter (g), subsection (3) should be reworded to „new or modified ATM/ANS equipment that is neither subject to certification or declaration...”, because issuing a statement of compliance is not a derogation but an equal solution as proposed in the first place in this NPA.

Also, we believe that a new subsection should be added to detail the way in which ATM/ANS providers must address EASA and/or the non-EU organisation involved with design and/or production to be sure they meet the requirements prior to putting into service ATM/ANS equipment. Should the ATM/ANS provider ask EASA before choosing a supplier to see wether integration of their equipment is suitable?

response *Accepted*

Following the order of the comments:

- The text is amended, i.e. the referenced phrase is removed.
- The comment is duly considered.

- The list of certified/declared ATM/ANS equipment will be publicly available to the stakeholders.

comment 300

comment by: *CANSO*

General comment:

The described need to amend the IR (EU) 2017/373 is strongly supported.

It is recommended to re-visit in this amendment also the definition of Terms in Annex 1, point (56), the term “functional system”. It will be essential to have European wide the same interpretation of the scope of the functional system to avoid confusion on the subjects addressed in this NPA, namely the ATM/ANS equipment.

We understand that ATM/ANS equipment according to this NPA will always part of a functional system when integrated according to IR (EU) 2017/373. As IR (EU) 2017/373 includes hard- and software explicitly, we need to define more specifically what this means in modern IT-architectures like data centre and cloud infrastructure.

We believe the beforementioned IT architectures will play an increasingly significant role in the ATM/ANS equipment as they provide enormous potential for cost efficiency, availability, harmonisation, interoperability and timely implementation of ATM/ANS services and functions. Already today major ATM/ANS providers (including the NM) are starting implementations of such architectures.

We recommend to exclude explicitly such basic IT architectures from functional systems as they have no specific function within the context of ATM/ANS and ATM networks. Instead they are providing the necessary IT platform based on IT industry standards. The main relevant characteristic of such platforms for ATM/ANS is the required availability for the functional system which may even vary concerning the criticality of the ATM/ANS function. The ATM/ANS function (i.e. the functional system) is in such architectures only the software application including some platform services which provide the specific ATM/ANS function.

Our proposal for the amendment of IR (EU) 2017/373 would read as follows:

(56) ‘functional system’ means a combination of procedures, human resources and equipment, including ATM/ANS specific hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions; and add a clause for hardware also in GM1 (56) and add, "e.g. in all other cases (especially in IT architectures providing Infrastructure as a service (IaaS, i.e. virtualisation) and Container as a service (CaaS)) the functional system includes only the ATM/ANS specific software application and platform services"

response *Noted*

The subject could be considered, but would require further discussion, analysis and evaluation.

Therefore, the comment will be further analysed as part of the activities of RMT.0719.



comment

357

comment by: CAA - Norway

Concerning the proposed changes in ATM/ANS.OR.A.045:

Has it been considered how service providers with a "limited certificate", see ATM/ANS.OR.A.010, who are not obliged to be in compliance with ATM/ANS.OR.A.045, shall handle the integration of ATM/ANS equipment into their ATM/ANS functional system?

Norway has not required non-complex service providers to comply with ATM/ANS.OR.A.040 and 045. In the current proposal, it is our understanding that non-complex service providers (in this relation: service providers with a "limited certificate") will not have a legal obligation to fulfil requirements laid down in ATM/ANS.OR.A.045, unless if this is decided by the competent authority. Does EASA plan to further explain this in AMC or GM?

response

*Noted*

The subject could be considered, but would require further discussion, analysis and evaluation.

Therefore, the comment is invited to put forward a proposal during the committee procedure.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

446 ❖

comment by: Tern Systems

**What happens to equipment in operations if approval/certificate is revoked?**

EASA can revoke approvals and certificates (ATM/ANS.EQMT.AR.C.020 Findings, corrective actions, and enforcement measures (b)). This instrument needs clearer definition under which conditions it is applicable and how safe operations can be ensured.

response

*Noted*

Please refer to topic 'DPO approval discontinuation'.

comment

482

comment by: Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)

**8.3, ATM/ANS.OR.A.045 g),h), page 82**

Is there any connection between the integration of new equipment, maintenance and the ATSEP demands in (EU) 2017/373?

There is lack of consistency as ATM/ANS.AR.C.025 should reflect what CA check when an ANSP present a change. What need to be reviewed?

response

*Noted*

The proposal does not change the status quo as regards the ATSEP scope of activities.

comment

492

comment by: DGAC (French CAA)

Reference: Draft IR amending regulation 2017/373, article 1, point 4(g)(3)

“(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 [...]”.

Comment: this situation does not constitute a “derogation” from the 2 previous points. It is just a third possible case amongst 3 mutually exclusive different scenarios (certification, declaration, statement of compliance).

Proposal : “(3) ~~by way of derogation from points (1) and (2), w~~**When the ATM/ANS equipment is neither subject to certification pursuant to point (1) nor to declaration pursuant to point (2) of Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment], the ATM/ANS provider shall make a statement of compliance [...]”**

response

*Accepted*

comment

513

comment by: Deutscher Wetterdienst

A new term “ATM/ANS equipment” is introduced in the preamble; should be added to the definitions in Annex I.

response

*Accepted*

It is already addressed/defined in Article 2 of the proposed Delegated Regulation on conformity assessment of ATM/ANS equipment.

comment

518

comment by: Belgian NSA

ATM.ANS.OR.A.045(g)(4) : The NPA states “by way of derogation from points (1) and (2)”.. The Statement of Compliance is not issued by an ATM/ANS provider as a derogation of the certificate or a declaration of compliance

ATM.ANS.OR.A.045(g)(4) *“the particular ATM/ANS equipment has been verified to comply with the equipment manufacturer’s specifications”*. What is the meaning of equipment specifications if they are nowhere described ? Does EASA mean the “operations manual” or “installation manual”?

response

*Partially accepted*

The text is amended to promote clarity.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

639

comment by: *Austro Control*

**Comment:**

ATM/ANS.EQMT.CERT.015 Shall all possible configurations of a system be certified? Currently systems offer a multitude of configuration options - it seems impossible to certify them all.

**Proposed Change:**

Please explain and revise

**Classification:**

Major/conceptual

response

*Noted*

Please refer to topic ‘Categorisation of ATM/ANS equipment subject to conformity assessment’.

The changes to an item of ATM/ANS equipment are to be done under the control of the DPO responsible for its certificate/declaration and oversight. This does not prevent those certain changes (e.g. under maintenance instruction, in the frame of configurable elements) from being implemented by the user (ANSP), but always under the conditions prescribed by the DPO in the relevant manuals.

In addition, taking into account the comment, the development of the associated AMC) and GM is under consideration.

comment

701

comment by: *NATS*

*Article 1  
(2) (a) (4)*

*Page 80*

Some of the requirements for obtaining DPO approval go beyond the requirements on ANSPs (e.g. independence of verification, which is currently required under the 552/2004 IRs).

2018/1139 requires that ANSP comply with the applicable Essential Requirements, and the framework for this was previously given by 552/2004 (TFs and DoVs); as the ERs go beyond safety, these changes to 2017/373 do not provide a replacement framework for ANSPs to demonstrate their ER/IR compliance.

National differences may develop in how ANSPs demonstrate their compliance; if the intent is to standardise / create a level playing field, these 373 changes should retain the need for ANSPs to demonstrate System compliance through a Technical File and - as TFs will necessarily contain the safety assurance - these should form the basis of the submission to the NSA and their audit/approval activities.

The TF should be kept up to date and verified by an independent function (as per today, and as will be required of DPOs going forward), and it can form the basis of an ANSP declaration of compliance for changes which are not subject to prior approval by the NSA.

response *Noted*

The comment is considered in the Opinion.

comment

702

comment by: *NATS*

Article 1  
(4) (g)

Page 82

ANSPs are increasingly making use of limited operational trials, and one of the big omissions from EU 552/2004 was a mechanism for utilising systems which are not yet fully approved; these changes should better accommodate the use of "uncertified" equipment for trial purposes.

response *Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

In addition, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

703

comment by: *NATS*

Article 1  
(4) (g) (4)

Page 82

Isn't the intent for ANSPs to assume a certified product is compliant with the specifications? As conditions of use are covered in (g) and the Declaration/Certificate is meant to ensure compliance with the applicable specifications, it is not clear what is meant by the "equipment manufacturer's specifications" or what this is asking ANSPs to do?

response *Noted*

The assumption is correct.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 740

comment by: IAA Aviation Regulator

Article 1 (2)(a)(4) - "*the implementation of safety and interoperability objectives [...]*" -

Suggest inclusion of 'Security' to align with objective set out in NPA; Section 2.2.

Proposed text - "*the implementation of safety, security and interoperability objectives, [...]*"

response *Accepted.*

comment 741

comment by: IAA Aviation Regulator

Article 1 (3)(f) "*[...] as per point (x) of point ATM/ANS.OR.A.045 [...]*" -

"*point (x)*" reference appears to be a placeholder as it is not contained in point ATM/ANS.OR.A.045.

It would appear to be an intended reference to point (g) of point ATM/ANS.OR.A.045.

response *Accepted*

The answer is affirmative. It should refer to point (g) of ATM/ANS.OR.A.045.

comment 742

comment by: IAA Aviation Regulator

Article 1 (4)(g) - "*(g) Before integrating ATM/ANS equipment into the ATM/ANS functional system, the ATM/ANS provider shall ensure that:*"

Suggest further clarification be provided through AMC/GM to ensure that ATM/ANS providers can complete points ATM/ANS.OR.A.045 (g)(1)(2) in a consistent manner.

Additionally, suggest a requirement to submit supporting evidence that ATM/ANS.OR.A.045(g) requirement is met to the national CA in advance of integrating the ATM/ANS equipment into the ATM/ANS functional system.

It is understood that the National CA may not have seen certificates or declarations for the ATM/ANS equipment, as referred to in ATM/ANS.OR.A.045(g)(1)(2), as EASA is the CA for ATM/ANS equipment certification and declarations of compliance.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

The commenter is invited to note that a list with the certified/declared ATM/ANS equipment will be publicly available.

comment

743

comment by: IAA Aviation Regulator

Article 1 (4)(g)(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]; [...]" -*

It is unclear what this statement of compliance must contain and if it should align with what is current practice (DSU, DoV, TF). Suggest that this is covered in AMC/GM.

Additionally, it is unclear if the National CA must review the SoCs and verify the content in advance of the ATM/ANS equipment being introduced into operational service. This should be clarified.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

755

comment by: POL CAA LOZ-4

Statement of compliance for the ATM/ANS equipment - will this be part of the sf change documentation (safety assessment)? The SoC is not subject to CAA approval - what if there are comments on this statement? Will the ATM/ANS provider be required to correct it, or at least address the CAA's comments?

response

*Noted.*

Please refer to topic 'Categorisation of ATM/ANS equipment subject to conformity assessment'.

In addition, it should be noted that the statement of compliance is not intended to be subject to approval; it is though subject to continuous oversight by the competent authorities.

Moreover, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

778

comment by: *EUROCONTROL*

How will the regulation be applied at combined Civil/Military ATS units where military is providing ATM/ANS equipment to the combined civil/military ANSP?

In the context of the NPA, the new point (g) and (h) to article ATM/ANS.OR.A.045 (Annex 8.3 to the NPA) would not directly apply to the MIL (unless it is itself certified under 373) nor to the CIV SP as the later would not "put ATM/ANS equipment into service" itself.

BUT... art. ATM/ANS.OR.B.015 would still apply and makes a clear reference to "The service provider shall ensure that the competent authority is given access to the contracted organization to determine continued compliance with the applicable requirements under this Regulation."...

So the new point ATM/ANS.OR.A.045 (g) and (h) would apply.

Currently, there are many places where MIL are not certified and SPs are using MIL infrastructure (SUR, COM...) with difficulties to comply with 373 (Art. ATM/ANS.OR.B.015 on Contracted Activities).

The fact that MIL is not certified for (eg) SUR or COM under 373 puts the CIV SP in troubled water having to 'perform oversight' on the MIL and the MIL not really ready to share data of precision, availability, ... of those infrastructures.

This proposed regulation will have an impact on the price of equipment procured by Military (what will happen at the level of NATO, will they buy non EU equipment?) including with EDA.

Proposed action:

EASA should clarify the situation related to collaboration/cooperation with entities that are not within the scope of EU.2017/373 like Military or 3<sup>rd</sup> country (SPs or manufacturers)

response

*Noted*

The commented proposed framework puts forward Delegated and Implementing Regulations on the basis of EASA Basic Regulation (EU) 2018/1139, i.e. it does not apply to ATM/ANS, including systems and constituents, personnel and organisations, that are provided or made available by the military.

However, Member States should ensure that such ATM/ANS when serving air traffic to which Regulation (EC) No 549/2004 applies, offer a level of safety and interoperability with civil systems that is as effective as that resulting from the application of the essential requirements for aerodromes and ATM/ANS set out in Regulation (EU) 2018/1139.

The comment is considered in the Opinion.

comment

801

comment by: *EUROCONTROL*

Modification to art. ATM/ANS.OR.A.045:

As this article is part of the “Change Management Procedures” (CMP) (ATM/ANS.OR.B.010) subject to formal approval by the CAs (ATM/ANS.AR.C.030); the impact of this modification shall not be overlooked.

The approval of those CMP by the CA has led to extensive, complicated discussions between the SPs and CAs and have been amongst the main element of compliance verified by EASA during the standardization inspections that have taken place since 02/01/2020.

The cost and effort of this should be specified and be integrated in the overall Cost/Benefit Analysis that should be part of the Regulatory Impact Assessment (but not presented in this NPA).

Proposed action:

Provide cost-benefit information regarding the change management procedures introduced in the proposed regulation.

response

*Noted*

Please refer to topic ‘Impact assessment’.

comment

905

comment by: *ENAV*

General comment:

The described need to amend the IR (EU) 2017/373 is strongly supported.

It is recommended to re-visit in this amendment also the definition of Terms in Annex 1, point (56), the term

“functional system”. It will be essential to have European wide the same interpretation of the scope of the functional system to avoid confusion on the subjects addressed in this NPA, namely the ATM/ANS equipment.



We understand that ATM/ANS equipment according to this NP A will always part of a functional system when integrated according to IR (EU) 2017/373. As IR (EU) 2017/373 includes hard- and software explicitly, we need to define more specifically what this means in modern IT-architectures like data centre and cloud infrastructure.

We believe the beforementioned IT architectures will play an increasingly significant role in the ATM/ANS

equipment as they provide enormous potential for cost efficiency, availability, harmonisation, interoperability and timely implementation of ATM/ANS services and functions. Already today major ATM/ANS providers (including the NM) are starting implementations of such architectures.

We recommend to exclude explicitly such basic IT architectures from functional systems as they have no specific function within the context of ATM/ANS and

ATM networks. Instead they are providing the necessary IT platform based on IT industry standards. The main relevant characteristic of such platforms for ATM/ANS is the required availability for the functional system which may even vary concerning the criticality of the ATM/ANS function. The ATM/ANS function (i.e. the functional system) is in such architectures only the software

application including some platform services which provide the specific ATM/ANS function.

Our proposal for the amendment of IR (EU) 2017/373 would read as follows:

(56) 'functional system' means a combination of procedures, human resources and equipment, including ATM/ANS specific hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions; and add a clause for hardware also in GM1 (56) and add, "e.g. in all other cases (especially in IT architectures providing Infrastructure as a service (IaaS, i.e. virtualisation) and Container as a service (CaaS)) the functional system includes only the ATM/ANS specific software application and platform services"

response

*Noted*

The subject could be considered, but would require further discussion, analysis and evaluation.

Therefore, the comment will be further analysed as part of the activities of RMT.0719.

comment

1087

comment by: DGAC (French CAA)

Reference: Appendix 3 – Article 1 - 4. (g)

Comment: "Before integrating" should be more precise. Does it concern any connection to the functional system whatever the intended usage is, including test for operation purposes.

response

*Noted*

The commenter is kindly invited to note that the commented proposal refers to ATM/ANS.OR.A.045 related to the 'Changes to a functional system'.

However, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1088

comment by: DGAC (French CAA)

Reference: Appendix 3 – Article 1 – 4

Comment: When the competent authority reviews the argument for a notified change, the scope of this review is "limited" to the validity of the argument of the safety (or safety support) assessment. In this proposal, there is no additional task allocated to the competent authority to assess the correct implementation of the requirements related to certified or declared equipment integration, the validity of statement of compliance or the respect of conditions of use or limitations (new points (g) and (h)).

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1089

comment by: DGAC (French CAA)

Reference : Appendix 3 – article 1 – 4 (g)(3)

Comment : the text supposes the existence of a standard which is far from always the case. The case where no standard exists should be addressed in the text.

Proposal : address the case where no standard exists.

response

*Not accepted*

Please refer to topics 'Categorisation of ATM/ANS equipment subject to conformity assessment' and 'Detailed certification/declaration/SoC (technical) specifications and their development/availability'.

comment

1090

comment by: DGAC (French CAA)

Reference : Appendix 3 - General

Comment: The assessment of the impact of this NPA on 373 is deemed insufficient and should be improved. The link between functional system change management process and the system certification/declaration (function/equipment?) process is not explicit enough and again raises the question of the scope of the certification/declaration process addressed in this NPA.  
For example, how will the safety analysis performed at the level of the functional change of the system that could lead to a certain level of performance, SWAL... be taken into account at the level of the certification of the equipment/function involved in the change?

response Noted.

Please refer to topic 'Impact assessment', especially 'Methodology used and scoring proposed' and 'Option chosen'.

comment

1123

comment by: AESA

Regarding page 79, point (7), this paragraph doesn't mention the possibility of ATM/ANS equipments subject to a statement of compliance by the ATM/ANS provider.

response

*Noted*

comment

1124

comment by: AESA

In page 80, Article 1.2, it's not established how the competent authority will have access to the information related to the certification/declaration in order to verify what is now said in this requirement (ATM/ANS.AR.B.001(a)(1))

response

*Noted*

In accordance with point (d) of ATM/ANS.EQMT.AR.B.015, 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. The list of the certified/declared ATM/ANS equipment will be publicly available.

comment

1125

comment by: AESA

In page 80, Article 1.3 c), why the level 1 finding is only considered for certifications and declarations, and not for the the statement of compliance (SoC)?

response

*Noted*

The oversight of SoC is addressed Regulation (EU) 2017/373, where ATM/ANS.AR. C.050 applies.

comment 1126

comment by: AESA

In page 81, ATM/ANS.AR.C.050 (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,..."

What does point (x) refer to?"

response *Noted*

It should refer to point (g) of ATM/ANS.OR.A.045

comment 1128

comment by: AESA

In page 82, Article 1.3 f), it is necessary to detail what is considered part of the ATM/ANS functional system and its relationship with the 'European air traffic management network (EATMN)'.

response *Noted*

A definition of EATMN is introduced.

comment 1129

comment by: AESA

In page 82, Article 1.4, has it been considered that the ATM/ANS provider may need to have information on the test(s) carried out by the manufacturer in order to carry out the integration test(s)?

response *Noted*

Please refer to topic 'Roles and responsibilities of the different actors'.

Moreover, taking into account the comment, the development of the associated AMC/GM is under consideration.

comment 1131

comment by: AESA

In page 82, Article 1.4 g) 4) and Article 1.4 h), with regard to the integration of the ATM/ANS equipment, a final declaration of test procedure(s)'s compliance should be mandatory for the ATM/ANS provider. Because of the supervision activities carried out by de Competent Authority, it would be appropriate to specify that such declaration has to be accompanied by the documentation that supports it.

response

*Noted*

The comment is considered.

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1139

comment by: *Federal Ministry for Climate Action, Environment, Energy, Mobili*

Art. 1(3)(f): There is no point (x) in ATM/ANS.OR.A.045. Please correct.

response

*Noted.*

It should refer to point (g) of ATM/ANS.OR.A.045.

comment

1148

comment by: *AESA*

Regarding page 82, Article 1.4, points (g) and (h) added to point ATM/ANS.OR.A.045:

When performing a Safety Case / Safety Support Case, new certification and declaration processes may inhibit the ATM/ANS provider from identifying barriers that prevent the occurrence of the hazard (in this case, requirements imposed on the ground equipment), and would replace it with mitigation measures that reduce the probability or severity of its effects. The ATM/ANS provider may prefer to introduce reactive measures in the system (for example, a recovery procedure) instead of proactive measures (a new control in the equipment, safety related functionality, etc) to avoid equipment changes.

For this reason, experts have considered that a preliminary safety assessment could be incorporated before the certified/declared system is purchased, or that the ANSPs could start their safety assessment activities sooner when changes imply the introduction of equipment subject to certification/declaration.

As part of RMT.0161 Subtask3, if possible, AMC or GM could be proposed for points (g) and (h):

- Requiring to carry out an Initial Safety Assessment before the purchase of the ground equipment.  
- Requiring the review of the procedures to ensure that the requirements arising from the safety (support) case be easily incorporated in the ground equipment."

response

*Noted*

The comment will be considered during the development of the associated AMC/GM under RMT.0161 Subtask 3.

comment

1149

comment by: AESA

Regarding page 82, Article 1.4, points (g) and (h) added to point ATM/ANS.OR.A.045:

Just as requirements for the provider have been incorporated by adding points (g) and (h) to ATM/ANS.OR.A.045, equivalent requirements should be provided for national authorities within ATM/ANS.AR.C.025 Changes, ATM/ANS.AR.C.030 or ATM/ANS.AR.C.035. Of special interest is how national authorities shall verify that the provider has made sure that the equipment is certified / declared by an approved DPO: by means of coordination with the Agency or accepting the evidence provided by the ATM/ANS providers.

response

*Noted*

The comment will be considered during the development of the associated AMC/GM to the referenced 'authority requirements' provisions under RMT.0161 Subtask 3.

comment

1156

comment by: FOCA Switzerland

Regarding art. 1, 4. (about ATM/ANS.OR.A.045), the amendments are fully supported but some further explanations on how the implementation will be welcomed.

response

*Noted*

Taking into account the comment, the development of the associated AMC/GM is under consideration.

comment

1167

comment by: Deutscher Wetterdienst

Art. 1 (4.) should be Art. 2 (1.) since this applies to annex III of (EU) 2017/373 (and not Annex II as stated).

response

*Accepted*

comment

1168

comment by: *Deutscher Wetterdienst*

Art. 1 (4.) (g) introduces a new term “ATM/ANS functional system” without formal definition. The terms needs to be added to Annex I of (EU) 2017/373 or revised to “functional system”.

response

*Accepted*

comment

1197

comment by: *FerroNATS*

Modification to art. ATM/ANS.OR.A.045: As this article is part of the “Change Management Procedures” (CMP) (ATM/ANS.OR.B.010) subject to formal approval by the CAs (ATM/ANS.AR.C.030); the impact of this modification shall not be overlooked. The cost and effort of this should be specified and be integrated in the overall Cost/Benefit Analysis that should be part of the Regulatory Impact Assessment

response


*Noted*

Please refer to topic ‘Impact assessment’, in particular topics ‘Methodology used and scoring proposed’ and ‘Certification costs and impacts on the market’.





## Appendix — Attachments

 [MET feedback on NPA 2022-09 V0 7 clean with Annex.pdf](#)  
Attachment #1 to comment [#1138](#)