



# Notice of Proposed Amendment 2025-11 (A)

issued in accordance with Article 6 of Management Board Decision 01-2022

## Alignment of Part 21 with Regulation (EU) 2018/1139

### Review of the ETSO system in relation to the demonstration of design capabilities

RMT.0727 – SUBTASK 4

WHAT THIS NPA IS ABOUT		
<p>This Notice of Proposed Amendment (NPA) proposes amendments to Annex I (Part 21) to Commission Regulation (EU) No 748/2012 and its associated acceptable means of compliance (AMC) and guidance material (GM) in order to align them with Regulation (EU) 2018/1139 (the Basic Regulation) in respect of the demonstration of design capability for European Technical Standard Order (ETSO) authorisation (ETSOA) applicants and holders.</p> <p>The aim of the proposed regulatory material is to provide ETSOA applicants and holders with revised options for design capability demonstration. These options include demonstration either by declaring their design capability for the respective ETSO article in accordance with the newly proposed Part 21 Subpart N, or by holding a design organisation approval (DOA) issued by EASA in accordance with Part 21 Subpart J. If the applicant/holder of an ETSOA holds a DOA, they may request that EASA grant them DOA privileges for the classification and approval of minor changes to an ETSOA and for obtaining the approval of certain major changes to an ETSOA without further verification by EASA.</p>		
<p><b>REGULATIONS INTENDED TO BE AMENDED</b></p> <ul style="list-style-type: none"> <li>— <a href="#">Regulation (EU) No 748/2012 (Initial Airworthiness)</a></li> </ul>	<p><b>ED DECISIONS TO BE AMENDED</b></p> <ul style="list-style-type: none"> <li>— <a href="#">ED Decision 2012/020/R – AMC &amp; GM to Part-21 Issue 2</a></li> </ul>	
<p><b>AFFECTED STAKEHOLDERS</b></p> <p>ETSOA applicants and holders; EASA</p>		
WORKING METHODS		
<b>Development</b>	<b>Impact assessment(s)</b>	<b>Consultation</b>
By EASA	Light	Public — NPA
<p><b>RELATED DOCUMENTS/INFORMATION</b></p> <ul style="list-style-type: none"> <li>— <a href="#">ToR RMT.0727 - Alignment of Part 21 of Regulation (EU) No 748/2012 with Regulation (EU) 2018/1139 (including simple and proportionate rules for GA)   EASA</a></li> <li>— <a href="#">Evolution of European Technical Standard Order Authorisation process - Online event   EASA</a></li> </ul>		
<p><b>PLANNING MILESTONES:</b> Refer to the latest edition of the EPAS <i>Volume II</i>.</p>		



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## 1. About this NPA

### 1.1. How this regulatory material was developed

The European Union Aviation Safety Agency (EASA) identified a set of issues (as described in Chapter 2), and after having assessed the impacts of a possible intervention identified rulemaking as the necessary intervention action.

This rulemaking activity is included in the 2025 edition of Volume II of the European Plan for Aviation Safety (EPAS)<sup>1</sup> under Rulemaking Task (RMT) 0727, Subtask 4.

EASA developed the regulatory material in question in line with Regulation (EU) 2018/1139<sup>2</sup> (the Basic Regulation) and the Rulemaking Procedure<sup>3</sup>, as well as in accordance with the objectives and working methods described in the Terms of Reference (ToR) for this RMT<sup>4</sup>.

### 1.2. How to comment on this NPA

The draft regulatory material is hereby submitted for public consultation.

NPA 2025-11 is divided in three parts: (A), (B) and (C).

- **NPA 2025-11 (A)** includes the background information pertaining to the subject regulatory proposal.
- **NPA 2025-11 (B)** includes the proposed amendments to Annex I (Part 21) to Commission Regulation (EU) No 748/2012.
- **NPA 2025-11 (C)** includes the proposed amendments to the AMC and GM to Annex I (Part 21) to Commission Regulation (EU) No 748/2012.

Please submit your comments using the **Comment-Response Tool (CRT)** available at <http://hub.easa.europa.eu/crt/><sup>5</sup>.

<sup>1</sup> [European Plan for Aviation Safety \(EPAS\) 2025 - 14th edition | EASA](#)

<sup>2</sup> Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (<http://data.europa.eu/eli/reg/2018/1139/oj>).

<sup>3</sup> EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 01-2022 of 2 May 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'), and repealing Management Board Decision No 18-2015 ([EASA MB Decision No 01-2022 on the Rulemaking Procedure, repealing MB Decision 18-2015 \(by written procedure\) | EASA](#)).

<sup>4</sup> [ToR RMT.0727 - Alignment of Part 21 of Regulation \(EU\) No 748/2012 with Regulation \(EU\) 2018/1139 \(including simple and proportionate rules for GA\) | EASA](#)

<sup>5</sup> In case of technical problems, please send an email with a short description to [crt@easa.europa.eu](mailto:crt@easa.europa.eu).



To facilitate the collection and technically support EASA's subsequent review of comments in an efficient, controlled and structured manner, stakeholders are kindly requested to submit their comments to the respective predefined segments of the NPA within the CRT, and refrain from submitting specific comments or all their comments to the 'General Comments' segment.

Further, once all comments are placed in the respective predefined segments, there is no need to submit them (as a pdf attachment) to the 'General Comments' segment.

The deadline for the submission of comments is **30 April 2026**.

### **1.3. The next steps**

Following the public consultation of the draft regulatory material, EASA will review all the comments received and will duly consider them in the subsequent phases of this rulemaking activity.

Considering the above, EASA may issue an opinion proposing amendments to Regulation (EU) No 748/2012. The opinion will be submitted to the European Commission, which shall consider its content and decide whether to issue amendments to that Regulation.

Following the amendment of Regulation (EU) No 748/2012, EASA may issue a decision amending the AMC and GM to support the implementation of that Regulation.

When issuing the opinion and the decision, EASA will also provide feedback to the commentators and information to the public on who engaged in the process and/or provided comments during the consultation of the draft regulatory material, which comments were received, how such engagement and/or consultation was used in rulemaking and how the comments were considered.



## 2. In summary — why and what

### 2.1. Why we need to act

Regulation (EU) 2018/1139 (the Basic Regulation) empowers the Commission to adopt delegated acts that prescribe the situations in which, with a view to achieving the objectives set out in Article 1 and taking account of the nature and risk of the particular activity concerned, design organisation approvals (DOAs) are to be required or are not to be required or declarations are to be permitted, as applicable.

Currently, in Subpart O of Annex I (Part 21) to Regulation (EU) No 748/2012, an applicant for an ETSO authorisation (ETSOA) shall demonstrate its capability as follows:

- for production, by holding a production organisation approval, issued in accordance with Subpart G, or through compliance with Subpart F procedures; and
- for design:
  1. for an auxiliary power unit (APU), by holding a DOA, issued by EASA in accordance with Subpart J;
  2. for all other articles, by using procedures setting out the specific design practices, resources and sequence of activities necessary to comply with Annex I (Part 21).

For the demonstration of design capability for all articles, except APUs, the above requirements lack clarity regarding the scope of the procedures and the rights and obligations of the respective design organisations.

Furthermore, when the ETSOA applicant/holder decides to set the above-mentioned procedures in the frame of a design management system and request a DOA under Subpart J, they will not have access to DOA privileges as such privileges are not yet defined for ETSOA activity.

Action is needed to better define the available options for design capability demonstration for ETSOA applicants/holders, consistent with the Basic Regulation and providing full potential benefits for applicants/holders that decide to demonstrate design capability by obtaining a DOA, as explained in more detail in the following section.

#### 2.1.1. Description of the issue

Currently, the requirement for the demonstration of design capability for ETSOA, for articles other than APUs (please refer to point 21.A.602B(b)(2)), is only asking the applicant to use ‘procedures setting out the specific design practices, resources and sequence of activities’. This requirement is complemented by an acceptable means of compliance (AMC 21.A.602B(b)(2)) providing further details on the expected scope of such procedures.

Even if, in practice, these procedures are presented to EASA and EASA assesses the compliance of these procedures with the applicable requirements in Part 21 (as a condition for confirming the design capability demonstration), Part 21 does not include explicit requirements for the approval or acceptance of these procedures or for the rights and obligations of the respective organisations. Therefore, EASA lacks clear criteria to oversee compliance of the procedures setting out the specific design practices, resources and sequence of activities with the applicable requirements in Part 21.



Specifically, the organisations are not required to keep the defined procedures up to date or to inform EASA, when relevant, about changes made to the procedures. Also, the current AMC 21.A.602B(b)(2) does not explicitly cover the full scope of the required procedures that have to be established to manage the ETSOA process (e.g. interface with production organisation, conformity of test articles). Finally, when shortcomings in the procedures/activity are identified, EASA lacks effective means to ask the ETSOA applicant/holder to define and implement the necessary corrective/improvement actions.

In addition, first-time applicants usually face the challenge of obtaining EASA acceptance of their procedures (which may involve an iterative process of exchanges with EASA) at the same time as managing and progressing their first ETSOA application.

Furthermore, the demonstration of design capability through the current system has reached its limit and proves not to be the most appropriate option for managing:

- the increased complexity of ETSO articles;
- the evolution of ETSO standards;
- the limited resources on both industry and EASA sides.

The ETSOA applicants/holders that have implemented only the minimum procedures currently required in Part 21 are failing to define and implement organisational functions<sup>6</sup> that may ensure adequate management of the risks associated with the above-listed hazards.

Besides design capability demonstration aspects, the review of the ETSO process offers the opportunity to address additional issues that have been identified in ETSOA projects. Among them are the following.

- **Classification and approval of article changes (ETSOA changes).** In this area, the main issues are:
  - lack of more detailed classification criteria;
  - management of all major changes as new ETSOA projects;
  - no flexibility in the determination of applicable technical conditions; and
  - apparent lack of an approval process for minor changes that are not defined as ‘anticipated’.
- **Design–production interfaces.** The main issue here is that, initially, in Part 21 requirements it was assumed that an applicant for an ETSOA has the capabilities to both design and manufacture the article. However, in practice EASA has noted more and more situations in which the articles are designed and manufactured by different organisations.
- **ETSOA transferability.** Part 21 allows an ETSOA transfer only in limited situations.

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<sup>6</sup> The ‘organisational functions’ referred to in the text are those included in the design management system required in Part 21, Subpart J (e.g. safety risk management, compliance verification, airworthiness, independent monitoring).



**2.1.2. Who is affected by the issue**

ETSOA applicants/holders and EASA.

**2.1.3. How the issue could develop**

The issues presented above do not raise direct and immediate safety concerns.

Nevertheless, without improving the design capability demonstration framework for the ETSOA applicants/holders, a potential negative safety impact should be expected on the ETSOA projects because of recurrent shortcomings and delays, potentially leading to critical compliance demonstration aspects being overlooked.

**2.1.4. Conclusion on the need for rulemaking**

EASA concluded, as explained further in Chapter 3, that intervention was necessary and that non-regulatory action cannot effectively address the issue. Therefore, amendments to Part 21 are required.



## 2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. The regulatory material presented here is expected to contribute to achieving these overall objectives by addressing the issues described in Section 2.1.

More specifically, with the regulatory material presented here, EASA intends to clarify the design capability demonstration options for ETSOA applicants/holders. This will include two options: self-declaration of design capability and the DOA. For self-declaration of design capability, the objective is to provide clear rights and obligations for the respective declarants (so-called declared design organisations (DDOs)). In addition, the requirements for the definition and implementation of a management system for design by the DDO do not impose on the declarant new organisational functions<sup>7</sup>. This will ensure the continuity between the current design capability framework and the new, proposed one. Nevertheless, if the declarant considers it necessary, they are able to improve their management system by implementing such functions.

In addition, EASA intends to define specific DOA privileges for the ETSOA-related activities. This should incentivise ETSOA applicants/holders to select the DOA option for design capability demonstration.

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<sup>7</sup> The 'organisational functions' referred to in the text are those included in the design management system required in Part 21, Subpart J (e.g. safety risk management, compliance verification, airworthiness, independent monitoring).



### 2.3. How we want to achieve it — overview of the proposed amendments

*Note:* Due to parallel rulemaking tasks affecting Part 21, the proposed regulatory material considers the already proposed amendments contained in NPA 2024-04 (RMT.0031 ‘Regular update of the Initial Airworthiness Regulation and associated AMC and GM’) and NPA 2025-02 (RMT.0727(3) ‘Alignment of Part 21 with Regulation (EU) 2018/1139 – Certification of non-installed equipment (NIE)’). To help the reader, in the below sections the following marks are used for the regulatory material in which the starting reference text for this NPA is the one proposed in these ongoing NPAs:

- \* denotes reference text proposed under NPA 2024-04;
- \*\* denotes reference text proposed under NPA 2025-02.

#### 2.3.1. Proposed amendments to Annex I (Part 21) to Commission Regulation (EU) No 748/2012

(A) In Subpart O Section A Part 21, the following points are proposed to be amended.

21.A.602B(a) Point (1) is amended to include the possibility that the ETSOA applicant does not hold a production organisation approval but has entered into a design organisation – production organisation (DO–PO) arrangement with a production organisation approval holder.

*NB: This possibility is also present in the current Part 21 but through the application of point 21.A.2. The proposed amendment in point 21.A.602B(a)(1) simplifies the requirements applicable in such cases.*

21.A.602B(b)\*\* Point (2) is amended to present the two options for design capability demonstration: either a declaration of design capability, under the new Subpart N, or a DOA, under Subpart J.

The current capability demonstration ‘by using procedures setting out ...’ is not retained.

For first-time applicants, the replacement of the procedures requiring pre-acceptance by the Agency with a self-declaration of design capability will provide a simplification and will facilitate the entrance to the ETSO domain.

21.A.605\*\* In point (a), subpoints (5), (6) and (7) are deleted as being redundant. The respective requirements are already covered in the applicable Subparts (F, G, J and N).

This simplifies the content of point 21.A.605.

21.A.605 In practice, no separate compliance statement is provided by the applicant. The compliance statement is directly included in the declaration of design and performance (DDP).

Therefore, it is proposed that the requirements are streamlined by moving the contents of point (a)(2) to new point 21.A.608(a)(9).

Point 21.A.605(a)(2) will be indicated as ‘Reserved’.



- 21.A.606 Replace the declaration regarding no unsafe features requested in point (d) with the submission of the declaration of design and performance (DDP), which includes such a declaration.
- This change streamlines the requirements for the issuance of an ETSOA.
- 21.A.607 Deleted.
- Manufacturing and marking the article are in fact obligations of the ETSOA holder covered by points 21.A.609 (a) and (e) respectively.
- In addition, deletion of this point will eliminate possible confusion with new DOA privileges relevant for ETSO articles (refer to new points 21.A.263(c)(10) and (c)(11)).
- 21.A.608 In point (a)(1), the cross reference to point 21.A.31(a) is replaced with the expected information required to identify the article (and its design and testing standard). With this replacement, there is no actual change to this requirement but only a correction of a confusing cross reference.
- NB: Point 21.A.31 is the type design definition requirement for a product, which is not applicable for an article.*
- 21.A.608 New points (a)(8) and (a)(9) are added to include statements required previously in points 21.A.606(d) and 21.A.605(a)(2) respectively.
- The justification of these changes is provided above.
- 21.A.611 The content of point 21.A.611 is restructured and the gaps that previously existed in the requirements for the change management are filled.
- Point (a) prescribes criteria for minor/major classification (no change in respect of current requirements).
  - Point (b) clarifies who may approve minor changes (to cover all available scenarios: by the Agency, by an appropriately approved design organisation and introduction of approval of anticipated minor changes by any ETSOA holder).
  - Point (c) prescribes the conditions for approval of a minor change (to cover the gap in the current requirements).
  - Point (d) prescribes the approval of the major changes by EASA (the principle of the approval of a major change is not changed but an application for a new ETSOA is no longer necessary).
  - Point (e) prescribes the conditions for approval of a major change. The applicant shall demonstrate that the modified article complies with the applicable ETSO on the date of application for major change approval or, when the Agency finds appropriate, of the ETSO incorporated by reference in the ETSOA authorisation.
  - Point (f) prescribes the conditions for the application for change approval (applicable to both minor and major change applications).



- Point (g) introduces a limitation regarding who can make changes to an ETSOA (no change in respect of current requirements).

21.A.619 In point (1), the first condition of continued validity for the ETSOA is corrected. As it is applicable to ETSOAs already issued, the condition shall refer to an ETSOA holder and not an ETSOA applicant.

In point (5), the condition is complemented by adding the ETSOA suspension case.

21.A.621 The transferability requirements are amended by allowing ETSOA transfer if the receiving organisation can undertake the obligations of an ETSOA holder and has demonstrated its capability for design and production.

In addition, it is prescribed that such transfer of an ETSOA shall be managed as a change to the ETSOA.

- (B) Subpart N ‘Declared Design Organisation’ is proposed to be introduced in Section A of Part 21. The proposed contents of new Subpart N are as follows.

new 21.A.501 Scope

The new Subpart N establishes the procedure for declaring design capability (point (a)) and the rights and obligations of the persons making such declarations (point (b)).

new 21.A.503 Eligibility

The eligibility is linked with the design capability demonstration required in 21.A.602B(b)(2).

new 21.A.505 Declaration of design capability

This point asks the design organisation to submit to EASA the design capability declaration, and subsequent changes thereto, in a form and manner established by EASA.

This point also prescribes the required content of the declaration of design capability.

new 21.A.507 Management system for design

The DDO is asked to establish, implement and maintain a management system for design. This system shall ensure the quality and proper control of the design and of design changes of articles and their compliance with the technical conditions of the applicable ETSO.

In addition, the DDO shall create and provide to EASA a handbook that describes, directly or by cross reference, the organisation, its relevant policies, processes and procedures, and the categories of articles for which the design organisation has declared design capability and, where relevant, the interfaces with, and the control of, its partners or subcontractors.



- The DDO is also required to keep the handbook up to date and provide copies of the amendments to EASA.
- new 21.A.509 Resources of the declared design organisation
- The DDO is required to nominate a head of the design organisation with appropriate authority over the design activities included in its scope of work.
- Also, the DDO shall ensure adequate and sufficient resources, in terms of staff (number and experience), accommodation, facilities and equipment for the design activities included in its scope of work.
- new 21.A.511 Findings and observations
- The DDO is asked to consider the findings and observations notified by EASA and, where applicable, define and implement corrective actions to address the cause of non-compliance.
- Such corrective actions shall be performed within the period agreed by EASA.
- new 21.A.513 Notification of changes and cessation of activities
- Finally, the DDO has the obligation to notify EASA of any changes to the information included in the declaration submitted under point 21.A.505, changes to the management system for design that are significant and the cessation of some or all the activities covered by the declaration.
- (C) The following points in Subpart J of Section A of Part 21 are proposed to be amended.
- 21.A.233 As an organisation is eligible for a DOA for the purpose of obtaining privileges under point 21.A.263, point 21.A.233(c) is amended to exclude from eligibility an organisation that may request privileges for changes to an ETSOA (new privileges under point 21.A.263(c)(10) or 21.A.263(c)(11)) but that is not the ETSOA holder.
- This is necessary for consistency with point 21.A.611(g), allowing only the ETSOA holder to make changes to the ETSOA.
- 21.A.239\*\* The text of the requirement is amended to include ‘articles’ and ‘ETSO’, as necessary.
- 21.A.243\*\* The text of the requirement is amended to include ‘articles’, as necessary.
- 21.A.245 The text of the requirement is amended to include ‘articles’, as necessary.
- 21.A.247\*\* The text of the requirement is amended to include ‘articles’, as necessary.
- 21.A.251\*\* The text of the requirement is amended to include ‘articles’, as necessary.
- Also, the terms of approval shall include, when applicable, the list of the ETSO standards.
- 21.A.259 The text of the requirement is amended to include ‘articles’, as necessary.



- 21.A.263 New point (c)(10) describes the privilege of an ETSOA holder to classify changes and to approve minor changes to an ETSOA.
- New point (c)(11) describes the privilege of an ETSOA holder to obtain the approval of certain major changes to an ETSOA without further verification by EASA.
- 21.A.265 The text of the requirement is amended to include ‘articles’ and ‘ETSO’, as necessary.

(D) In Section A of Part 21, additional points are proposed to be amended.

- 21.1 Point (b) is amended to indicate that EASA is the competent authority for the new Subpart N.
- 21.A.5\* Point (d) is amended to add the cross reference to the new point 21.A.509(a) for records of the competence and qualifications for the head of a DDO.

(E) Furthermore, the following points in Section B of Part 21 are proposed to be amended.

- 21.B.55 The record-keeping requirements for the competent authorities are amended to include records related to declared organisations (i.e. the declaration of capability).
- Also, the competent authority shall maintain a list of registered declarations.
- 21.B.65 This point is amended to include the ‘deregistration’ action (see the title of this point and the new point (e)).
- 21.B.100 Point (b) is amended to delete the reference to ETSOAs.
- The level of involvement requirement for ETSOAs is moved in Section B Subpart O, in new point 21.B.482.
- new 21.B.461 A new requirement for the registration of the declaration of design capability.
- new 21.B.463 A new requirement for the oversight of DDOs.
- new 21.B.465 A new requirement for the findings, corrective actions and observations for DDOs.
- The proposed findings and observations system is similar to the one implemented in Part 21 for approved design organisations (refer to point 21.B.433) — that is, it has the same definition of finding levels and observations, the same requirements for corrective actions and their implementation period, and the same provisions for extension and



	escalation. However, the wording is adapted to reflect the DDO terminology.
new 21.B.467	A new requirement for managing the changes to the declaration notified by the DDOs.
21.B.480	In point (b), the cross reference to the level of involvement requirement is updated.
new 21.B.482	A new requirement for the level of involvement in ETSOA projects. The content is the same as previously in point 21.B.100. It was simply relocated to the correct subpart (Subpart O).

### 2.3.2. Proposed amendments to the AMC and GM to Annex I (Part 21) to Commission Regulation (EU) No 748/2012

The following AMC and GM to Part 21 are proposed to be amended.

AMC1 21.A.5	Introduction of a reference to ETSOAs in paragraph (d)(2).
GM1 21.A.5	Minor improvement in first paragraph, second bullet, to include articles (i.e. part or non-installed equipment).
GM1 21.A.5(a) and (b)	Introduction of declared organisations and articles, and update of cross references.
AMC1 21.A.239(d)	Introduction of articles, ETSOs and ETSOA, and update of cross references.
GM1 21.A.239(d)	Introduction of articles and ETSOs.
AMC1 21.A.239(d)(2)	Introduction of articles.
AMC1 21.A.243(a)	Introduction of articles and the ETSOA process.
AMC1 21.A.245(a)	Introduction of articles and ETSOA.
AMC1 21.A.245(d)	Introduction of article ETSOA.
AMC1 21.A.245(e)	Introduction of articles, ETSOs and ETSOA.
GM1 21.A.247	Introduction of articles and ETSOA.  Also, inclusion of procedures linked to the new privileges in 21.A.263(c)(10) and 21.A.263(c)(11).
GM1 21.A.251	‘GM No 1 to 21.A.251’ amended to read ‘GM1 21.A.251’.  Addition of paragraph (6) for the specific content of the terms of approval in the case of ETSO activities.
new AMC1 21.A.263(c)(10)	Acceptable means of compliance for the new privilege for the classification of the ETSOA and the approval of the minor changes to ETSOA.



new AMC1 21.A.263(c)(11)	Acceptable means of compliance for the new privilege for obtaining the approval of certain major changes to ETSOA without further verification by EASA.  This AMC also includes the eligibility criteria for the major changes under this privilege.
GM1 21.A.265(b)	Introduction of articles.
GM1 21.A.265(h)	'GM 21.A.265(h)' amended to read 'GM1 21.A.265(h)'.  Introduction of articles and ETSOA.
new GM1 21.A.505(b)	Guidance on the EASA form for submission of the declaration of design capability.
new AMC1 21.A.505(c)	Declaration form.
new AMC1 21.A.507(b)	Acceptable means of compliance for the processes/activities that should be covered by the management system for design.
new GM1 21.A.507(c)	Guidance referring to the handbook template published on the EASA website.
new AMC1 21.A.509(a)	Acceptable means of compliance for the position of the head of a DDO and required competence.
new AMC1 21.A.509(b)	Acceptable means of compliance for DDO personnel, facilities and organisation.
new GM1 21.A.511	Guidance material for defining the declared scope of work.
new AMC1 21.A.511(a)(2)	Acceptable means of compliance for the corrective action plan and implementation related to findings notified to DDOs.
AMC1 21.A.125B(c), 21.A.158(c), 21.A.258(c), 21.A.511(c)	Only the title of this AMC is amended to extend its applicability to the observations notified to a DDO (inclusion of point 21.A.511(c) in the title).
new AMC1 21.A.515	Acceptable means of compliance for changes to the information included in the declaration and for significant changes to the management system for design that should be notified to EASA.
AMC1 21.A.602B(b)(2)**	The content of this AMC is deleted as the option to demonstrate design capability through procedures for ETSOAs has been eliminated. New content is added (see explanation below).
AMC1 21.A.602B(b)(2)	New acceptable means of compliance indicating that an ETSOA applicant/holder should choose one of two design capability demonstration options: declared design capability or DOA. Both a DOA and a DDO in the same organisation (e.g. for different categories of article) may be acceptable only for a limited period, during the transition from a DDO to a DOA.



AMC1 21.A.605(a)(1)	Reference in the title change from ‘AMC 21.A.605(a)(1)’ to ‘AMC1 21.A.605(a)(1)’.  Revised acceptable means of compliance for the contents of the certification programme. Introduction of the possibility for the applicant to define compliance demonstration items (CDIs) and propose EASA’s level of involvement (LoI).
GM 21.A.605(b)	Update of cross references to acceptable means of compliance for level of involvement (due to the relocation of the respective AMC in Section B, from Subpart B to Subpart O).
AMC1 21.A.608*	Update of the form for the declaration of design and performance.
AMC1 21.A.608(a) (former AMC1 21.A.606(d)*)	Renumbering of the former AMC1 21.A.606(d) due to the relocation of the requirement for applicants’ statements. In addition, for DOA, a cross reference to Subpart J is introduced.
AMC1 21.A.609(c) and (d)	This AMC specifies that, if the ETSOA holder/applicant has a DOA, the respective instructions are subject to the 21.A.265(h) obligation.
new GM1 21.A.611	New guidance material presenting the change classification and approval workflow in the case of a DDO.
new GM2 21.A.611	New guidance material presenting the change classification and approval workflow in the case of a DOA.
new AMC1 21.A.611(a)	New acceptable means of compliance for the criteria for minor and major classification of ETSOA changes.
new AMC1 21.A.611(b)(3)	New acceptable means of compliance for introducing anticipated minor changes and for the definition of the list of such changes.
new AMC1 21.A.611(c)(2)	Acceptable means of compliance for the documentation required for minor changes. This covers three cases: anticipated minor changes, minor changes approved by EASA and minor changes approved under DOA privileges.
new AMC1 21.A.611(e)(1)	Acceptable means of compliance for the criteria to determine when the latest CS-ETSO amendment should be considered for compliance demonstration of the changed article.
new AMC1 21.A.611(e)(2)	Acceptable means of compliance for the documentation required for major changes. This covers both when privilege 21.A.263(c)(11) applies and when it does not.
new GM1 21.A.621	New guidance material explaining the conditions for the transfer of an ETSOA.
GM1 21.B.55	Minor wording corrections.
GM1 21.B.65	Extension of the existing guidance material to cover ‘deregistration’ (amendment of the title and introduction of paragraph (d)).



GM2 21.B.65	Extension of the existing guidance material to cover ‘deregistration’ (amendment of the title and introduction in the guidance text of ‘deregistration’).
AMC No 2 to 21.B.100(b)	Deletion of this AMC as point 21.B.100(b) no longer covers the level of involvement in ETSOA projects.
new AMC1 21.B.461	Acceptable means of compliance for the allocation of a registration number to a declaration of design capability.
new AMC1 21.B.463	Acceptable means of compliance for the DDO oversight activities performed by the competent authority.
AMC1 21.B.433(d) and 21.B.465(d)	This AMC amends the applicability of the current AMC1 21.B.433(d) to also cover DDOs (by inclusion of point 21.B.465(d) in the AMC title).
new AMC1 21.B.482	New acceptable means of compliance for the determination of EASA’s level of involvement in ETSOA projects. It includes the option for the applicant to break down the certification programme into meaningful groups of compliance demonstration activities and data and to provide to EASA a proposal for its level of involvement.

### 2.3.3. Applicability of the amended regulatory material

The applicability date will depend on the progress of the rulemaking task (the issuance of the related EASA opinion and decision).

The amendments to Annex I (Part 21) to Regulation (EU) No 748/2012 will become applicable once adopted by the European Commission and published in the *Official Journal of the European Union*. The related AMC and GM will become applicable afterwards through the issue of the related EASA decision.

EASA will propose that, at the time of the above-mentioned amendments becoming applicable, the existent ETSOA holders shall be deemed compliant with the revised capability demonstration requirements (through grandfathering of existent design capability demonstrations). However, when such an ETSOA holder applies to EASA for a new ETSOA, they will have a period of six months, since that ETSOA application, to either apply for a DOA, under Part 21, Subpart J, or submit a new declaration of design capability, under Part 21, Subpart N.

### 2.3.4. The legal basis

The legal basis for amending Regulation (EU) No 748/2012 and its Annex I (Part 21) is Article 19 of the Basic Regulation.

## 2.4. Stakeholders’ views

During some events (e.g. TSO Workshops in 2023 and 2024) that were organised by airworthiness authorities for the equipment manufacturers’ community, EASA presented the considered approaches as regards the alignment of the Initial and Continuing Airworthiness Regulations with the



Basic Regulation in respect of the ETSO system review, including revised design capability demonstration requirements.

Also, through its stakeholder advisory bodies (e.g. Certification Strategy Activity Group (AG.005)), EASA organised expert consultations to verify the contemplated concepts and collect inputs for drafting this NPA.

EASA invited interested parties (the ETSO industry, (supplemental) type certificate holders, competent authorities, EASA bilateral partners) to an online event (webinar) for collecting the views of affected stakeholders, which was held on 23 June 2025. Most of the comments and questions put forward by the audience requested additional clarification and have been used where relevant in the development of the AMC/GM contained in this NPA. At this event, the stakeholders did not express major concerns regarding the presented principles of the draft requirements.

## 2.5. Other relevant information

Initially, RMT.0727, Subtask 3, combined the certification of non-installed equipment with the review of the ETSO system in relation to the demonstration of design capabilities (please refer to the 2023–2025 EPAS, Volume II, 2023 edition<sup>8</sup>).

Considering the stakeholders' views and the need to prioritise its rulemaking activities, EASA decided to separate the two topics. The certification of non-installed equipment has been maintained under Subtask 3 and led to NPA 2025-02.

The review of the ETSO system in relation to the demonstration of design capabilities has been re-identified as RMT.0727, Subtask 4, and led to this NPA.

### 2.5.1. How this proposal contributes to rule simplification

#### (A) Design capability declaration

Currently, an ETSOA applicant that is not an approved design organisation must demonstrate its capability by submitting procedures setting out the specific design practices, resources and sequence of activities to comply with Part 21. EASA assesses these procedures to determine eligibility before issuing an ETSOA. However, the current requirements are insufficiently explicit, leading to iterative assessments, significant administrative burden and delays — particularly for first-time applicants or scope extensions.

The proposal introduces a declaratory system, reducing initial applicant effort and streamlining the certification process.

#### (B) Clear privileges for design organisation approvals

While holding a DOA currently allows an applicant to demonstrate capability, Subpart J does not grant DOAs specific privileges in relation to ETSOA. The proposal explicitly defines these privileges, expanding DOA scope and reducing the need for EASA intervention.

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<sup>8</sup> [European Plan for Aviation Safety \(EPAS\) 2023-2025 | EASA](#)

(C) Change management process

Under the current rules, major ETSOA changes require a full recertification, triggering the need for demonstration of compliance with the latest applicable CS-ETSO — a burdensome process. The proposal introduces a streamlined change management process, reducing administrative effort for ETSOA holders.

(D) ETSOA transferability

Part 21 does not currently allow ETSOA transfers, except for ownership changes, requiring a full recertification. The proposal enables ETSOA transferability, treating it as a managed change rather than a new certification — significantly reducing administrative burden.



### 3. Expected benefits and drawbacks of the proposed regulatory material

EASA has considered several options to address the issues described in Section 2.1. These options can be summarised as follows:

- Option 0 No policy change (rules remain unchanged and risks as outlined in the issue analysis)
- Option 1 Require capability demonstration through obtaining a DOA for certain categories of articles (certain ETSOs, in addition to APUs)
- Option 2 Require capability demonstration either through obtaining a DOA or through declaring the design capability (with ETSOA applicants/holders being able to choose one of the two capability demonstration routes)

In order to select the most appropriate option, in terms of benefits and limited drawbacks, the following qualitative impact assessment has been performed considering the following dimensions: safety impact, economic impact, proportionality issues and level playing field, and impact on bilateral partners in non-EU countries (validation / mutual acceptance of ETSOAs).

#### (a) Safety impact

##### Option 0

The present framework does not raise any direct and immediate safety concerns. However, a potential negative safety impact should be expected in the long term for future ETSOA projects because of recurrent shortcomings and delays, with critical compliance demonstration aspects potentially being overlooked, specifically considering the increasing complexity of ETSO articles and the evolution of ETSO standards.

This risk could even increase with the limited resources on both the industry and EASA sides.

##### Option 1

Requiring a DOA for the demonstration of design capability is expected to introduce a clear safety benefit. The design management system of a DOA includes organisational functions that contribute to the effective control and mitigation of the safety risks associated with the safety hazards currently developing in relation to the certification of ETSO articles (refer to Section 2.1.1).

##### Option 2

In Option 2, as the DOA is voluntary, the full safety benefits can be achieved only if the ETSOA holders/applicants choose to demonstrate their design capability through a DOA. Nevertheless, for the rest of the ETSOA holders/applicants, which will continue to require a declaration of design capability, the introduction of the EASA oversight capabilities will allow for effective corrective actions to be taken when shortcomings are identified in ETSO certification activities. Overall, Option 2 is still expected to bring a safety benefit, although not to the same extent as Option 1.



**(b) Economic impact**Option 0

The current framework does not induce a change in cost. ETSOA applicants would continue to be subject to a fee for initial application then, later, as ETSOA holders, fees in relation to changes to their procedures or for a new ETSOA.

Option 1

Compared with the current framework of Option 0, the change of design capability demonstration requirements through either Option 1 or Option 2 would represent, at first glance, an increase in cost for the affected organisations, in terms of initial certification and oversight.

The costs related to obtaining and maintaining a DOA are to a certain extent (or even fully, in some cases) compensated by the possible access to DOA privileges that may directly reduce certification costs (i.e. no requirement to apply to EASA for approval of minor changes) or reduce the time for approval (i.e. major changes can be approved by EASA without further verification).

Option 2

This increase of costs is limited in the case of Option 2 compared with Option 1, as each ETSOA applicant/holder may make its own decision regarding the design capability demonstration route based on its own cost–benefit analysis.

**(c) Proportionality issues and level playing field**Option 0

The current framework does not offer the means to consider a proportionate approach for design capability demonstration depending on complexity and criticality of the designed articles.

However, it can be stated that the current framework for capability demonstration offers a level playing field for all ETSOA applicants/holders (i.e. they are all subject to the same capability demonstration requirements).

Option 1

This option is the one that best accommodates the proportionality aspect. Requiring a DOA would be based on proportionality considering the complexity and the criticality of the developed articles. However, the main difficulty in implementing this option is related to the exercise of determining which ETSOs should be considered complex and/or critical. In addition, these parameters (i.e. complexity and criticality) may vary within the same ETSO, when the ETSO evolves / is revised or, in the case of criticality, depending on the article installation.

Furthermore, requiring a DOA may be seen as a disadvantage for the EU industry considering its competitors under other regulatory systems do not require such organisation approvals for technical standard order authorisations/approvals.



Option 2

The merit of this option is the maintenance of the potential benefit of a proportionate approach with a minimum drawback in terms of level playing field. The two options for design capability demonstration are expected to target two different categories of ETSOA applicants/holders. While the declaration of design capability may best fit smaller organisations or organisations targeting less complex ETSOA, the DOA may be more appropriate for large organisations and/or organisations designing more complex ETSO articles. Also, this route would fit the case of organisations already holding a DOA with a certain scope and wishing to extend it to ETSO activities. In any case, smaller organisations may see benefits too in opting for a DOA. The possibility (and its related privileges and customised level of involvement (LoI) will be available to all types of ETSO design organisations.

**(d) Impact on bilateral partners**Option 0

There is no change in the ETSOA acceptance framework covered by the current bilateral aviation safety agreements concluded by the EU with certain third countries / bilateral partners.

Options 1 and 2

The change in design capability demonstration for ETSOA applicants/holders should not raise concerns regarding the acceptance by EASA's bilateral partners. In particular, there is no amendment regarding ETSOA issuance. EASA would continue to issue ETSOAs for both initial authorisations and major changes. Only minor changes may be approved by an appropriately approved design organisation (i.e. an organisation with a DOA that has this privilege). The production of the article would continue to be under the responsibility of an approved production organisation, and the ETSO articles would continue to be delivered with an EASA Form 1.

The above impact analysis can be summarised in the following table comparing the three options.

**Table 1: Comparison of the options**

<i>Impact criteria</i>	<i>Option 0</i> <i>No policy change</i>	<i>Option 1</i> <i>Requiring a DOA</i>	<i>Option 2</i> <i>Requiring either a DOA</i> <i>or</i> <i>a declaration of design capability</i>
Safety impact	0  (with a potential negative trend in the future)	++  (DOAs ensure the most appropriate design management system)	+  (incentives for choosing DOA and better control of ETSO applicant/holder performance)



## 3. Expected benefits and drawbacks of the proposed regulatory material

Economic impact	0 (no change in costs)	-- (high costs of implementing and maintaining a DOA)	- (cost-benefit analysis by each ETSOA applicant/holder)
Proportionality and level playing field	-- (no proportionality considered)	- (the proportionality benefit is negatively impacted by the competitiveness disadvantage)	+ (ensures the best compromise between proportionality and competitiveness)
Impact on bilateral partners	0 (no impact)	0 (no impact expected)	0 (no impact expected)
Total	--	-	+

Explanation of the symbols used in Table 1:

- '0' no impact
- '-' negative impact
- '--' very negative impact
- '+' positive impact
- '++' very positive impact

Considering the results of the above analysis, EASA has selected and presents in this NPA a proposal for the implementation of Option 2. EASA assessed the proposed regulatory material to ensure that the industry will considerably benefit from the proposed regulatory material with a limited economic drawback.

The proposed regulatory material is expected to be beneficial by:

- providing the industry with considerable legal certainty by including in Part 21 explicit requirements for the demonstration of design capability for ETSOA, for articles other than APUs;
- providing EASA with effective means to ask the ETSOA applicant/holder to define and implement the necessary corrective/improvement actions, should shortcomings in the organisation's procedures/activity be identified;
- addressing the potential safety risks triggered by the increased complexity of the ETSO articles, the evolution of ETSO standards and limited resources on both industry and EASA sides;



- introducing, where possible, DOA privileges in relation to certain ETSO activities and better adjusting the level of involvement of EASA in the ETSOA project based on the applicant's DOA performance;
- providing acceptable means of compliance for the criteria used for the classification of ETSOA changes and clarifying the approval options for each category of changes;
- introducing flexibility in the establishment of design–production interfaces and for ETSOA transferability.

Furthermore, the proposed regulatory material has been developed in accordance with the better regulation principles, and particularly the regulatory fitness principles.



#### 4. Proposed regulatory material

The regulatory material is proposed in the following documents.

**NPA 2025-11 (B) Proposed amendments to Annex I (Part 21) to Commission Regulation (EU) No 748/2012**

**NPA 2025-11 (C) Proposed amendments to AMC and GM to Annex I (Part 21) to Commission Regulation (EU) No 748/2012**

*Note:* Due to parallel rulemaking tasks affecting Part 21, the proposed regulatory material considers the already proposed amendments contained in NPA 2024-04<sup>9</sup> and NPA 2025-02<sup>10</sup>.

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<sup>9</sup> [NPA 2024-04 - Regular update of Commission Regulation \(EU\) No 748/2012 and the associated acceptable means of compliance and guidance material \(RMT.0031 Subtask 3\) | EASA](#)

<sup>10</sup> [NPA 2025-02 - Alignment of Regulations \(EU\) Nos 748/2012 and 1321/2014 with Regulation \(EU\) 2018/1139 — Certification and continuing airworthiness of non-installed equipment | EASA](#)



## 5. Monitoring and evaluation

No monitoring provisions are considered necessary.



## 6. Actions to support implementation

In order to support affected stakeholders in the implementation of the amended regulatory material, in particular to support the design organisations that need to declare their design capability, EASA plans to organise a workshop after the adoption of the regulation.



## 7. References

n/a



## Appendix — Quality of the NPA

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

Please provide your feedback on the quality of this document as part of the other comments you have on this NPA. We invite you to also provide a brief justification, especially when you disagree or strongly disagree, so that we consider this for improvement. Your comments will be considered for internal quality assurance and management purposes only and will not be published (e.g. as part of the CRD).

### 1. The regulatory proposal is of technically good/high quality

*Please choose one of the options*

Fully agree / Agree / Neutral / Disagree / Strongly disagree

### 2. The text is clear, readable and understandable

*Please choose one of the options*

Fully agree / Agree / Neutral / Disagree / Strongly disagree

### 3. The regulatory proposal is well substantiated

*Please choose one of the options*

Fully agree / Agree / Neutral / Disagree / Strongly disagree

### 4. The regulatory proposal is fit for purpose (achieving the objectives set)

*Please choose one of the options*

Fully agree / Agree / Neutral / Disagree / Strongly disagree

### 5. The regulatory proposal is proportionate to the size of the issue

*Please choose one of the options*

Fully agree / Agree / Neutral / Disagree / Strongly disagree

### 6. The regulatory proposal applies the better regulation principles<sup>[1]</sup>

*Please choose one of the options*

Fully agree / Agree / Neutral / Disagree / Strongly disagree

### 7. Any other comments on the quality of this document (please specify)

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<sup>[1]</sup> For information and guidance, see:

[https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how\\_en](https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en)

[https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox\\_en](https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en)