



European Union Aviation Safety Agency

Notice of Proposed Amendment 2025-11 (B)

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

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



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Proposed amendments

The amendments are arranged to show deleted, new and unchanged text as follows:

- deleted text is ~~struck through~~;
- new text is highlighted in blue;
- an ellipsis '[...]' indicates that the rest of the text is unchanged.



21.1 Competent authority

For the purpose of this Annex, the 'competent authority' shall be:

- (a) [...]
- (b) for Section A, Subparts B, D, E, J, K, M, N, O and Q, the Agency;
- [...]



SECTION A — TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

21.A.5 Record-keeping

All natural or legal persons that hold or have applied for a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, design or repair approval, permit to fly, production organisation approval certificate or letter of agreement under this Regulation shall:

[...]

- (d) retain records of the competence and qualifications, referred to in points 21.A.139(c), 21.A.145(c), 21.A.145(d), 21.A.239(c), 21.A.245(a), ~~and~~ 21.A.245(e)(1), **and 21.A.509(a)**, of the personnel that are involved in the following functions:

[...]

[...]



SUBPART J — DESIGN ORGANISATION APPROVAL

[...]

21.A.233 Eligibility

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart:

[...]

- (c) for the purpose of obtaining privileges under point 21.A.263 regarding approval of minor changes **to a type certificate or to a supplemental type certificate** or minor repair design, or issuing declarations of compliance regarding minor changes or minor repair design of aircraft for which design compliance has been declared in accordance with Subpart C of Section A of Annex Ib (Part 21 Light).

[...]

21.A.239 Design management system

[...]

- (d) As part of the design assurance element of the design management system, the design organisation shall:
1. establish, implement and maintain a system for the control and supervision of the design, and of design changes and repairs, of products, parts, UAS, CMUs, ~~or~~ CMU components **or articles** covered by the terms of approval; that system shall:
 - (i) include an airworthiness function responsible for ensuring that the design of products, parts, UAS, CMUs, ~~or~~ CMU components **or articles**, or the design changes and repairs, comply with the applicable type-certification basis, the applicable operational suitability data certification basis and the applicable environmental protection requirements **or with the applicable ETSO, as relevant;**

[...]

[...]

[...]



21.A.243 Handbook

- (a) As part of the design management system, the design organisation shall create and provide to the Agency a handbook that describes, directly or by cross reference, the organisation, its relevant policies, processes and procedures, the type of design work, and the categories of products, parts, UAS, CMUs, ~~or~~ CMU components **or articles** for which the design organisation holds a design organisation approval, as identified in the terms of approval issued in accordance with point 21.A.251 and, where relevant, the interfaces with and the control of its partners or subcontractors.

[...]

- (b) Where any parts, CMU components or any changes to the products, UAS, ~~or~~ CMU **or articles** are designed by partner organisations or subcontractors, the handbook shall include a statement of how the design organisation is able to demonstrate, for all the parts, ~~or~~ CMU components **or articles**, compliance in accordance with point 21.A.239(d)(2), and shall contain, directly or by cross reference, descriptions of and information on the design activities and the organisation of those partner organisations or subcontractors, as necessary to establish the statement.

[...]

21.A.245 Resources

[...]

- (e) The design organisation shall ensure that:
1. the staff in all technical departments are of sufficient numbers and experience and have been given the appropriate authority to be able to discharge their allocated responsibilities and the facilities, equipment and accommodation that are adequate to enable the staff to fulfil the airworthiness, operational suitability data and environmental protection requirements as regards the product, the UAS, ~~or~~ the CMU **or the article**;

[...]

21.A.247 Changes in the design management system

After the issue of a design organisation approval, each change to the design management system that is significant for the demonstration of compliance or for the airworthiness, operational suitability data and environmental compatibility of the product, part, UAS, CMU, ~~or~~ CMU component **or article** shall be approved by the Agency before being implemented. The design organisation shall submit to the Agency an application for approval demonstrating, on the basis of the proposed changes to the handbook, that it will continue to comply with this Annex.



21.A.251 Terms of approval

The terms of approval shall identify the types of design work, the categories of products, parts, UAS, CMUs, ~~or~~ CMU components **or the list of the ETSO standards** for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform with regard to the airworthiness, operational suitability data and environmental compatibility characteristics of the products, UAS, ~~or~~ CMUs **or articles**. For design organisation approvals covering type-certification or European Technical Standard Order (ETSO) authorisation for auxiliary power units (APUs), the terms of approval shall additionally contain the list of products, CMUs or APUs. Those terms shall be issued as part of a design organisation approval.

21.A.259 Duration and continued validity

- (a) A design organisation approval shall be issued for an unlimited period of time. It shall remain valid subject to the design organisation's compliance with all the following conditions:
- [...]
3. the design organisation is able to provide the Agency with evidence showing that the design management system of the organisation maintains satisfactory control and supervision of the design of products, ~~and~~ CMUs **and articles**, repairs and changes thereto under the approval;
- [...]

21.A.263 Privileges

- (a) (Reserved)
- (b) (Reserved)
- (c) The holder of a design organisation approval shall be entitled, within the scope of its terms of approval issued under point 21.A.251 and under the relevant procedures of the design management system:
- [...]
8. to approve certain major changes to a type certificate under Subpart D of this Annex or under Subpart D of Section A of Annex Ib (Part 21 Light); ~~and~~
9. to issue certain supplemental type certificates under Subpart E of this Annex or under Subpart E of Section A of Annex Ib (Part 21 Light) and approve certain major changes to those certificates;
- 10. to classify changes and approve minor changes to an ETSO authorisation for which they are the holder; and**



11. to obtain the approval of certain major changes to an ETSO authorisation for which they are the holder, without further verification by the Agency, when submitting the declaration required under point 21.A.608.

21.A.265 Obligations of the holder

The holder of a design organisation approval shall, within the scope of its terms of approval, as established by the Agency:

[...]

- (c) determine that the design of the product, the UAS, ~~or~~ the CMU or the article, or of the changes or repairs to them, complies with the applicable type-certification basis, technical specifications concerning the making of declarations, operational suitability data certification basis, ~~and the~~ environmental protection requirements and ETSO, as applicable, and have no unsafe features;

[...]



SUBPART N — DECLARED DESIGN ORGANISATION

21.A.501 Scope

This Subpart establishes:

- (a) the procedure for declaring design capability by natural and legal persons who design ETSO articles under Section A of this Annex; and
- (b) the rights and obligations of the persons making declarations of design capability referred to in point (a).

21.A.503 Eligibility

Any natural or legal person required by point 21.A.602B(b)(2) to demonstrate their design capability may declare their capability under the conditions laid down in this Subpart.

21.A.505 Declaration of design capability

- (a) Prior to applying for an ETSO authorisation under point 21.A.603 of Subpart O, the organisation shall submit a declaration of design capability to the Agency.
- (b) The declaration, and any subsequent changes thereto, shall be made in a form and manner established by the Agency.
- (c) The declaration shall include the information necessary for the Agency to become familiar with the organisation and the intended scope of work, and shall include at least the following:
 - (1) the registered name of the organisation;
 - (2) the contact details, including the registered address, of the organisation's principal place of business and, where applicable, of the operating sites of the organisation;
 - (3) the name and contact details of the head of the design organisation;
 - (4) the intended scope of work;
 - (5) a statement confirming that the organisation:
 - (i) has a management system for design in accordance with point 21.A.507; and
 - (ii) will maintain the management system for design in compliance with this Subpart;



- (6) a statement confirming that the organisation will adhere to the processes and procedures established in accordance with point 21.A.507(c);
- (7) a statement that the organisation agrees to undertake the obligations of a declared design organisation in accordance with this Subpart.

21.A.507 Management system for design

- (a) The declared design organisation shall establish, implement and maintain a management system for design with clear accountability and lines of responsibility throughout the organisation. The management system shall:
 - (1) correspond to the nature and complexity of the organisation's activities and the size of the organisation;
 - (2) be established under the accountability of a single manager nominated as the head of the design organisation in accordance with point 21.A.509(a).
- (b) The management system for design shall ensure the quality and proper control of the design and of design changes to articles and their compliance with the technical conditions of the applicable ETSO.
- (c) As part of the management system for design, the declared design organisation shall create and provide to the Agency 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.
- (d) The handbook shall be amended as necessary to remain an up-to-date description of the organisation, and copies of the amendments shall be provided to the Agency.

21.A.509 Resources of the declared design organisation

- (a) The declared design organisation shall nominate a head of the design organisation with the authority for ensuring that, within the organisation, all design activities are performed to the required standards and that the declared design organisation is continuously in compliance with the requirements for the management system for design defined in point 21.A.507.
- (b) The declared design organisation shall ensure that the staff in all technical departments are of sufficient numbers and have sufficient experience and have been given the appropriate authority to be able to discharge their allocated responsibilities and that these, together with the accommodation, facilities and equipment, are adequate to enable the staff to ensure that the articles designed are compliant with the technical conditions of the applicable ETSO;



21.A.511 Findings and observations

- (a) After the receipt of the notification of findings in accordance with point 21.B.465, the declared design organisation shall:
 - (1) establish a corrective action plan addressing the cause of non-compliance;
 - (2) demonstrate the implementation of the corrective action to the satisfaction of the Agency.
- (b) The actions referred to in point (a) shall be performed within the period agreed by the Agency in accordance with point 21.B.465.
- (c) The observations received in accordance with point 21.B.465(e) shall be given due consideration by the declared design organisation. The organisation shall record the decisions taken in respect of those observations.

21.A.513 Notification of changes and cessation of activities

The declared design organisation shall notify the Agency without undue delay of the following:

- (a) any changes to the information that has been declared in accordance with point (c) of point 21.A.505;
- (b) changes to the management system for design that are significant for the demonstration of compliance of the article designed by the organisation;
- (c) the cessation of some or all of the activities covered by the declaration.



SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

[...]

21.A.602B Demonstration of capability

Any applicant for an ETSO authorisation shall demonstrate its capability as follows:

(a) for production:

1. by holding, **or entering into an arrangement with an organisation that holds,** a production organisation approval, issued in accordance with Subpart G, or through compliance with Subpart F procedures;

[...]

(b) for design:

[...]

2. for all other articles, **either** by ~~using procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Annex I (Part 21), declaring their design capability for the respective ETSO article in accordance with Subpart N or by holding a design organisation approval, issued by the Agency in accordance with Subpart J.~~

21.A.605 Data requirements

(a) The applicant shall submit to the Agency the following documents:

1. a certification programme for the ETSO authorisation, setting out the means to demonstrate compliance with point 21.A.606(b);
2. ~~a statement of compliance certifying that the applicant has met the requirements of this Subpart~~ **(Reserved)**;
3. a declaration of design and performance (DDP), stating that the applicant has demonstrated that the article complies with the applicable ETSO in accordance with the certification programme;
4. a copy of the technical data required in the applicable ETSO;
5. ~~when not exempted under point 21.A.602B(a)(2), the exposition, or a reference to the exposition, referred to in point 21.A.143 for the purpose of obtaining an appropriate~~



- ~~production organisation approval under Subpart G or the manual, or a reference to the manual, referred to in point 21.A.125A(b) for the purpose of manufacturing under Subpart F without a production organisation approval;~~
- ~~6. for an APU, the handbook, or a reference to the handbook, referred to in point 21.A.243 for the purpose of obtaining an appropriate design organisation approval under Subpart J;~~
- ~~7. for all other articles, the procedures, or a reference to the procedures, referred to in point 21.A.602B(b)(2);~~

[...]

21.A.606 Requirements for the issuance of an ETSO authorisation

In order to be issued an ETSO authorisation, the applicant shall:

[...]

- (d) ~~declare that no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.~~ submit the declaration of design and performance in accordance with point 21.A.608.

~~21.A.607 ETSO authorisation privileges~~

~~The holder of an ETSO authorisation is entitled to produce and to mark the article with the appropriate ETSO marking.~~

21.A.608 Declaration of Design and Performance (DDP)

- (a) The DDP shall contain at least the following information:
- ~~information corresponding to point 21.A.31(a) and (b), identifying~~ identification of the article and its design and testing standard; including:
 - a list of drawings and specifications, necessary to define the configuration and the design features of the article shown to comply with the applicable ETSO;
 - information on materials and processes and on methods of manufacture and assembly of the article necessary to ensure the conformity of the article;
 - the rated performance of the article, where appropriate, either directly or by reference to other supplementary documents;
 - a statement of compliance certifying that the article has met the appropriate ETSO;
 - reference to relevant test plans and reports;
 - reference to the appropriate Maintenance, Overhaul and Repair Manuals;



6. the levels of compliance, where various levels of compliance are allowed by the ETSO;
7. list of deviations accepted in accordance with point 21.A.610;
8. a statement that no feature or characteristic has been identified that may make the article unsafe for the uses for which the authorisation is requested;
9. a statement of compliance certifying that the applicant has met the requirements of this Subpart.

[...]

21.A.611 **Design** ETSO authorisation changes

(a) Design changes or ETSO authorisation changes to an article are classified as minor or major. Major changes are those extensive enough to require a substantially complete investigation to determine compliance with an ETSO. All other changes are minor.

~~(a)(b) The holder of the ETSO authorisation may make minor design changes (any change other than a major change) without further authorisation by the Agency.~~

Any minor design change made by the ETSO authorisation holder shall be approved by:

- (1) the Agency; or
- (2) the approved design organisation ETSO authorisation holder, within the scope of its privilege provided for in point 21.A.263(c)(10), as recorded in the terms of approval; or
- (3) the ETSO authorisation holder, only if the change is an anticipated minor change under point 21.A.603(b), agreed with the Agency.

In this case, the changed article keeps the original model number (part number changes or amendments shall be used to identify minor changes) ~~and the holder shall forward to the Agency any revised data that are necessary for compliance with point 21.A.603(b).~~

(c) For the approval of a minor change, the ETSO authorisation holder shall:

- (1) demonstrate that the modified article complies with the technical conditions of the ETSO incorporated by reference in the ETSO authorisation; and
- (2) prepare the data required under point 21.A.605(a) and, if required, submit this data to the Agency.

~~(b)(d) Any major design change made by the holder of the ETSO authorisation that is extensive enough to require a substantially complete investigation to determine compliance with an ETSO is a major change shall be approved by the Agency.~~

(e) For the approval of a major change, the ETSO authorisation holder shall:

- (1) demonstrate that the modified article complies with the technical conditions of the applicable ETSO valid on the date of application for major change approval or, if the Agency deems it appropriate, complies with the technical conditions of the ETSO incorporated by reference in the ETSO authorisation; and



(2) prepare the data required under point 21.A.605(a) and, if required, submit this data to the Agency.

(f) When the Agency's approval is required (i.e. under points (b)(1) or (d) above), an application for a change to the ETSO authorisation shall be made in a form and manner established by the Agency and shall include the revised data indicated under points (c)(2) or (e)(2).

(e)(g) No design change by any natural or legal person other than the holder of the ETSO authorisation who submitted the statement of compliance for the article is eligible for approval under this Subpart O unless the person seeking the approval applies under point 21.A.603 for a separate ETSO authorisation.

21.A.619 Duration and continued validity

An ETSO authorisation shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the conditions set when the ETSO authorisation was granted continue to be observed by the applicant ETSO authorisation holder;

[...]

4. it has been proved that the ETSO article does not give rise to unacceptable hazards in service;

5. the ETSO authorisation has not been revoked or suspended by the Agency under point 21.B.65, or surrendered by its holder.

21.A.621 Transferability

~~Except for a change in ownership of the holder, which shall be regarded as a change of significance, and shall therefore comply with points 21.A.147 and 21.A.247 as applicable, an ETSO authorisation issued under this Annex I (Part 21) is not transferable.~~ The transfer of an ETSO authorisation shall only be made to a natural or legal person who is able to undertake the obligations laid down in point 21.A.609 and, for this purpose, has demonstrated their capability in accordance with point 21.A.602B. The transfer application shall be managed as a change to the ETSO authorisation under point 21.A.611.



SECTION B — PROCEDURES FOR COMPETENT AUTHORITIES

SUBPART A — GENERAL PROVISIONS

[...]

21.B.55 Record-keeping

- (a) The competent authority shall establish a record-keeping system that allows the adequate storage, accessibility and reliable traceability of:

[...]

4. certification processes and the continuing oversight of certified and, if applicable, declared organisations, including:

[...]

(x) declarations of capability;

5. [...]

[...]

- (c) The competent authority shall maintain a list of all the certificates, authorisations and letters of agreement it has issued and any declarations that it has registered.

[...]

21.B.65 Suspension, limitation, and revocation and deregistration

The competent authority shall:

[...]

- (d) suspend or limit in whole or in part a certificate, approval, permit to fly, authorisation or letter of agreement if unforeseeable circumstances outside the control of the competent authority prevent its inspectors from discharging their oversight responsibilities over the oversight planning cycle;

- (e) limit or prohibit the activities of an organisation or a natural or legal person that has declared its design capabilities and, if appropriate, take action to temporarily or permanently deregister a declaration of design capability if such action is required pursuant to point 21.B.465. Also, a declaration of design capability will be deregistered when the declarant has given notification, under point 21.A.513(c), of the cessation of all activities covered by the respective declaration.



SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

[...]

21.B.100 Level of involvement

[...]

- (b) For the approval of a minor repair design, **or** minor change ~~or ETSO authorisation other than for APU~~, the Agency shall determine its involvement at the level of the entire certification project, taking into account any novel or unusual features, complexity of the design and/or demonstration of compliance, criticality of the design or technology, as well as the performance and experience of the applicant's design organisation.

[...]



SUBPART N — DECLARED DESIGN ORGANISATION

21.B.461 Registration of a declaration of design capability

- (a) Upon receiving a declaration from an organisation declaring its design capability, the Agency shall verify that:
- (1) the declarant is eligible to declare their design capability in accordance with point 21.A.503;
 - (2) the declaration contains all the information specified in point (c) of point 21.A.505; and
 - (3) the declaration does not contain information that indicates non-compliance with the requirements of Subpart N of Section A of this Annex.
- (b) The Agency shall acknowledge receipt of the declaration and assign an individual declared design organisation reference number to the declarant.
- (c) The Agency shall register the declaration of design capability on a suitable register, including the declared scope of work, provided that:
- (1) the declarant has declared their capability in accordance with point 21.A.505;
 - (2) the declarant has made a commitment that the obligations laid down in this Annex will be undertaken;
 - (3) there are no unresolved issues in accordance with point (a) above;
 - (4) the declarant had no previous declaration of design capability permanently deregistered in accordance with point 21.B.65.

21.B.463 Oversight activities

- (a) The Agency shall initiate oversight activities as it deems necessary.
- (b) The Agency shall collect and process any information it deems necessary for performing oversight activities.



21.B.465 Findings and corrective actions; observations

- (a) The Agency shall have a system in place to analyse findings for their safety significance.
- (b) A level 1 finding shall be issued by the Agency when non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's handbook and procedures, or with the design organisation's declaration of design capability including the declared scope of work, which may lead to uncontrolled non-compliance and to a potential unsafe condition.
- Level 1 findings shall also include:
- (1) any failure to grant the Agency access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;
 - (2) obtaining the registration of the declaration of design capability or maintaining such registration by falsification of the submitted documentary evidence;
 - (3) any evidence of malpractice or fraudulent use of the declaration of design capability;
 - (4) failure to appoint a head of the design organisation pursuant to point 21.A.509(a).
- (c) A level 2 finding shall be issued by the Agency when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's handbook and procedures, or with the declaration of design capability including the declared scope of work, which is not classified as a level 1 finding.
- (d) When a finding is detected during oversight or by any other means, the Agency shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance identified.
- (1) If there are any level 1 findings, the Agency shall:
 - (i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding and that in any case shall not be more than 21 working days; that period shall commence from the date of the written communication of the finding to the organisation requesting corrective action to address the non-compliance identified;
 - (ii) assess the corrective action plan and implementation plan proposed by the organisation and, if it concludes that they are sufficient to address the non-compliance, accept them;
 - (iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted by the Agency, take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, take action to temporarily or permanently deregister the organisation's declaration of design capability, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.



- (2) If there are any level 2 findings, the Agency shall:
- (i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months; that period shall commence from the date of the written communication of the finding requesting corrective action; during the corrective action implementation period, and subject to the nature of the finding, the Agency may extend the corrective action implementation period provided that a corrective action plan, or update thereto, has been agreed with the Agency;
 - (ii) assess the corrective action and the implementation plan proposed by the organisation and, if it concludes that they are sufficient to address the non-compliance, accept them;
 - (iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the Agency, raise the finding to level 1 and take action as laid down in point (d)(1).

(e) The Agency may issue observations for any of the following cases not requiring level 1 or level 2 findings:

- (1) for any item whose performance has been assessed to be ineffective;
- (2) when it has been identified that an item has the potential to cause non-compliance under points (b) or (c);
- (3) when suggestions or improvements are of interest for the overall performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the Agency.

21.B.467 Changes to the declaration

- (a) Upon receiving a notification of changes in accordance with point 21.A.513, the Agency shall verify the completeness of the notification in accordance with point 21.B.461.
- (b) When the change affects any aspect of the declaration that is registered in accordance with point 21.B.461, and upon satisfactory completion of the verification required by point (a), the Agency shall update the register.
- (c) Upon completion of the activities required by points (a) and, if relevant, (b), the Agency shall acknowledge receipt of the notification to the declared design organisation.
- (d) The Agency shall update its oversight activities established in accordance with point 21.B.463.



SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.B.480 Issuance of an ETSO authorisation

The Agency shall issue an ETSO authorisation, provided that:

[...]

- (b) the Agency, through its verifications of the demonstration of compliance in accordance with the level of involvement pursuant to point ~~21.B.100(b)~~ 21.B.482, has not found any non-compliance with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any; and

[...]

21.B.482 Level of involvement in ETSO authorisation projects

- (a) For ETSO authorisation, other than for APUs, the Agency shall determine its involvement at the level of the entire certification project, taking into account any novel or unusual features, the complexity of the design and/or demonstration of compliance, the criticality of the design or technology, and the performance and experience of the applicant's design organisation.
- (b) The Agency shall notify its level of involvement to the applicant, and it shall update its level of involvement when this is warranted by information with an appreciable impact on the risk previously assessed pursuant to point (a). The Agency shall notify the applicant about the change in the level of involvement.

