European Union Aviation Safety Agency

Notice of Proposed Amendment 2025-11 (C)

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

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

Contents

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.

AMC1 21.A.5 Record-keeping

GENERAL

[…]

(d) The organisation should ensure that copies of all the documents and supporting information that are developed:

(1) under the privileges that are defined under points 21.A.163 and 21.A.263; or

(2) for type certificates (TCs), restricted type certificates (RTCs), supplemental type certificates (STCs), major changes, ~~and~~ major repairs and European Technical Standard Order (ETSO) authorisations that are not issued under the privileges that are defined under point 21.A.263,

are retained throughout the operational life of the product, ~~or~~ part or non-installed equipment.

[…]

GM1 21.A.5 Record-keeping

GENERAL

For organisations that hold or have applied for a type certificate (TC), restricted type certificate (RTC), supplemental type certificate (STC), a European technical standard order (ETSO) authorisation, a change to the TC approval, a repair design approval, a permit to fly, a production organisation approval (POA), or a letter of agreement under Part 21, the relevant design information/data includes at least the following, as applicable:

— […]

— drawings and test reports, including inspection records for the product, part or non-installed equipment tested;

— […]

[…]

GM1 21.A.5(a) and (b) Record-keeping

RECORDING AND ARCHIVING SYSTEM

[…]

Therefore, the ~~approved DO or PO~~ design organisations and production organisations (~~or~~ i.e. a design organisation approval (DOA) holder, a declared design organisation, a production organisation approval (POA) holder, a natural or legal person that is demonstrating their design capability through an agreement on alternative procedures or through the acceptance of the organisation's certification programme, or a natural or legal person that produces products and parts under Part 21, Subpart F) are required to implement a system for the compilation and retention of records during all stages of

design or production, which covers short-term and long-term records as appropriate to the nature of the product and its processes.

The management of such information is subject to the appropriately documented procedures in the management system that is required by points 21.A.139, ~~and~~ 21.A.239 and 21.A.507 or to the manual/procedures that are required by point~~s~~ 21.A.14(b)~~,~~ or point 21.A.125A(b), ~~or 21.A.602B(b)(2),~~ as appropriate. This also applies in case of demonstrating the design capability through the acceptance of the certification programme under point 21.A.14(c).

[…]

The related procedures are required to:

— […]

— define an archiving period for each type of data as follows:

[…]

— design data, including data that supports the compliance of a product, part, or ~~appliance~~ non-installed equipment with the certification basis (see GM1 21.A.5), as well as data that is considered essential for continuing airworthiness, is kept throughout the operational life of the product, part, or ~~appliance~~ non-installed equipment; such continued airworthiness data may include, but are not limited to, in-service occurrence reports and mandatory continuing-airworthiness information;

— for organisations that are approved according to Part 21, Subparts G and J, organisations that declare their design capability according to Part 21, Subpart N, and organisations that demonstrate their design capability through an agreement on alternative procedures or acceptance of their certification programme by EASA, ensure that the recording and record-keeping systems that are used by the partners, suppliers, and subcontractors meet the record-keeping objectives with the same level of confidence as they do for their own system;. in each case, it should be defined who should retain the data record (organisation, partner, supplier, or subcontractor), as well as the method of surveillance of the recording/record-keeping system of the partners, suppliers, or subcontractors; and

— […]

[…]

AMC1 21.A.239(d) Design management system

DESIGN ASSURANCE ELEMENT

[…]

(c) Design assurance system

[…]

1. Planned and systematic tasks

[…]

(i) General

(A) Issue or, where applicable, supplement, or amend the handbook in accordance with point 21.A.243, in particular to indicate the initiation of design activities on a product or, as applicable, on an article.

[…]

(G) Ensure that there is full and complete liaison between the design organisation and the related organisations that have responsibility for the products, ~~and~~ parts and non-installed equipment that are manufactured according to the type design.

[…]

(ii) Head of the design organisation (or deputy)

The head of the design organisation (HDO), or an authorised representative, should sign a declaration of compliance (see points 21.A.20(d), ~~and~~ 21.A.97(b)(3) and 21.A.608(b)) with the applicable type certification basis, OSD certification basis, and environmental protection requirements or, where relevant, with the applicable ETSO after verifying the satisfactory completion of the certification process. In accordance with point 21.A.20(e) or 21.A.608, the signature of the HDO on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).

(iii) Compliance verification

(A) Approval through the signing of all the compliance documents, including test programmes and data that are necessary for the verification of compliance with the applicable type certification basis, OSD certification basis and environmental protection requirements or, where relevant, with the applicable ETSO, as defined in the certification programme.

(B) […]

(iv) Airworthiness function

[…]

(C) cooperation with EASA in developing procedures to be used for the type certification process or, if applicable, the ETSO authorisation process;

[…]

(F) ensuring procurement and distribution of the applicable type certification basis, OSD certification basis, as well as environmental protection requirements, the applicable ETSO and other specifications;

(G) cooperating with EASA in proposing the type certification basis, OSD certification basis, and environmental protection requirements or, where relevant, the applicable ETSO;

(H) the interpretation of the type certification basis, OSD certification basis, and environmental protection requirements, or, upon the case, the technical

conditions of the applicable ETSO, and requesting EASA to take decisions in case of doubt;

[…]

(N) checking that all the compliance documents that are necessary to demonstrate compliance with the type certification basis, OSD certification basis, and environmental protection requirements, or, upon the case, with the technical conditions of the applicable ETSO, are prepared and complete, and signing the documents for release;

[…]

(S) monitoring significant events on other aeronautical products and articles, as far as they are relevant, to determine their effect on the airworthiness or operational suitability of the products or articles that are designed by the DO;

[…]

(v) Maintenance and operating instructions

A. […]

(a) establish the list of all the documents they produce to comply with CS 2X.1581 (CS 23.2620) and with the Appendix that is referred to in CS 2X.1529, CS-E 20/25, or CS-P 30/40, or CS 23.2625, or, in the case of ETSO articles, with point 21.A.609(c);

[…]

(vi) Operational suitability data

[…]

GM1 21.A.239(d) Design management system

DESIGN ASSURANCE ELEMENT

[…]

(b) Definitions

[…]

2 'Design assurance' refers to all planned and systematic action necessary to provide adequate confidence that the organisation has the capability to:

— design products, ~~or~~ parts or non-installed equipment in accordance with the applicable type certification basis, the operational suitability data (OSD) certification basis, and the environmental protection requirements or, where relevant, with the applicable ETSO;

— demonstrate and verify compliance with the type certification basis, the OSD certification basis, and the environmental protection requirements or, where relevant, with the applicable ETSO; and

— demonstrate to EASA that compliance.

3 'Type investigation' refers to the tasks of the organisation in support of the type certificate (TC), supplemental type certificate (STC) or other design approval processes necessary to demonstrate, verify and maintain compliance with the applicable type certification basis, OSD certification basis, and environmental protection requirements or, upon the case, with the applicable ETSO.

AMC1 21.A.239(d)(2) Design management system

INDEPENDENT VERIFICATION FUNCTION OF THE DEMONSTRATION OF COMPLIANCE

[…]

(c) For a product or an article, there is normally only one compliance verification engineer that is nominated for each relevant subject. A procedure should cover the non-availability of nominated persons and their replacement, when necessary.

[…]

AMC1 21.A.243(a) Handbook

GENERAL

(a) […]

(b) The handbook should provide the following information for each product or, if applicable, for each (category of) article that is covered by the design organisation approval (DOA).

(1) A description of the tasks that can be performed under the approval, according to the following classification (as relevant):

(i) general areas, like subsonic turbojet aeroplanes, turboprop aeroplanes, small aeroplanes, rotorcraft, ETSO articles, etc.;

(ii) technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.);

(iii) a list of types and models for which the design approval has been granted and for which privileges may be exercised, supported by a brief description for each product; ~~and~~

(iv) for repair design, classification and (if appropriate) approval activities~~.~~, it is necessary to specify the scope of activity in terms of structures, systems, engines, etc.; and

(v) a list of ETSO standards for which design approval has been granted and for which privileges may be exercised.

(2) […]

(3) […]

(4) A general description of the way in which the organisation performs all the design functions in relation to airworthiness, operational suitability and environmental protection approvals, including:

[…]

(iii) the procedures for classifying and approving unintentional deviations from the applicable design data occurring in production (concessions or non-conformity); ~~and~~

(iv) the procedure for classifying and obtaining approval for repairs~~.~~; and

(v) if applicable, the procedures followed and forms used in the ETSO authorisation process to ensure that the design of, or the change to the design of, the article is identified and documented, and complies with the technical conditions of the applicable ETSO.

(5) A general description of the way in which the organisation performs its functions in relation to the continuing airworthiness and continued operational suitability of the product or article it designs, including cooperation with the production organisation when dealing with any continuing airworthiness action that is related to the production of the product, part, or ~~appliance~~ non-installed equipment, as applicable.

(6) […]

(7) […]

(8) […]

(9) […]

(10) A description of the means by which the organisation collects, monitors, analyses and responds to reports of problems that cause or might cause an adverse effect on the airworthiness or operational suitability of its product, part, or ~~appliance~~ non-installed equipment during design, production, and in service, in particular to comply with point 21.A.3A (see also AMC~~3~~1 21.A.3A(a) and AMC1 21.A.239(d)).

[…]

(c) […]

AMC1 21.A.245(a) Resources

HEAD OF THE DESIGN ORGANISATION

(a) The head of the design organisation (HDO) should:

(1) have sufficient knowledge and authority to be able to respond to the competent authority regarding major issues concerning the design organisation (DO) and the product design approval or, if applicable, article ETSO authorisation, and to carry out any necessary improvements;

[…]

(b) The handbook that is submitted in accordance with point 21.A.243 should show that the HDO has the direct or functional responsibility for all the departments of the organisation which are responsible for the design of the product or article. If the departments responsible for design are functionally linked, the HDO still has the ultimate responsibility for compliance of the DO with Part 21.

[…]

AMC1 21.A.245(d) Resources

MANAGEMENT REPORTING LINES AND COMPETENCIES

(a) […]

(b) […]

(c) The chief of the airworthiness function should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the product certification or, if applicable, article ETSO authorisation, and continued airworthiness, including knowledge of, and experience in, managing the design assurance system.

(d) […]

(e) […]

AMC1 21.A.245(e) Resources

STAFF, FACILITIES, AND COORDINATION

(a) […]

(b) *Personnel*

The organisation should show that the personnel that is available to comply with point 21.A.245(e)(1) are able, based on their special qualifications and numbers, to provide assurance of the design or modification of a product or article, as well as of the compilation and verification of all the data that is needed to meet the applicable type certification basis, operational suitability data (OSD) certification basis, and environmental protection

requirements or, where relevant, the technical conditions of the applicable ETSO, while taking into account the state of the art and new experience.

[…]

(c) *Technical*

The organisation should have access to:

[…]

(2) accommodation and test facilities that are suitable for carrying out the tests and measurements that are needed to demonstrate compliance with the type certification basis, OSD certification basis, and environmental protection requirements or, where relevant, the technical conditions of the applicable ETSO; the test facilities may be subject to additional technical conditions that are related to the nature of the tests performed.

(d) *Organisation*

The handbook that is submitted in accordance with point 21.A.243 should show that:

(1) the responsibilities for all the tasks that are related to the certification or ETSO authorisation process are assigned in such a way that gaps in authority are excluded;

[…]

(e) […]

GM1 21.A.247 Significant changes to the design management system

In addition to a change in ownership (see point 21.A.249), the following changes to the design management system should be considered ~~to be~~ 'significant' for the demonstration of compliance, or for the airworthiness, operational suitability, or environmental compatibility of the products or articles:

(a) […]

(b) […]

(c) Procedures

Change to the principles of procedures related to:

— the type certification;

— the ETSO authorisation;

[…]

— the approval of certain major changes to certain STCs~~;~~ (see point 21.A.263(c)(9));

— the classification and approval of minor changes to an ETSO authorisation (see point 21.A.263(c)(10));

— the approval of certain major changes to an ETSO authorisation (see point 21.A.263(c)(11));

— continued airworthiness or continued operational suitability (see point 21.A.3B);

— the configuration control, when airworthiness, operational suitability, ~~or~~ environmental protection or compliance with technical conditions of the applicable ETSO is affected;

[…]

(d) […]

GM1 ~~No 1 to~~ 21.A.251 Terms of approval

1. […]
2. […]
3. […]
4. […]
5. […]
6. For ETSO authorisation activities, the scope of work is stated by providing the reference of the ETSO standard or a list of ETSO standards which is applicable for the designed articles.

AMC1 21.A.263(c)(10) Classification of changes and approval of minor changes to ETSO authorisations

1. INTENT

This AMC provides the means applicable to ETSO approval holders to:

— develop a procedure for the classification of changes to the relevant ETSO article;

— develop a procedure for the approval of minor changes to the relevant ETSO article.

Each design organisation approval (DOA) applicant/holder should develop its own internal classification and approval procedures following this AMC, in order to obtain the associated privilege under point 21.A.263(c)(10).

2. PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO AN ETSO AUTHORISATION

2.1. Content

The procedure should address the following topics:

— identification of changes to an ETSO authorisation;

— classification;

— justification of the classification;

— acceptance of the classification by authorised signatories; and

— supervision of changes to an ETSO authorisation initiated by subcontractors.

2.2. Identification of changes to an ETSO authorisation

The procedure should indicate how the following are identified:

— major changes without an impact on the certification basis;

— major changes with an impact on the certification basis; and

— minor changes.

The procedure should address cases where the pre-existing configuration of the ETSO article is the result of multiple changes applied to the same areas or items and where these changes have had a significant cumulative effect when compared with the originally certified article.

2.3. Classification

The procedure should show how the extent of the compliance demonstration is analysed and assessed against the criteria of point 21.A.611(a) and the associated acceptable means of compliance (AMC1 21.A.611(a)) and guidance material (GM1 21.A.611(a)), from the very beginning, by reference to the specific applicable Certification Specifications for European Technical Standard Orders (CS-ETSO) requirements and the incorporated technical conditions for the article.

Note: If the design change introduces or modifies a non-ETSO function, then the non-interference with the main functionality of the article needs to be maintained and/or verified. Please refer to AMC1 21.A.606(b), Section A, for guidance on assessing the impact of the required development assurance process on the change classification.

The procedure should define provisions to contact EASA if there is doubt regarding the classification.

2.4. Justification of the classification

All decisions on the classification of changes should be recorded and, for those that are not straightforward, also justified in accordance with the procedure and criteria mentioned in point 2.3 above.

These records should be easily accessible to EASA for sample checking.

2.5. Acceptance of the classification by the authorised signatories

All classifications of changes should be accepted by an appropriately authorised signatory, belonging to the airworthiness function, as explained in AMC1 21.A.239(d).

The procedure should indicate the authorised signatories for the various ETSO standards listed in the terms of approval.

For those changes that are handled by subcontractors, as described under point 2.6 below, a description should be provided of how the DOA holder manages its classification responsibility.

2.6. Supervision of changes to an ETSO authorisation initiated by subcontractors

The procedure should indicate, directly or by cross reference to written procedures, how changes to an ETSO article may be initiated and classified by subcontractors, and how such changes are controlled and supervised by the DOA holder, taking into consideration the requirements laid down in point 21.A.239(d)(3) and its associated guidance material.

3. PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO AN ETSO AUTHORISATION

3.1. Content

The procedure should address the following topics:

— compliance documentation;

— approval under the DOA privilege;

— authorised signatories; and

— supervision of minor changes to an ETSO authorisation handled by subcontractors.

3.2. Compliance documentation

For minor changes to an ETSO article, compliance documentation should be established and independently verified as required by point 21.A.239(d)(2).

The procedure should describe how the compliance documentation is produced and checked.

For the scope, contents and identification of compliance documentation, AMC 21.A.20(c) should be used.

3.3. Approval under the DOA privilege

The procedure should define a document to formalise the approval under the DOA privilege. This document should include at least:

— a brief description of the change and the reasons for the change;

— the applicable ETSO article configuration;

— the relevant technical conditions of the ETSO incorporated by reference in the ETSO authorisation, and the applicable methods of compliance;

— references to the compliance documents;

— the effects, if any, on the limitations and on the approved documentation;

— reference to the declaration of design and performance, and any revision thereto introduced by the change;

— evidence of the approval under the privilege of point 21.A.263(c)(10) by an authorised signatory; and

— the date of the approval.

3.4. Authorised signatories

The persons authorised to sign for the approval under the privilege of point 21.A.263(c)(10) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

3.5. Supervision of minor changes to an ETSO authorisation handled by subcontractors

When partners or subcontractors are involved in the classification or the compliance demonstration process, provisions from point 21.A.239(d)(3) should be incorporated in the change classification and change approval process procedures.

AMC1 21.A.263(c)(11) Procedure to obtain the approval of certain major changes to an ETSO authorisation without further verification by the Agency

This AMC describes the process to be followed in order to obtain and use the privilege to obtain the approval of certain major changes to an ETSO authorisation without further verification by the Agency.

1. DEFINITION OF 'CERTAIN MAJOR CHANGES' TO AN ETSO AUTHORISATION

'Certain major changes' to an ETSO article for which privileges may be granted as per point 21.A.263(c)(11) are a subset of major changes with the following characteristics:

(a) initial certification assumptions are valid and applicable to the major change;

(b) the ETSO standard(s) referred to in the authorisation letter is(are) maintained;

(c) no new features or functionalities covered by different ETSO standards or revisions of the same ETSO standards are introduced;

(d) no new deviations are introduced when compared with the initial certification of the article;

(e) no new means of compliance are introduced when compared with the initial certification of the article;

(f) the change is not part of an airworthiness directive (AD) corrective action or a termination action of an AD;

(g) there are no novelties in compliance demonstration when compared with the initial certification of the article;

(h) the change does not require more than 80 % of the initial investigation of compliance with the applicable certification basis to be repeated.

2. PROCESS FOR OBTAINING THE PRIVILEGE

A DOA holder that applies for the privilege referred to in point 21.A.263(c)(11) should do the following.

(a) Submit to EASA an application for a significant change in the design assurance system (see points 21.A.247 and 21.A.253).

(b) Establish internal procedures for the application of the privilege covering the following elements, and add them to the application.

(1) Procedural provisions detailing the assessment of the eligibility of the major change for the point 21.A.263(c)(11) privilege. These should include at least the following elements:

(i) classification, in accordance with point 21.A.611;

(ii) verification that the eligibility criteria (as per Section 1 above) have been fulfilled and the decision on the usage of the privilege;

(iii) recording of the eligibility assessment and the decision to use the privilege; this can be done in a separate document or included in the certification programme;

(iv) authorised signatories — the person(s) authorised to sign for the decision indicated in point (iii) above.

(2) The major change approval process and ETSO certificate issuance. Under the privilege, the approval (certificate) will be issued by EASA based on an administrative process with no EASA involvement in the verification of compliance demonstration. The DOA procedure should include the following steps.

(i) Establishment of the certification programme.

(ii) Completion of the design and compliance demonstration data.

(iii) Application to EASA for the update of the ETSO certificate. Together with the application, the minimum documents to be provided are:

— the certification programme;

— if issued separately, the document capturing the eligibility assessment and decision to use the privilege;

— the updated DDP that introduces the major change;

— the original ETSO authorisation certificate.

GM1 21.A.265(b) Obligations of the holder

USE OF THE HANDBOOK

1. The handbook should be signed by the senior company manager and the head of the design organisation and declared as a binding instruction for all personnel charged with the development and type investigation of products or articles. This binding statement should be provided independently of the means chosen by the design organisation to document its processes and procedures.

[…]

GM1 21.A.265(h) Designation of data and information issued under the authority of a design organisation approval (DOA) holder

1. […]
2. […]
3. […]
4. […]
5. STATEMENT

The statement provided with the data and information should also cover those items prepared by subcontractors or vendors that the DOA holder has declared as applicable to their products or articles. The technical content of the statement is related to data and information relating to the type certificate or, if applicable, ETSO authorisation ~~data and information~~.

The approval included in the statement means that:

— data relating to the type certificate or, if applicable, ETSO authorisation, ~~data~~ has been appropriately approved; and

— the information contains practical and well-defined installation or inspection methods, and, when those methods are implemented, the product or article is in conformity with data relating to the approved type certificate or, if applicable, ETSO authorisation ~~data~~.

[…]

GM1 21.A.505(b) Declaration of design capability

SUBMISSION OF THE DECLARATION

The EASA form to request the registration of the declaration of design capability is available on the EASA website. The documents to be sent with the request are indicated in the form and include the declaration of design capability (see AMC1 21.A.505(c) / EASA Form xxx).

AMC1 21.A.505(c) Declaration of design capability

DECLARATION FORM

The natural or legal person who declares their design capability should provide the information required by point 21.A.505(c) in the declaration form that is available on the EASA website.

EASA Form xxx

Request for Registration and Declaration of Design Capability

in accordance with Part 21 Subpart N

1. Declarant reference		
☐ **Initial declaration** ☐ **Notification of changes** — declared design organisation (DDO) customer/registration number:		
2. Declarant address and contact details		
2.1. Name and address *registered (business) name and address/legal seat of the company*	(Company) Name	
	Street/No	
	Postcode	
	City	
	Country	
2.2. Head of design organisation *contact person responsible for this declaration*	Title	☐ Mr ☐ Ms
	Name	
	First name	
	Job title	
	Phone number	
	Email address	
2.3. Operating site(s) *where design and testing activities take place; this may be left blank if details are the same as in 2.1*	Address(es), phone number(s), email address(s)	

3. Intended scope of work

3.1. Article categories

List of applicable ETSOs

ETSO No	Subject title
e.g. ETSO-C127	*Rotorcraft, Transport Aeroplane, and Small Aeroplane Seating Systems*

3.2. Certification activities

☐ ETSO authorisation under Part 21 Subpart O
☐ Changes to ETSO articles
☐ Anticipated minor changes to ETSO articles
☐ Repairs to ETSO articles

3.3. Limitations

(when relevant)
e.g. For article model xyz, only continued airworthiness activities

4. Declarant's statement

4.1. Declaration of compliance

The declared design organisation (DDO) has established and implemented a management system for design in accordance with point 21.A.507. This management system will be maintained in compliance with Subpart N of Annex I (Part 21) to Regulation (EU) No 748/2012.

References to the elements of the management system for design are included in the Annex to this Declaration.

All the personnel of the DDO must adhere to the processes and procedures referred to in the Annex to this Declaration.

I hereby commit to undertake the obligations of a declared design organisation in accordance with Part 21.

I confirm that all information contained in this Declaration, including its Annex, is complete and correct.

4.2. Signature

Date/location	Name (Head of design organisation)	Signature

EASA Form xxx (continuation)

ANNEX TO THE DECLARATION OF DESIGN CAPABILITY

This Annex includes references to the declared design organisation's handbook (DDOH), Issue xxx, showing compliance with the applicable requirements of Annex I (Part 21) to Regulation (EU) No 748/2012.

No	Part 21	Subject	DDOH reference
1. General			
1.1.	21.A.507(c)	Process and procedure documentation issuance, approval or change	
2. Organisation and key personnel			
2.1.	21.A.507(d) 21.A.509(b)	Organisational structure documented and kept updated	
2.2.	21.A.509(a)	Identification of the head of the design organisation *Note: When the design organisation has decided to nominate additional key personnel for managing the ETSO authorisation activities and interfacing with EASA, these personnel should be identified in the DDOH as well.*	
2.3.	21.A.509(b)	Procedure(s) to ensure that the numbers of staff in all technical departments and their level of experience are sufficient, and staff have been given the appropriate authority to be able to discharge their allocated responsibilities	
3. Subcontracting			
3.1.	21.A.507(c)	Subcontracting procedure(s) and a list of subcontractors	
4. Changes to the DDO			
4.1.	21.A.513	Procedure for the notification of organisational changes to EASA in accordance with point 21.A.513	
5. Design and ETSO authorisation processes			
5.1.	21.A.507(b) 21.A.603 21.A.605 21.A.606 21.A.608 21.A.610	Procedure(s) for the management of the ETSO authorisation process	
5.2.	21.A.507(b)	Procedure(s) for article configuration control	

	21.A.603(b) 21.A.608(a)(1) 21.A.611		
5.3.	21.A.507(b) 21.A.603(b) 21.A.611	Procedure(s) for the management of the design changes, including the list of anticipated minor changes as per point 21.A.603(b)	
5.4.	21.A.507(b) 21.A.605 21.A.606(b) 21.A.608(a)	Testing procedure and conformity of test specimens	
5.5.	21.A.431A(e) 21.A.507(b) 21.A.611	Procedure(s) for the management of the repair design *Note: According to point 21.A.431A(e) a repair to an ETSO article shall be treated as a change to the ETSO design and shall be processed in accordance with point 21.A.611.*	
6. Obligations and privileges			
6.1.	21.A.507(b) 21.A.602B(a) 21.A.609(a) 21.A.4 21.A.133(d)	Procedure(s) for coordination with the production organisation manufacturing the articles These should include procedure(s) for the management of the production deviations.	
6.2.	21.A.507(b) 21.A.609(c)	Procedure(s) to prepare, maintain and update master copies of all manuals required by the applicable airworthiness specifications for the article	
6.3.	21.A.507(b) 21.A.609(d)	The system to make available to users of the article and to the Agency, on request, those maintenance, overhaul and repair manuals necessary for the usage and maintenance of the article, and changes to those manuals	
6.4.	21.A.609(f) 21.A.3A 21.A.3B	Procedure(s) for the reporting system required under point 21.A.3A and to fulfil the obligations under point 21.A.3B(c) when an airworthiness directive is issued	
6.5.	21.A.3B(c)(2)	Procedure(s) for the issuing of information and instructions to operators, including those required under point 21.A.3B(c)(2)	
6.6.	21.A.609(e) 21.A.807	Procedure(s) for specifying the ETSO marking	
6.7.	21.A.609(b) 21.A.5	The record-keeping system for the complete set of technical data and records related to each authorised article	

6.8.	21.A.511	Procedures to respond to and address the findings and observations notified by the Agency	
6.9.	21.A.609(f) 21.A.9	Provision(s) for granting EASA access to any article, facility, document, record, data, process or procedure or to any other material in order to review any report, make any inspection or perform or witness any test, as necessary, in order to verify the initial and continued compliance of the organisation with the applicable requirements of Part 21	

AMC1 21.A.507(b) Management system for design

As part of its management system for design, the declared design organisation should do as follows.

1. Define a system for the management of resources as per point 21.A.509(b).

2. Define a system for the management of changes to the management system and, when applicable, the notification of such changes as per point 21.A.513.

3. Establish procedures for the management of the ETSO authorisation process.

   Those procedures should explain how the application to EASA is made and detail the certification process to obtain an ETSOA.

4. When relevant, define procedures for the article's hardware and software development assurance activities.

5. Establish procedures for article configuration control.

6. Establish procedures for the management of design changes as per point 21.A.611, including the anticipated minor changes as per point 21.A.603(b).

   Those procedures should:

   (i) explain the classification and approval of design changes on articles under ETSO authorisation, and how those are documented;

   (ii) identify the list of anticipated minor changes and define the process to amend this list.

7. When tests and inspections are needed to demonstrate that the article complies with the technical conditions of the applicable ETSO, define a system to ensure:

   (i) the conformity of the test article; and

   (ii) that the test and measuring equipment to be used for the test are adequate for the purpose of the test and appropriately calibrated.

   For further acceptable means of compliance for the conformity of test articles and the test and measuring equipment, refer to AMC 21.A.33 and GM 21.A.33.

8. Establish procedures for the management of repair designs.

   This procedure should be established in accordance with point 5 of this AMC on the management of design changes.

9. Establish procedures for specifying the ETSO marking.

10. Establish procedures for coordination with the production organisation manufacturing the articles, including the management of production deviations.

11. Establish procedures to prepare, maintain and update master copies of all manuals required by the applicable airworthiness specifications for the article.

12. Define the system to make available to users of the article and to EASA, on request, those maintenance, overhaul and repair manuals necessary for the usage and maintenance of the article, and changes to those manuals.

13. Define the reporting system required under point 21.A.3A.

14. Establish procedures for the issuing of information and instructions to operators, including those required under point 21.A.3B(c)(2).

15. Define a record-keeping system for the complete set of technical data and records related to each authorised article.

16. Define procedures for the assessment and control of the design subcontractors.

17. Establish procedures to answer and address the findings and observations notified by EASA.

GM1 21.A.507(c) Management system for design

DECLARED DESIGN ORGANISATION HANDBOOK TEMPLATE

The DDO handbook describes the resources, policies, processes and procedures relevant to the ETSO articles for which design capability is declared, taking into account Part 21 requirements.

It is recommended that the information provided be concise and limited to what is needed to ensure that quality is maintained and for the adequate control of activities exercised by the applicant/holder and by EASA.

A DDO handbook template is available on the ETSO page of the EASA website[1].

The template provides a recommended structure, but the handbook needs to be drafted considering the organisation, its scope of work and its way of working.

The handbook may be completely or partially integrated into another organisation manual (or manuals). In this case, identification of the information required by point 21.A.507 must be provided

[1] ETSO | EASA

by giving appropriate cross references, and these documents must be made available, on request, to EASA.

AMC1 21.A.509(a) Resources of the declared design organisation

HEAD OF THE DESIGN ORGANISATION

The nominated head of the design organisation should have direct or functional responsibility for all departments of the organisation that are responsible for the design of articles. If the departments responsible for design are functionally linked, the head of the design organisation still carries the ultimate responsibility for the compliance of the organisation with Subpart N.

The head of the design organisation should:

(a) have sufficient knowledge and authority to be able to respond to EASA regarding major issues regarding the declared design organisation and the article ETSO authorisation and to implement any necessary improvements;

(b) have an understanding of this Annex sufficient to discharge the relevant responsibilities.

AMC1 21.A.509(b) Resources of the declared design organisation

PERSONNEL, FACILITIES AND ORGANISATION

1. Personnel

The declared design organisation should ensure that the personnel available to comply with point 21.A.509(b) are able, based on their special qualifications and numbers, to provide assurance of the design or modification of an article, and assurance of the compilation and verification of all the data needed to meet the technical conditions of the applicable ETSO. Sufficient personnel, in terms of number and qualifications, should also be available to ensure the necessary continued airworthiness activities in support of in-service articles.

The organisation should have a system in place to schedule staff availability to ensure that the organisation has sufficient and appropriately qualified staff to plan, perform, supervise, inspect and monitor the organisation's activities in line with the organisation's scope of work.

The declared design organisation should establish and control the competency of the staff involved in the activities of the organisation, in line with the organisation's scope of work, in accordance with documented procedures.

Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. This training should be adapted based on experience that is gained within the organisation.

2. Facilities

The declared design organisation should have access to:

— workshops and production facilities that are suitable for manufacturing prototype models and test specimens;

— accommodation and test facilities that are suitable for carrying out tests and measurements needed to demonstrate compliance with the technical conditions of the applicable ETSO.

3. Organisation

The declared design organisation should ensure both of the following.

— Responsibilities for all tasks related to ETSO authorisation are assigned in such a way that gaps in authority are avoided. The responsibility for a number of tasks may be assigned to one person, especially in the case of simple projects.

— In the case of complex organisations, adequate coordination is ensured between various technical departments involved in both design and ETSO authorisation processes.

AMC1 21.A.511(a)(2) Findings and observations

FINDINGS-RELATED CORRECTIVE ACTION PLAN AND IMPLEMENTATION

After receipt of a notification of findings, the organisation should identify and define the corrective action for all findings, to address the effects of non-compliance.

Depending on the issues identified, the organisation may need to take immediate corrective action.

The corrective action plan should:

— include the correction of the issue, corrective and preventive action, and the planning to implement them; and

— be submitted in a timely manner to EASA for acceptance before it is effectively implemented.

After receiving EASA's acceptance of the corrective action plan, the organisation should implement the associated action.

Within the agreed period, the organisation should inform EASA that the corrective action plan has been implemented and should send the associated pieces of evidence, at the request of EASA.

AMC1 21.A.125B(c), 21.A.158(c), 21.A.258(c), 21.A.511(c) Findings and observations

DUE CONSIDERATION TO OBSERVATIONS

[…]

AMC1 21.A.513 Notification of changes and cessation of activities

CHANGES AND THEIR TIMELY NOTIFICATION

The declared design organisation should notify EASA of the following changes.

1. Changes to the information that has been declared in accordance with point 21.A.505(c):
   - the registered name of the organisation;
   - the registered address of the organisation's principal place of business and, where applicable, the operating sites and/or their addresses;
   - the head of the design organisation and/or their contact details;
   - the scope of work;
   - the references provided in the Annex of the declaration, including the revision level of the DDOH.

These changes should be notified to EASA by submitting a revised declaration of design capability.

2. Significant changes to the management system for design:
   - change in the organisation structure;
   - new distribution of responsibilities, affecting ETSO authorisation;
   - changes to the principles of procedures related to:
     - the ETSO authorisation process;
     - the management of the design changes;
     - continued airworthiness;
     - configuration control, when ETSO authorisation is affected;
     - the acceptability of design tasks undertaken by partners or subcontractors.

These changes may or may not impact the information declared in accordance with point 21.A.505(c). When there is an impact, these changes are notified to EASA by submitting a revised declaration of design capability. Otherwise, these changes are notified without revising the declaration of design capability.

Timely notification

The declared design organisation should notify the change(s) as soon as it has taken the decision to introduce the respective change(s) but no later than 10 working days after the change(s) came into effect.

~~AMC1 21.A.602B(b)(2) Demonstration of capability~~

~~**DESIGN CAPABILITY — PROCEDURES FOR ETSO AUTHORISATIONS**~~

~~1. Scope~~

~~1.1 A manual of procedures should set out specific design practices, resources and sequence of activities relevant for the specific projects, taking Part 21 requirements into account.~~

~~1.2 These procedures should be concise and limited to the information needed for quality and proper control of activities by the applicant/holder, and by the Agency.~~

~~2. Management of the ETSO authorisation process~~

~~A procedure explaining how the application to the Agency and certification process to obtain an ETSOA will be made, should be established.~~

~~3. Management of design changes~~

~~3.1 A procedure taking into account point 21.A.611, should be established for the classification and approval of design changes to articles under the ETSO authorisation~~

~~3.2 A procedure for the classification and approval of repairs and unintentional deviations from the approved design data occurring in production (concessions or non-conformances) should be established.~~

~~4. Obligations addressed in point 21.A.609~~

~~The applicant should establish the necessary procedures to show to the Agency how it will fulfil the obligations under point 21.A.609.~~

~~For the issue of information and instructions, a procedure following the principles of AMC 21.A.14(b), paragraph 4 should be established.~~

~~5. Control of design subcontractors~~

~~The applicant should establish the necessary procedures to show to the Agency how it will control design subcontractors.~~

~~6. Distribution of software applications~~

~~When an applicant for an ETSO authorisation for non-installed equipment which consists only of software applications is not required to demonstrate its capability for production, i.e. the derogation under point 21.A.602B(a)(2) applies, the applicant should establish procedures for the distribution of authorised articles, and changes to them, to the end users. Such procedures~~

~~should ensure that the distributed articles are exact copies of the authorised software application.~~

~~The software should be distributed together with the following accompanying information as applicable:~~

~~— software and media identification;~~

~~— reference to the design approval for software (e.g. ETSOA certificate number);~~

~~— integrity check instructions;~~

~~— hardware and software compatibility (e.g. minimum hardware requirements, minimum operating system requirements);~~

~~— loading instructions;~~

~~— procedures for the verification of the software installation, including specific configuration items according to the user operational needs;~~

~~— any specific instruction for functional checks (desk, ground or flight, as required);~~

~~— description of open problems and/or limitations;~~

~~— any other relevant, useful information.~~

AMC1 21.A.602B(b)(2) Demonstration of capability

DESIGN CAPABILITY

An ETSO authorisation applicant/holder may decide to use one of the options for design capability demonstration specified in point 21.A.602B(b)(2). However, both options should not be used at the same time.

Nevertheless, for existing ETSO authorisation holders, EASA recognises that the transition from a declared design capability to holding a design organisation approval may require a step-by-step approach.

A possible example is an ETSO authorisation holder developing different categories of articles. This ETSO authorisation holder may decide to define its design management system and obtain the EASA DOA initially only for a category of articles. Later on, the DOA will be extended to cover all categories of articles. In such a case and for a period of time agreed with EASA, the DOA and the declared design capability may coexist.

AMC1 21.A.605(a)(1) Certification programme

(a) For the purpose of the compliance demonstration in accordance with point 21.A.606(b), the applicant should:

(1) establish a certification programme;

(2) submit the certification programme to EASA; and

(3) keep the certification programme updated during the authorisation process.

(b) The certification programme is a document that allows the applicant and EASA to manage and control the process of compliance demonstration.

The certification programme may be based on modules that may be updated independently.

The certification programme should contain the following information~~:~~.

(1) A~~a~~ detailed description of the relevant European technical standard order (ETSO) article, including all of its configurations to be certified, and the identification of ETSO and non-ETSO functions, if any.~~;~~

(2) ~~t~~The applicable CS-ETSO, in case of different minimum performance standard (MPS) available, the selected MPS, the other requirements and any optional aspects (applicable standards, applicable requirements, choice of classes (if applicable)) as well as the expected deviations.~~;~~

(3) ~~t~~The operating characteristics and the expected limitations.~~;~~

(4) ~~t~~The intended use of the article and the kind of operations for which the approval is requested.~~;~~

(5) A proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred to as compliance demonstration items (CDIs), including references to their proposed means of compliance and related compliance documents.

Note: Definition of a unique CDI for the entire project is acceptable.

(6) Information relevant for the determination of the level of involvement (LoI).

The applicant should provide sufficient detailed information about the novelty, complexity and criticality aspects of each proposed CDI. If there is no detailed information on the criticality aspect, this is assumed to be 'undefined' as per AMC1 21.B.482.

It is recommended that this information is provided at the level of each EASA discipline affected by a proposed CDI. Further interpretative material on the necessary level of detail is provided in AMC1 21.B.482.

(~~5~~7) the proposed means of compliance (see Appendix A to AMC 21.A.15(b)), including the list of documents and deliverables for EASA;

(~~6~~8) an overview of the safety assessment for the functions supported by the article, including the main failure conditions, their classification, the associated assumptions, and architectural features supporting the safety aspects;

(~~7~~9) the way in which the applicant will record the justifications of compliance; and

(~~8~~10) a project schedule, including major milestones.

(c) CDI determination

(1) What is a CDI?

A CDI is a meaningful group of compliance demonstration activities and data, identified in the certification programme, that can be considered in isolation for the purpose of performing the risk assessment that allows EASA to determine its LoI using a risk-based approach.

The possibility of creating this grouping of compliance demonstration activities and data is intended to facilitate the risk assessment. However, there may be cases in which the risk assessment may also be performed at the level of the compliance demonstration activity or data, or at the level of the whole certification project.

The chosen breakdown into CDIs may affect the resulting risk classes (please refer to AMC1 21.B.482) but should not have any effect on the compliance demonstration itself or on EASA's LoI.

(2) Grouping of compliance demonstration activities and data

The compliance demonstration activities and data grouped in a CDI may demonstrate compliance with a requirement, a group of requirements or even part of a requirement. In this context, 'requirement' means any element of the technical conditions of the applicable ETSO.

A CDI may comprise any of the means of compliance listed in Appendix A to AMC 21.A.15(b).

CDIs may be tailored to the scope and size of the project. In simple projects, a CDI may address all the compliance demonstration activities within a given technical discipline (e.g. static strength, crashworthiness, airborne electronic hardware (AEH), occupant crashworthiness/restraint) or of the whole project.

If multiple CDIs are defined within a project, the following guidance should be considered.

— A CDI should not be so large — i.e. should not combine completely unrelated compliance demonstration activities or data — that it becomes meaningless, but neither should it be so small that it may not be considered in isolation from some other related compliance demonstration activities or data.

— One way of meaningfully grouping compliance demonstration activities and data is to select some activities and data and group them into a single CDI, as the certification programme must already contain the applicable requirements, the proposed means of compliance for each requirement and the associated compliance documents for each means of compliance.

— Another way to meaningfully group the data is to do so at the level of the technically related compliance demonstration activities and data. This may facilitate the assessment of those activities and data against the novelty, complexity and criticality criteria (see AMC1 21.B.482). The resultant CDI may encompass various means of compliance.

3. Description of CDIs

Each CDI should be sufficiently described in the certification programme, which should detail the following:

— the scope of the CDI; and

— the information on the novelty, complexity and criticality of the item being certified.

However, in cases where the rationale of the assessment is obvious, it is considered sufficient to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

Note: Cases in which the rationale of the assessment is obvious are those for which the classification is straightforward and does not require additional clarification. In general, applicant explanations/notes regarding the proposed classification should be provided, since this will also facilitate the acceptance of the LOI proposal. Nevertheless, to avoid unnecessary additional effort, these explanations can be omitted if they are obvious.

Additionally, it is recommended that the EASA discipline(s) affected by each CDI is (are) identified, as this will support the determination of the novelty, complexity and criticality, and finally identify the performance of the design organisation approval (DOA), if the applicant holds a DOA.

For DDOs, the performance of the organisation will be considered 'unknown'.

GM 21.A.605(b) Reporting from the compliance demonstration process and updates to the certification programme

The applicant should report to EASA any unexpected difficulty or event encountered during the compliance demonstration which invalidates or appreciably affects the assumptions previously made, e.g.:

— an increase in the severity of the consequences of a certain condition (e.g. a failure mode) of the article;

— one or more significantly reduced margins on the 'pass–fail' criteria of the compliance demonstration;

— an unusual interpretation of the results of the compliance demonstration;

— a deviation from the agreed means as defined in the certification programme;

— a change to the conditions set out in ~~the AMC No 2 to 21.B.100(b)~~AMC1 21.B.482; and

— any potential deviations discovered by the applicant.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact on the certification programme and, if necessary, they should amend the certification programme as per point ~~21.A.603~~21.A.605.

AMC1 21.A.608 Declaration of Design and Performance (DDP)

Note 1: If certain sections of the DDP are not applicable for the ETSO article in question, please state 'N/A' in those sections (but keep the section numbering).

Note 2: The DDP template has been designed with consideration of the possibility that the ETSOA applicant/holder is different from the manufacturer. If this is not the case, Section 1 may be simplified, with just the single entity being stated.

STANDARD FORM

Declaration of Design and Performance

DDP No. ……

ISSUE No. ……

Date: ……..

1. Name and address of the ETSOA applicant/holder~~.~~

   Name and address of the ETSOA applicant/holder

   DOA/DDO number

   Name and address of the manufacturer, if different from the ETSO applicant/holder.

   POA number (mandatory)

2. Description and identification of article ~~including:~~

   Article designation: ……..

   (Describe the main equipment function, e.g. inertial reference system.)

   Model/Type No: ……

   (This will be included in the list of ETSOAs, e.g. IRS-1000.)

   Open bracket part number(s) (P/N(s)): ……..

   (The open bracket P/N system, including eventual provision for minor changes and modification standards, if any, should be described here.)

Part number(s): ……..
~~(including eventual provision for minor changes, modification standard if any)~~

(The P/N shall be filled with the specific digits applicable to this declaration. For a list of multiple P/Ns, each entry shall include a short description, e.g. 'mounting tray'.)

Note: When several articles constitute the approved part, the part number of each article should be listed. In particular, for articles embedding software for which the configuration is not set by the hosting hardware part number, the software loadable part number(s) should be identified. A compatibility matrix or equivalent information should be provided showing the authorised configurations.

When the part number includes open brackets, the DDP should also list the individual approved part numbers covered by the open brackets. The DDP should address the performance of these individual part numbers.

3. List of ETSO and associated functions ~~and non-ETSO functions (when present).~~

~~Identification of the article functions, making clear the distinction between the ETSO functions and the non-ETSO functions.~~

Identification of the article functions, with clear reference to the ETSO standards. Each ETSO function shall be identified with classes/categories, if applicable. Each incomplete ETSO function shall be clearly identified.

~~4. Specification reference, (i.e. ETSO standard and applicable CS-ETSO amendment and/or the aircraft manufacturer design specification, if applicable).~~

~~ETSO-…..~~

4. Non-ETSO functions and additional specification references

Identification of the article non-ETSO functions, with clear reference to the applicable specification. List the applicable additional specifications (extended environmental qualification, military environmental qualification, aircraft manufacturer procurement specifications, etc.).

5. Master drawing reference: ……

Note: Optionally add article marking drawing reference, if not already specified in the certification programme.

6. ~~The~~ Rated performance ~~of the article directly or by reference to other documents.~~

~~Equipment type, class, etc.~~

~~Mass and overall dimensions~~

~~Limits of accuracy of measuring instruments~~

The rated performance of the article, directly or by reference to other documents, to be tailored to the specific article purpose.

— *Article(s) mass and overall dimensions with ± tolerances.*

— *Power supply and consumption.*

— *COG.*

— *Colour.*

— *…*

7. Failure condition classification

~~A statement of the assumed failure condition classification used as a design input (see CS-ETSO Subpart A).~~

When applicable in accordance with CS-ETSO Subpart A, Section 2.4, the failure condition classification used as design input.

~~8. A statement of the software level(s) used (or 'None' if not applicable), along with the applicable development assurance standards and/or other means of compliance with their version.~~

~~(Note: For Software levels and applicable standard, refer to CS-ETSO subpart A)~~

~~For those articles containing software, and as required per the software standard, references to:~~

- ~~plan for software aspects of certification;~~
- ~~software configuration index;~~
- ~~software accomplishment summary.~~

8. System development assurance

There should be a statement on the system development assurance process (or 'None' should be stated if not applicable), along with the applicable development assurance standards and/or other means of compliance, with their version.

(Note: For the applicable standard, refer to CS-ETSO, Subpart A.)

This statement should include references to:

— *the Plan for System Aspects of Certification;*

— *the System Configuration Index;*

— *the Summary of Development Assurance Process Outputs.*

~~9. For airborne electronic hardware, a statement of design assurance level for the complex hardware used, or 'None', if not applicable, along with the applicable development assurance standards and/or other means of compliance with their version.~~

~~Note: For design assurance levels, refer to CS-ETSO Subpart A.~~

~~For those articles containing complex electronic hardware, as required by the airborne electronic hardware standard, references to:~~

- ~~plan for hardware aspects of certification;~~
- ~~hardware configuration index;~~
- ~~hardware accomplishment summary.~~

9. Software development assurance

There should be a statement of the software development assurance level(s) used (or 'None' should be stated if not applicable), along with the applicable development assurance standards and/or other means of compliance, with their version.

(Note: For software levels and applicable standards, refer to CS-ETSO, Subpart A.)

For those articles containing software, and as required by the software standard, this statement should include references to:

— *the Plan for Software Aspects of Certification;*

— *the Software Configuration Index;*

— *the Software Accomplishment Summary.*

~~10. Any other known limitations (including open problem reports for SW and AEH) that may limit the application on the aircraft, for example restrictions in mounting attitude or non-compliance with the article specification, or installation limitation.~~

~~*Note 1: If the ETSO article has no limitations, this should be explicitly stated (i.e. 'None') in this section.*~~

~~*Note 2: For software and airborne electronic hardware, the open problem report's description should follow the applicable guidelines (as provided in AMC 20-189).*~~

10. Hardware development assurance

For airborne electronic hardware, there should be a statement of design assurance level for complex hardware used (or 'None' should be stated if not applicable), along with the applicable development assurance standards and/or other means of compliance, with their version.

(Note: For design assurance levels, refer to CS-ETSO, Subpart A.)

For those articles containing complex electronic hardware, as required by the airborne electronic hardware standard, this statement should include references to:

— *the Plan for Hardware Aspects of Certification;*

— *the Hardware Configuration Index;*

— *the Hardware Accomplishment Summary.*

~~11. Deviations from ETSO standard(s) (if applicable).~~

~~*Note 1: Deviations that have already been published should be referenced with their publication number (such as 'Deviation ETSO-Cxxx#yy published in ETSO.DevP.zz').*~~

~~*Note 2: If the ETSO article has no deviation from the ETSO standard, this should be explicitly stated (i.e. 'None') in this section.*~~

11. Limitations

Any known limitations that may limit the application on the aircraft, for example restrictions in mounting attitude, non-compliance with the article specification and installation limitations.

Note: If there isn't any limitation to the ETSO article, it is still worth having a limitations section (with 'None' stated).

12. Deviations

Deviations from ETSO standard(s) (if applicable).

Note 1: Deviations that have already been published should be referenced with their publication number (e.g. 'Deviation ETSO-Cxxx#yy published in ETSO.DevP.zz')

Note 2: If there isn't any deviation from the ETSO standard, it is still worth having a deviations section (with 'None' stated).

~~12~~13. Environmental qualification

A statement of the level of compliance of the article with the ability to withstand various environmental conditions, in the form of an environmental qualification form.

With a reference to the environmental qualification test plan and report(s) (refer to EUROCAE ED-14/RTCA document DO-160).

~~13~~14. RF transmission characteristics

For radio transmitters the transmitting frequency band, maximum transmitting power, and emission designator (European Telecommunications Standards Institute (ETSI) or US Federal Communications Commission (FCC)).

~~14~~15. Approvals held for the article

(i.e. foreign TSO authorisations, ~~initial approval,~~ other non-airworthiness certification approval).

~~15~~16. Certification programme

Reference to the certification programme for the article, with identification of the deviations from the certification programme.

~~16~~17. ETSO compliance reports

Reference to ETSO compliance reports (compliance matrix, test plans/reports, other qualification reports).

~~17~~18. Documents supporting installation reliability and safety assessment

Reference to the safety documents (failure mode effect analysis, single event effects analysis, system safety analysis) relevant to the article.

19. Information security

An ETSO article may be designed with a security assurance level (SAL) that is appropriate for specified security measures.

A statement of security assurance level should be used (or 'None' should be stated if not applicable), along with the applicable standards and/or other means of compliance, with their version.

This statement should include references to, for example:

— the Plan for Security Aspects of Certification;

— the Security Accomplishment Summary.

(Note: Refer to CS-ETSO, Subpart A.)

20. Problem reports

If applicable in accordance with CS-ETSO Subpart A, Section 2.7, list the open problem reports classified in accordance with the established classification scheme.

If an open-problem-report summary report is established as per AMC 20-189, it should also be referenced.

~~18~~21. Manuals

Service and instruction, installation, maintenance and operation manuals reference number (CMM, IM, OM).

~~19~~22. Declaration

It is hereby declared that:

(a) the article(s) described and identified in Section 2 of ~~in~~ this document has (have) been designed in compliance with Part 21, Subpart O ~~(reference: 21.A.605(a)(2))~~ *(ref. point 21.A.608(a)(9))*;

(b) in accordance with the certification programme, the article(s) comply(ies) with the ~~referenced~~ following applicable ETSO standard(s) [references of applicable ETSO standard(s)] *(ref. point 21.A.605(a)(3))* ~~(reference: 21.A.605(a)(3))~~:

— without limitations / with the limitations listed in Section ~~10~~11;

— without deviations / with the deviations listed in Section ~~11~~12;

— the non-ETSO functions listed in Section ~~3~~4 do not interfere with the ETSO functions.

(c) no feature or characteristic (including non-ETSO functions) has been identified that may make the article unsafe for the uses for which certification is requested *(ref. point 21.A.608(a)(8))* ~~(reference: 21.A.606(d))~~.

This declaration is made under the authority of

…… (name of ETSOA applicant/holder)

(Name of ETSOA applicant/holder) cannot accept responsibility for equipment used outside the limiting conditions stated above without their agreement.

Date: ……. Signed……..(Authorised representative of ETSOA applicant/holder; ~~alternative procedure for DOA reference~~ DDO/DOA number)

AMC1 21.A.60~~6~~8(~~d~~a) Declaration ~~requirements for the issuance of an ETSO authorisation~~ of design and performance (DDP)

DECLARATION

[…]

Additionally, the applicant should demonstrate and declare that the non-ETSO functions do not interfere with the ETSO functions.

~~The above declaration should be included in the Declaration of Design and Performance (see point 21.A.608 and AMC1 21.A.608).~~

[…]

Where the applicant holds an appropriate design organisation approval, the declaration of compliance should be made in accordance with Subpart J.

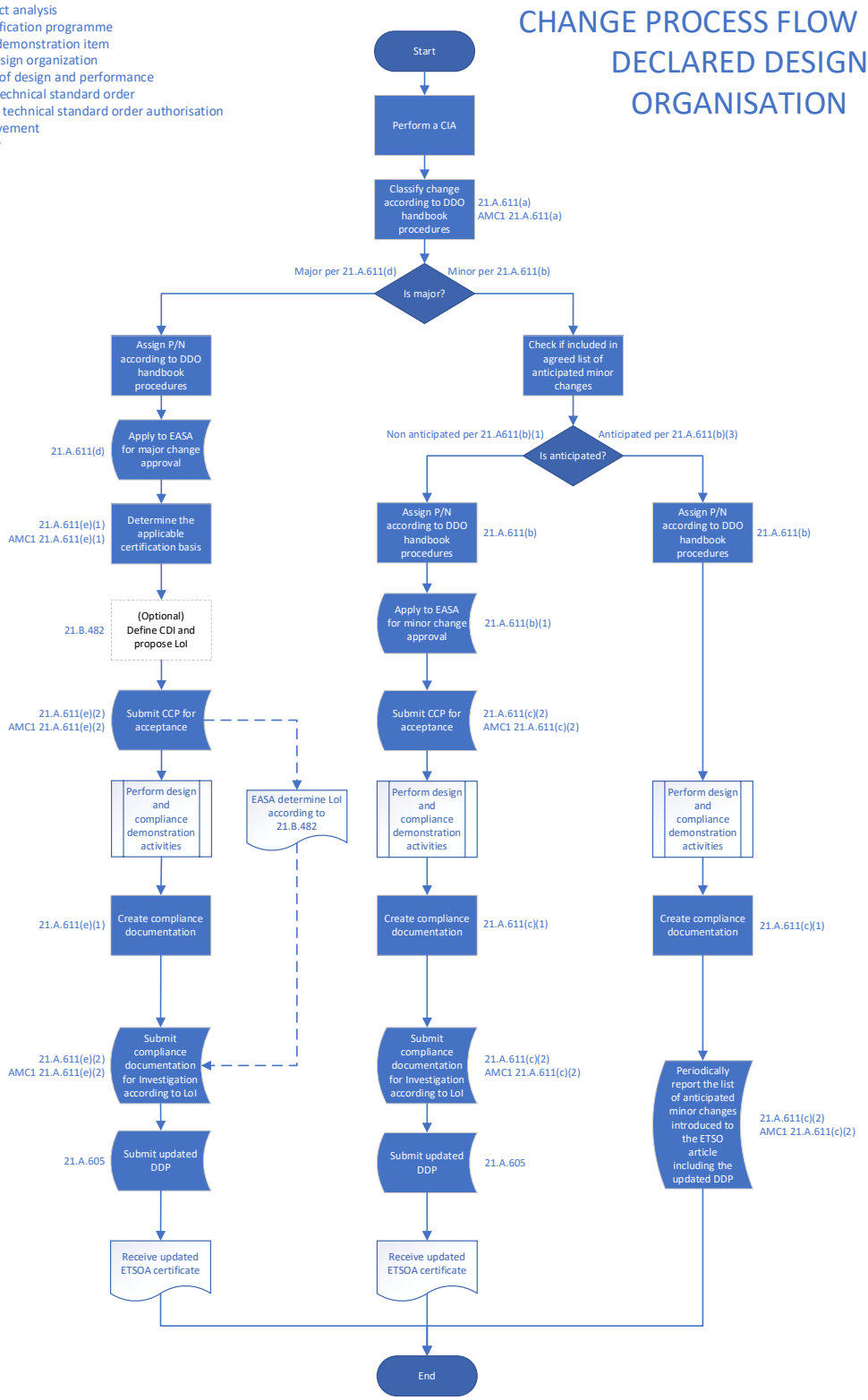
AMC1 21.A.609(c) and (d) Obligations on holders of ETSO authorisations

[…]

If the ETSOA applicant holds a DOA, the instructions and recommendations issued are subject to the obligations in point 21.A.265(h).

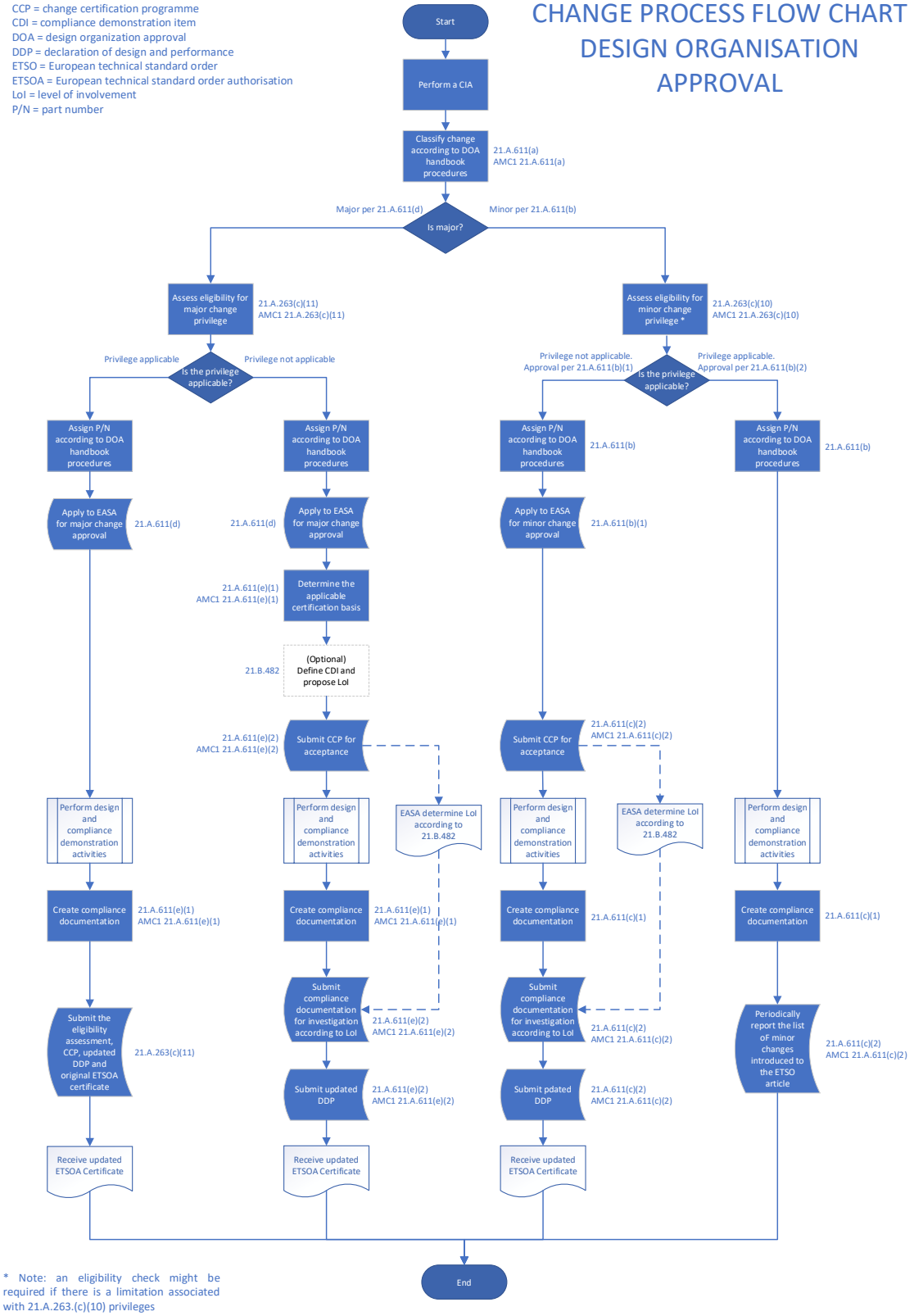
GM1 21.A.611 ETSO authorisation changes

AMC = acceptable means of compliance
CIA = change impact analysis
CCP = change certification programme
CDI = compliance demonstration item
DDO = declared design organization
DDP = declaration of design and performance
ETSO = European technical standard order
ETSOA = European technical standard order authorisation
LoI = level of involvement
P/N = part number



GM2 21.A.611 ETSO authorisation changes

AMC = acceptable means of compliance
CIA = change impact analysis
CCP = change certification programme
CDI = compliance demonstration item
DOA = design organization approval
DDP = declaration of design and performance
ETSO = European technical standard order
ETSOA = European technical standard order authorisation
LoI = level of involvement
P/N = part number



* Note: an eligibility check might be required if there is a limitation associated with 21.A.263.(c)(10) privileges

AMC1 21.A.611(a) ETSO authorisation changes

CLASSIFICATION CRITERIA

1. PURPOSE OF CLASSIFICATION

The classification of changes to an ETSO authorisation or article design is to determine the approval route to be followed in Part 21, Subpart O, point 21.A.611.

2. INTRODUCTION

Point 21.A.611(a) proposes generic, high-level criteria for the classification of changes to an ETSO article as minor or major.

This AMC is intended to provide acceptable means of compliance regarding the term 'substantially complete investigation' to determine the compliance of the ETSO article with the applicable CS-ETSO requirements, including approved deviations (if any).

This AMC should also be used to assess a change to an ETSO article under the DOA privilege in point 21.A.263(c)(10), when classification is the first step of the procedure for the impacted organisations.

3. ASSESSMENT OF A CHANGE FOR CLASSIFICATION

3.1. Classification process

Point 21.A.611(a) requires all ETSO changes to be classified as either major or minor.

Wherever there is doubt as to the classification of a change, EASA should be consulted for clarification.

When the strict application of the paragraph 3.2 criteria results in a 'major' classification, the applicant may request reclassification to 'minor', if justified, and EASA could take the responsibility for reclassifying the change.

A simple design change planned to be mandated by an airworthiness directive may be reclassified as minor due to the involvement of EASA in the continued airworthiness process when this is agreed between EASA and the applicant.

The classification should address cases where the pre-existing configuration of the ETSO article is the result of multiple changes applied to the same areas or items and the cumulative effect of changes when compared to the originally certified article to avoid any detrimental effect on the article's prescribed technical conditions, required performance and functional or operational characteristics.

The reasons for a classification decision should be recorded.

3.2. Complementary guidance for classification of changes

According to the definitions provided by point 21.A.611, the following types and subclasses of changes to an ETSO authorisation or article design can be identified:

— anticipated minor changes,

— minor changes,

— major changes.

3.2.1. Anticipated minor changes to an ETSO authorisation or article design

As per point 21.A.611(b)(3), the holder of an ETSO authorisation may make anticipated minor changes to an ETSO article without further authorisation by the Agency.

AMC1 21.A.611(b)(3) provides the criteria to be considered for the definition of the 'List of anticipated minor changes to an ETSO article design' and the condition for its approval by the Agency.

The ETSO authorisation holder should report to the Agency the list of anticipated minor changes applied to an ETSO article design. The Agency retains the rights to request any evidence to demonstrate how those anticipated minor changes have been validated.

3.2.2. Minor changes to an ETSO authorisation or article design

With reference to the point 21.A.611(a) definition, any change that does not meet the classification criteria of paragraph 3.2.3 below may be considered a minor change.

3.2.3. Major changes to an ETSO authorisation or article design

According to point 21.A.611(a), major changes to an ETSO article design are those extensive enough to require a substantially complete investigation to determine compliance with ETSO requirements.

A change to an ETSO article design should be classified as major if any of the following criteria are met:

— the assumptions used for certification have been invalidated;

— the change introduces a new ETSO or a new deviation;

— the change modifies the principle of intended design;

— the change necessitates new guidance material or means of compliance to the existing certification basis (including approved deviations, if any);

— the change is a corrective action mandated by an airworthiness directive;

— the change introduces a significant amount of complexity/novelty in the compliance demonstration;

— the change affects the form, fit and functions (FFF or F^3) compatibility of the ETSO article (excluding non-ETSO functions);

— the change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required (above 50 %).

Note: Quantitative threshold criteria shall be considered indicative and apply to each single ETSO standard applicable to the ETSO article. The applicant shall contact EASA for agreement.

AMC1 21.A.611(b)(3) ETSO authorisation changes

ANTICIPATED MINOR CHANGES

This AMC does not apply to applicants that have a design organisation approval (DOA), in accordance with Subpart J of Section A of this Annex, with the privilege for minor change approval under point 21.A.263(c)(10). This privilege encompasses the possibility for the organisation to approve any change classified as minor.

In the case of applicants with a declared design organisation (DDO), in accordance with Subpart N of Section A of this Annex no privilege is given for the classification of changes and approval of minor changes. Nevertheless, when a series of minor changes is anticipated as per point 21.A.603(b), the applicant can define a list of anticipated minor changes. This allows the Agency to agree with the processing of these minor changes beforehand, so that no further Agency involvement or authorisation is needed at the time of the change. The ETSO holder should nevertheless report to the Agency the list of anticipated minor changes applied to the ETSO article designs.

When a series of minor changes is anticipated for an ETSO article, the applicant should provide in its declared design organisation procedures a list of changes classified as minor that are expected to be applied and that may be processed without further authorisation by the Agency. The following elements should be considered when defining the list of anticipated minor changes.

1. The ETSO article design and applicable ETSO standard(s).

   The applicant may have a different set of anticipated minor changes depending on the article and on the specific ETSO standard affected.

2. The scope definition.

   The scope definition may, for example, include differentiating the assurance levels for software and airborne electronic hardware. Some anticipated minor changes may then only be applicable if a component with a lower assurance level is changed rather than one with a higher assurance level. Ultimately, each anticipated minor change should be described accurately to ensure it is used only when appropriate.

   It is important to recognise that the list of anticipated minor changes is not meant to take precedence over the change classification criteria (refer to AMC1 21.A.611(a) for further details). The cumulative effect of anticipated minor changes should be considered, as should quantitative and qualitative change classification criteria.

3. The means and methods of compliance with the applicable ETSO technical conditions that will be applied to each change.

   The applicable standards to be used in each case and the methods that will be used for showing compliance (e.g. testing, environmental qualification, analysis, design assurance) should be described. The level of detail to be provided is similar to what is expected in a certification programme, meaning that the applicant does not need to anticipate all the revised data, only the expected compliance demonstration.

4. The expected impact on the ETSO article part number.

The applicant should clarify how each of the changes will be identified through each article's part numbering system.

This list of anticipated minor changes in the DDO handbook may change over time for various reasons. Although, in principle, the DDO handbook can be revised at any time, any update of the list of anticipated minor changes should be properly coordinated with the Agency and performed in conjunction with one of the following.

— An application for ETSO authorisation for a major change, when additional or specific minor anticipated changes are expected for the concerned ETSO article.

— An application for a minor change in accordance with point 21.A.611(c)(1), when similar minor changes are expected. This prevents having to apply at a later time for those similar minor change cases if the change can be described in a generic and clearly defined way in the list.

Any modification to the list of anticipated minor changes is to be regarded as a significant change to the design management system, in accordance with AMC1 21.A.513. Such modifications are considered changes to the principles of procedures governing the management of design changes. Consequently, after the proposed updates to the list of anticipated minor changes have been agreed by the Agency in the scope of the application, the significant change to the design management system should be communicated to the Agency in accordance with AMC1 21.A.513.

AMC1 21.A.611(c)(2) ETSO authorisation changes

DATA SUPPORTING MINOR CHANGE APPROVALS

1. PURPOSE

This AMC sets the acceptable means of compliance for the fulfilment of the data requirements set by point 21.A.611(c)(2) for minor changes to an ETSO authorisation or article design.

2. INTRODUCTION

Point 21.A.611(c)(2) proposes generic, high-level requirements for the data to be submitted for the approval of a minor change to an ETSO authorisation or article design.

This AMC is intended to provide guidance on the minimum set of data required by the various organisations, holders of ETSO authorisations.

3. DATA REQUIREMENTS

Minor changes to an ETSO shall be supported, where appropriate, by a subset of the data required under point 21.A.605(a). The following table summarises the acceptable means of compliance with the requirement set by point 21.A.611(c)(2).

	Anticipated minor changes	Minor changes approved by EASA	Minor changes approved under DOA privileges

Certification programme for the change	n/a	Required	n/a
Declaration of design and performance (DDP)	Annual reporting	Required	Annual reporting
Supporting technical data	On request	Required	n/a (*)

(*) Data may subject to sampling during DOA oversight activities by EASA.

3.1. Data requirements for anticipated minor changes

As per point 21.A.611(b)(3), the holder of the ETSO authorisation may make anticipated minor design changes without further authorisation by the Agency. However, the ETSO authorisation holder shall maintain all the revised data that are necessary to demonstrate compliance of the changes.

The ETSO authorisation holder is required to periodically report to the Agency, at least once per year, the list of the anticipated minor changes introduced to the ETSO authorisation or article design, including the updated DDP applicable to the specific P/N subject to the update.

All other supporting technical data (e.g. test results, updated software and airborne electronic hardware Accomplishment Summaries) shall be kept available for delivery on request in case clarifications are deemed necessary or during periodic oversight activities performed by EASA in accordance with the provisions of point 21.B.463.

3.2. Data requirements for minor changes approved by EASA

According to point 21.A.611(b)(1), an ETSO authorisation holder may apply to EASA for the approval of minor changes to an ETSO authorisation or article design. The application should be supported by the following documents.

— The certification programme for the change (CCP), which should include the following minimum information (as relevant):
  — ETSO article designation,
  — ETSO authorisation number,
  — applicable ETSO standards and approved deviations,
  — reference to the initial certification programme,
  — reference to the pre-mod DDP,
  — identification of the article P/N: pre-mod and post-mod,
  — reference to the change classification according to the organisation procedures,
  — description of the change,

— change impact analysis, highlighting the affected areas of the change:
  — article functions,
  — structural elements,
  — airborne electronic hardware (AEH),
  — software,
  — interfaces (either electrical or protocol level),
  — for mechanical articles, the mass,
  — article configuration (configuration tree),
  — marking,
  — functional tests (non-regression),
  — qualification tests (non-regression),
  — acceptance test procedures (ATP),
  — technical documentation (please specify),
  — installation and maintenance manuals,
  — open problem reports addressed by the change,
  — any other information useful for the scope.
— The DDP, including the ETSO article part number subject to the change.
— Supporting technical data. The following minimum technical data are expected to be delivered as part of the minor change application:
  — a Software Accomplishment Summary, when software is affected,
  — a Hardware Accomplishment Summary, when AEH is affected
  — Qualification Test Reports, when qualification tests are affected,
  — an updated top-level drawing,
  — an updated drawing for the marking.

Any other supporting data shall be made available to EASA on request.

3.3. Data requirements for minor changes approved under DOA privilege

Minor changes approved under DOA privilege are not subject to EASA investigation.

The ETSO authorisation holder is required to periodically report to the Agency, at least once per year, the list of the minor changes introduced to the ETSO authorisation or article design, including the updated DDP applicable to the specific P/N subject to the update.

All supporting data shall be kept available for delivery on request in case clarifications are deemed necessary or for sampling during periodic oversight activities performed by EASA in accordance with the provisions of point 21.B.432.

AMC1 21.A.611(e)(1) ETSO authorisation changes

MAJOR CHANGES NECESSITATING AN UPDATE OF THE ETSO CERTIFICATION BASIS

1. INTRODUCTION

This AMC is intended to provide acceptable means of compliance to determine the applicability, in accordance with the provisions given by point 21.A.611(e)(1), of the technical conditions of the applicable ETSO that is current at the date of application for a major change to the ETSO article.

2. MAJOR CHANGES UPDATING THE ETSO CERTIFICATION BASIS

With reference to point 21.A.611(e)(1), a change to an ETSO article design can be classified as major, necessitating an update of ETSO certification basis, if any of the following criteria are met:

— the assumptions used for an existing certification have been invalidated;

— the change introduces a function, feature or characteristic that is covered by a later ETSO revision;

— the change introduces a function that is covered by an ETSO standard in addition to the existing one(s);

— the change introduces a new ETSO deviation;

— the change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required (above 80 %).

Note: Quantitative threshold criteria should be considered indicative and apply to each single ETSO standard applicable to the ETSO article. The applicant shall contact the EASA for agreement.

Any change classified as major in accordance with the above criteria should be justified in a detailed change impact analysis, part of the certification programme for the change, which should address the following aspects.

— Upgrade to new revisions of ETSO standards or addition of ETSO standards to ETSOA articles is only allowed by selecting the latest amendment of published ETSO standards, including the latest amendment of CS-ETSO, Subpart A, which becomes applicable to all the standards that are part of the certification basis.

— Downgrade to old revisions of ETSO standards and/or Subpart A is not allowed.

— Existing approved deviations applicable to the original ETSO authorisation should be validated for compatibility with the revisions of the ETSO standards applicable to the change in subject. Any change to an existing approved ETSO deviation is subject to the same approval process as that for any new ETSO deviation in accordance with point 21.A.610.

AMC1 21.A.611(e)(2) ETSO authorisation changes

DATA REQUIREMENTS FOR MAJOR CHANGES

1. INTRODUCTION

Point 21.A.611(e)(2) sets the data requirements for the approval of major changes to ETSO authorisation or design.

However, some DOAs may have granted the privilege of receiving approval for major changes without further assessment by EASA. This AMC clarifies the data requirements for such cases.

2. DATA REQUIREMENTS FOR MAJOR CHANGES

When the privilege in point 21.A.263(c)(11) applies, refer to AMC1 21.A.263(c)(11) for the required documentation.

In all other cases, all the documents specified by point 21.A.605(a) shall be provided to EASA and subject to investigation according to the level of involvement determined in accordance with point 21.B.482.

GM1 21.A.621 Transferability

The use of the criteria for the demonstration of capability (see point 21.A.602B) as eligibility criteria for an ETSO authorisation applicant refers to the joint effort of a design organisation and a production organisation. This is the reason why each change of the organisations referred in the ETSO authorisation necessitates a re-evaluation by EASA and a reissuance of the authorisation.

In addition, the change of the approved production organisation, which manufactures the article, cannot exclude in principle an impact on the performance of the article, which therefore needs to be (re)assessed by the ETSO authorisation holder and by EASA, in terms of classification and impacted compliance demonstration.

Therefore, classification of an application for a change approval is expected as per point 21.A.611.

GM1 21.B.55 Record-keeping

DATA RELATED TO DESIGN APPROVALS

[…]

(a) Type-certificate

[…]

(7) Airworthiness directives

~~(8) Master Minimum Equipment List~~

(~~9~~8) Maintenance Review Board Report

(b) Supplemental type certificate

(1) Copy of the STC (this includes those STCs issued by DOAs under the privilege in point 21.A.263(c)(9))

[…]

(c) ~~J~~ETSO Authorisation

[…]

[…]

GM1 21.B.65 Suspension, limitation, ~~and~~ revocation and deregistration

DEFINITIONS

[…]

(d) DEREGISTRATION OF DECLARATIONS

In the case of declarations of design capabilities, point 21.B.65 provides that a declaration may be temporarily or permanently deregistered. No activities that invoke the declaration may take place while the declaration is deregistered. In particular, the respective natural or legal person may not apply for a new ETSO authorisation and may not continue to mark the manufactured articles with the ETSO marking. The normal activities of the natural or legal person may be reinstated when the circumstances that caused the deregistration are corrected and the natural or legal person can once again demonstrate full compliance with the applicable requirements.

GM2 21.B.65 Suspension, limitation, ~~and~~ revocation and deregistration

LINK BETWEEN FINDINGS AND SUSPENSION OR LIMITATION OR REVOCATION OR DEREGISTRATION

The level 1 findings are those which may lead, if not properly addressed, to suspension, limitation or revocation of the approval or to deregistration of the declaration. If appropriate, these negative decisions on the approval or on the registration of the declaration may be taken immediately, or after the organisation fails to comply within the time period agreed by the competent authority.

The type of the negative decision — i.e. suspension, limitation, ~~or~~ revocation or deregistration — should depend upon the contents and the extent of the level 1 finding. Normally, a limitation or a suspension should be considered first.

~~AMC No 2 to 21.B.100(b) Level of involvement (LoI) in European technical standard order authorisation (ETSOA) projects~~

~~The applicant for an ETSOA is required to demonstrate its capability by obtaining EASA's agreement for the use of procedures that incorporate its specific design practices.~~

~~The assessment by EASA that these procedures are properly applied is performed solely through the various ETSOA projects of the applicant. No regular audits of the organisation are performed by EASA outside the ETSOA projects.~~

~~A properly completed Form 34 and the certification programme, including a technical description of the proposed design of the ETSO article, are the basis for the determination of EASA's initial LoI.~~

~~EASA assesses the compliance of the proposed ETSO article with the ETSO requirements as defined in the applicable CS-ETSO standards, as well as compliance with Part 21 Subpart O (e.g. the declaration of design and performance (DDP), ETSO marking, rating of performance, etc.). The ETSOA applicant should deliver a complete data package per point 21.A.605.~~

~~EASA's LoI is further reassessed and adapted throughout the certification project until the ETSOA is issued, depending on the applicant's data, as well as on the ETSO project changes regarding the applicant's compliance demonstration (e.g. methods, design changes, deviations, limitations, problem reports, etc.).~~

~~1. Principles~~

~~EASA's LoI in ETSO projects is defined based both on the responsibility of EASA to assess the applicant's demonstration of compliance, and on the risk evaluated, according to the following criteria:~~

- ~~the applicant's level of experience in the ETSO process and scope of work;~~
- ~~the applicant's level of performance in the ETSO scope of work;~~
- ~~the use of novelties in the technology/design or in the means of compliance; and~~
- ~~the complexity of the ETSO article.~~

~~1.1. Applicant's experience in the ETSOA process and scope of work~~

~~This Section addresses the experience of the applicant's organisation in the ETSOA process, as well as in the scope of the certification basis of the ETSO article, and of the related requirements. The presence of any of the following aspects contributes to EASA's identification of the risk related to the level of experience of the applicant in the ETSOA process, or to the scope of work of the article:~~

- ~~the applicant is new and has just applied for the acceptance of its procedures by EASA, or it is the first project of the applicant after EASA has accepted such procedures;~~
- ~~the organisation has changed significantly the agreed procedures; and~~
- ~~the scope of work of the ETSOA project (ETSO standards) is new to the applicant.~~

~~1.2. ETSOA applicant's performance within its scope of work~~

~~The ETSOA applicant's level of performance within its scope of work is evaluated using criteria that enable EASA to identify risks in the applicant's performance due to the following situations:~~

- ~~the applicant has deficiencies in the procedures that it uses to demonstrate compliance with the certification requirements;~~
- ~~the applicant has changed its methods or procedures to demonstrate compliance with the certification requirements;~~
- ~~the assessment of the applicant's compliance on previous projects in the same ETSO scope of work has revealed significant issues in complying with the certification requirements, in the completion of data, or in the repetition of errors;~~
- ~~the scope of work is new to the applicant's team at the facilities where the project is developed, or the team had significant issues on preceding projects;~~
- ~~EASA has not conducted an ETSOA project assessment of the applicant in the same ETSO scope of work for a long period (i.e. 2 or 3 years); and~~
- ~~the applicant did not regularly report minor changes or occurrences in a timely manner.~~

~~1.3. Novelty in the technology or in the means of compliance~~

~~A 'novelty' is understood to be the use of new technology, new sensors, new material, the use of new requirements or the use of new means of compliance. When an applicant is faced with a technology for the first time, or when that applicant is relatively unfamiliar with the technology, this is considered to be 'novel' even if other applicants may be already familiar with that technology.~~

~~Also related to novelty is the extent to which requirements, means of compliance or guidance need to be adapted due to particular novel features of the design. The following list includes some examples:~~

- ~~recently issued CS-ETSO standards, with which the applicant has limited experience;~~
- ~~novel deviations;~~
- ~~new guidance;~~
- ~~new means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices);~~
- ~~the use of new industry standards or new in-house methods, as well as EASA's familiarity with these new standards and methods;~~
- ~~changes in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs.~~

~~Technology or means of compliance may be new/novel either from a global industry, applicant or EASA perspective.~~

~~1.4. Complexity~~

~~Complexity may result from the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), as well as from the variety of ETSOs with which the applicant intends to comply, and their possible interactions.~~

~~The demonstration of compliance may be 'complex' for complex (or highly integrated) equipment, so it typically requires more effort from the applicant.~~

~~1.5. Criticality of the design and of the technology~~

~~The criticality levels of the design and of the technology of the ETSO article are considered, but have a minor impact on the definition of EASA's LoI. The main reasons are:~~

- ~~the assessment of ETSO compliance is as important for an ETSO article that hosts a critical function as it is for equipment that host less critical functions (e.g. flight data recorders); and~~
- ~~the criticality of the design or technology is not always defined for an ETSO article, and it may depend on the installation of the design or technology (e.g. a multifunction display), which may only occur later.~~

~~2. Determination of EASA's LoI~~

~~EASA's LoI in the assessment of the applicant's compliance demonstration is determined by EASA on the basis of the qualitative risk class and EASA's responsibilities in assessing the ETSO project certification data package, together with the procedures for compliance with the ETSO requirements (Part 21 Subpart O, and CS-ETSO).~~

~~EASA's LoI is defined in the following paragraph 2.1 and, as per point 21.B.100(c), the EASA's LoI that is applicable to each project is notified to the applicant.~~

~~To every LoI class corresponds a list of activities that govern EASA's involvement. By means of these activities, EASA verifies the demonstration of compliance (e.g. by document review and acceptance, test witnessing, sampling on the applicant's site, desktop assessments, etc.).~~

~~The ETSO applicant is responsible for providing a complete ETSO certification data package.~~

~~2.1. Definition of the LoI classes~~

~~EASA's LoI for an ETSO certification project is classified as one of the following:~~

- ~~class high,~~
- ~~class high reduced,~~
- ~~class medium, or~~
- ~~class basic.~~

~~Class 'high reduced' is, by default, EASA's initial LoI in an ETSO project.~~

~~The following is a description of each LoI class:~~

- ~~High~~

  ~~EASA evaluates and samples/checks in an extensive manner all the compliance data to assess the applicant's demonstration of compliance with the applicable ETSO standards. EASA assesses the applicant's DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews, as well as on-site assessments of compliance demonstrations. This occurs when design and verification evidence is available.~~

- ~~High reduced~~

  ~~EASA assesses all the compliance data; sampling/checking is significant and adapted to the likelihood of an unidentified non-compliance. The sampling rate may be reduced if the content of the life cycle data provides confidence in compliance and is focused in the area where confidence needs to be gained. EASA assesses the DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews, as well as an on-site assessment of the applicant's compliance demonstration. This occurs when design and verification evidence is available.~~

- ~~Medium~~

  ~~EASA assesses all the compliance data, but for some compliance data, it performs no or limited sampling/checking. EASA adapts its sampling and focuses on the likelihood of an unidentified non-compliance, taking into account the level of complexity and novelty of the project. EASA assesses the DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews and may perform an on-site assessment of the applicant's compliance demonstration.~~

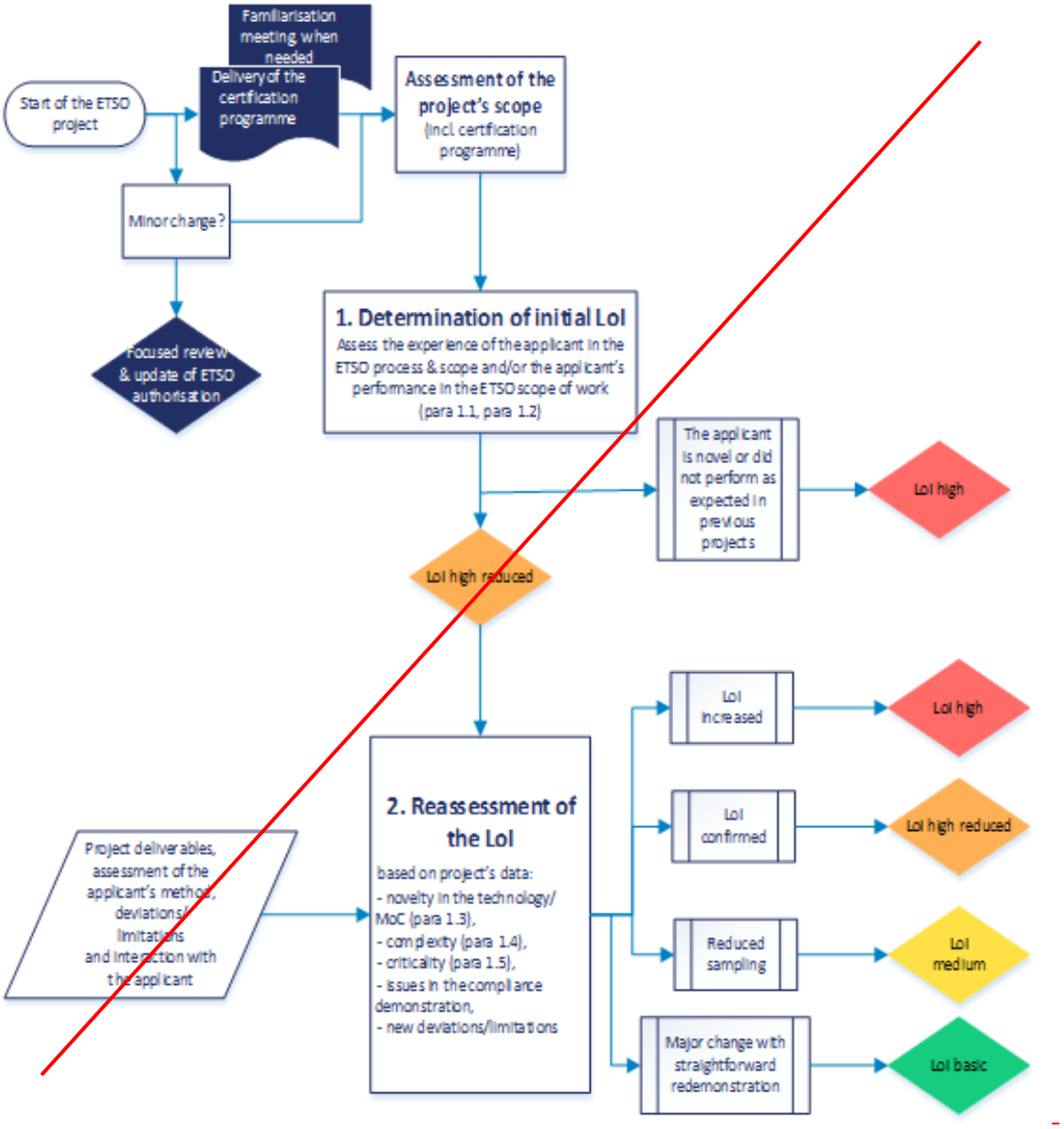
- ~~Basic~~

  ~~EASA assesses the DDP and general compliance with Part 21 Subpart O, and verifies the completeness of the data package.~~

~~Generally, EASA performs a desktop assessment.~~

~~3. The process of determining EASA's LoI~~

~~The determination of EASA's LoI is captured as a process. This process is performed mainly in three steps and is illustrated in the following figure:~~



~~Figure 1: Process of determination of EASA's LoI in ETSO certification projects~~

~~Step 1~~ ~~consists of the initial LoI determination which EASA evaluates by assessing:~~

— the applicant's experience in the ETSOA process and scope of work according to Section 1.1 above, and
— the ETSOA applicant's performance within its scope of work according to Section 1.2 above.

The result of this determination of EASA's initial LoI is either high or high reduced.

Step 2 consists of reassessing EASA's LoI. Throughout the ETSO project, EASA receives project deliverables (e.g. plans, reports), means of compliance, requests for deviations, limitations, etc., and interacts with the applicant.

If EASA's LoI has been initially set to high reduced, EASA re-evaluates it considering:
— the novelty in the technology or in the means of compliance according to Section 1.3 above, and
— the complexity of the ETSO project according to Section 1.4 above.

The result of this reassessment may vary from high to medium according to the following table:

Assessment results	**LoI adaptation**
The ETSO article is novel and complex or a significant issue is detected during the compliance demonstration.	LoI is increased to high.
The ETSO article is novel or complex or a new deviation is requested ([1]).	LoI is confirmed as high reduced.
The ETSO article is non novel and non complex, no issue is detected during the compliance demonstration or method, and no novel deviation or new limitation is requested.	LoI is decreased to medium.
There is a major change with straightforward redemonstration of the ETSO compliance ([2]).	LoI is reduced to basic.

[1] It refers to deviations from ETSO minimum operational performance standards (MOPSs), excluding deviations for requesting compliance with a new revision of an industry MOPS standard.

[2] When EASA agrees that a major change only requires a straightforward redemonstration of the ETSO compliance using previous methods, without any identified risk, then EASA's LoI is reduced to basic. Please note that this may only be defined after a minimum assessment of the applicant's compliance demonstration methods.

Note: For a minor change, this process does not apply; in that case, EASA's LoI consists of an assessment of the minor change classification, an update of the certificate, and, when needed, an assessment of the DDP.

AMC1 21.B.461 Registration of a declaration of design capability

REGISTRATION NUMBER

EASA should assign a unique and consecutive declared design organisation (DDO) reference number to the declarant.
EASA should publish an up-to-date list of the registered declarations of design capability. This list should include the declared scope of work of those declared design organisations.

AMC1 21.B.463 Oversight activities

(a) When determining the necessary oversight activities, the competent authority should consider in particular the following elements, as applicable:

(1) evidence collected during the investigation of the ETSO authorisation projects;

(2) results of past oversight activities, if available (i.e. assessments, audits, inspections or unannounced inspections);

(3) the overall volume of activities (e.g. minor anticipated changes); and

(4) changes to the declaration notified by the organisation (as per point 21.A.513).

(b) The competent authority should prepare procedures for the oversight activities that cover at least the following elements:

(1) identification of the investigation team;

(2) collection and review of evidence of projects and results of past oversight activities, as defined in point (a), above;

(3) assessment of the organisation documentation (declared design organisation handbook, procedures, etc.), especially in cases of notification of changes;

(4) definition of when auditing activities and inspections need to be conducted;

(5) sharing of the results of the oversight activities with the concerned organisation;

(6) notification of findings and follow-up of corrective actions (as per point 21.A.511); and

(7) recommendations for the amendment to or the temporary or permanent deregistration of the declared design organisation.

AMC1 21.B.433(d) and 21.B.465(d) Findings and corrective actions; observations

NOTIFICATION OF FINDINGS

[…]

AMC1 21.B.482 Level of involvement in ETSO authorisation projects

1. Definitions

Risk. The combination of the likelihood and the potential effect of non-compliance with part of the ETSO technical conditions.

Likelihood. A prediction of how likely an occurrence of non-compliance with part of the ETSO technical conditions is, based on a combination of the novelty and complexity of the proposed design and its related compliance demonstration activities, and on the performance of the design organisation.

Criticality. A measure of the potential impact of non-compliance with part of the ETSO technical conditions on safety.

Compliance demonstration item (CDI). A meaningful group of compliance demonstration activities and data of the certification programme, which can be considered in isolation for the purpose of performing a risk assessment.

EASA panel. A panel composed of one or more experts who are responsible for a particular technical area. Each technical area addressed during product certification is covered by an EASA panel.

EASA discipline. A technical subarea of an EASA panel.

EASA's level of involvement (LoI). The compliance demonstration activities and data that EASA retains for verification during the certification process, and the depth of the verification.

2. Background

The applicant has to submit a certification programme for their compliance demonstrations in accordance with point 21.A.605(a)(1). The applicant may break down the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred to as CDIs. The applicant may also provide their proposal for EASA's LoI.

Breaking down the certification programme into CDIs will allow the applicant to propose an EASA LoI for each CDI and will allow EASA to tailor its LoI to each specific discipline. This benefits both parties, as some CDIs may need lower LoIs than others.

When the applicant chooses not to break down the certification programme into CDIs, EASA's LoI will be defined for the entire project.

This AMC explains:

(a) how to propose EASA's LoI for each CDI and include it in the certification programme required as per point 21.A.605(a)(1);

(b) how EASA will determine its LoI on the basis of the criteria established in point 21.B.482(a) at the level of the entire certification project, or, if proposed by the applicant, at the level of meaningful groups of compliance demonstration activities and data of the certification programme.

EASA will review the proposal and determine its LoI. Both parties, in mutual trust, should ensure that the certification project is not delayed by the LoI proposal and determination.

Additionally, in accordance with AMC1 21.A.605(a)(1), the applicant should update the certification programme, as necessary, during the certification process, and in accordance with point 21.A.605(b) to report to EASA any difficulty or event encountered during the compliance demonstration process that may impact the ETSO authorisation, thus requiring a change to the LoI that was previously communicated to the applicant.

In such a case, or when EASA has other information that affects the assumptions on which the LoI was based, EASA will revisit its LoI determination.

In accordance with point 21.A.9, irrespective of the LoI, EASA has the right to review any data and information related to compliance demonstration.

Note: For minor changes, this process does not apply. In such cases, EASA's LoI consists of an assessment of the certification programme for the change (CPC) and the DDP, and, when needed, an assessment of supporting technical data.

3. Principles and generic criteria for the LoI determination

EASA determines its LoI based on the applicant's proposal taking into account the risk, focusing on the likelihood of unidentified non-compliance and the potential impact of an instance of non-compliance.

The potential impact of an instance of non-compliance may depend on the installation of the article and the assumptions made in the safety assessments. Criticality of the design or technology is not always defined for an ETSO article. For articles that do not have a defined criticality level, the potential impact of an instance of non-compliance is considered 'undefined' as per Section 3.3 of this AMC.

The LoI determination is performed, after adequate familiarisation with the certification project, in three steps:

— step 1: identification of the likelihood of unidentified non-compliance,

— step 2: identification of the risk class,

— step 3: determination of EASA's LoI.

This AMC sets out criteria in the following areas, common to all EASA panels involved in ETSO authorisation projects, which are used to determine the likelihood (and, when defined, the potential impact) of unidentified non-compliance:

— the performance and experience of the applicant and of the applicant's design organisation (when available);

— the use of novelties in the technology, design or means of compliance;

— the complexity of the ETSO article design or compliance demonstration;

— the criticality of the ETSO article, where applicable.

3.1. LoI determination at the project/CDI level

The determination of EASA's LoI is performed at the project level or, if proposed by the applicant, at the CDI level.

The applicant should demonstrate that all the ETSO technical conditions, the corresponding means and methods of compliance, and the corresponding certification activities and data are fully covered by the proposed CDI(s).

3.2. Method for determining the likelihood of unidentified non-compliance

3.2.1. Principle

The likelihood of unidentified non-compliance is assessed on the basis of criteria in the following areas:

— the performance and experience of the applicant and of the applicant's design organisation (when available);

— novelty;

— complexity.

3.2.2. Performance of the applicant and of the applicant's design organisation

As per point 21.A.602(b), the design organisation of an ETSO applicant is either a declared design organisation under Subpart N or an approved design organisation under Subpart J.

3.2.2.1. Declared design organisation

For declared design organisations, the assessment by EASA that the organisation procedures are properly applied is performed solely through the various ETSOA projects of the applicant. No regular audits of the organisation are performed by EASA.

The level of performance of the organisation is therefore considered as unknown.

3.2.2.2. Approved design organisation (DOA)

For approved design organisations, the assessment of the level of performance of the organisation takes into account the applicant's experience with the ETSO authorisation process, including their performance on previous projects and their degree of familiarity with the applicable ETSO technical conditions.

AMC 21.B.100(a) and 21.A.15(b)(6), Section 3.2.4 'Performance of the design organisation', should be considered for the proposal and determination of the performance level of the organisation.

3.2.3. Novelty

For the purpose of the LoI determination, a CDI may be either novel or non-novel.

The determination that a CDI is novel may be driven by the use of new technology, new sensors, new material, new requirements or new means of compliance.

When an applicant is using a technology for the first time, or when that applicant is relatively unfamiliar with the technology, this is considered 'novel' even if other applicants may already be familiar with that technology. Also related to novelty is the extent to which requirements, means of compliance or guidance need to be adapted due to particular novel features of the design.

The following list includes some examples:

— the use of recently issued CS-ETSO standards, with which the applicant has limited experience;

— novel deviations;

— the use of new industry standards or new in-house methods, as well as considering EASA's familiarity with these new standards and methods;

— the use of new means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices);

— changes in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs; technology or means of compliance may be novel from a global industry perspective or the perspective of the applicant or EASA.

3.2.4. Complexity

For the purpose of LoI class determination, a CDI may be either complex or non-complex.

The determination of whether the CDI is complex or not may vary based on factors such as the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), as well as from the variety of ETSOs with which the applicant intends to comply, and their possible interactions.

The demonstration of compliance is considered complex for complex (or highly integrated) equipment, for example, that typically requires more effort from the applicant.

For major changes, the complexity of the change, rather than the complexity of the original system, should be taken into account.

Whether or not a CDI is complex should be determined in a conservative manner if it cannot be determined at an early stage of the certification project. When greater clarity has been achieved, the complexity may be re-evaluated and the LoI adapted accordingly.

3.2.5. Likelihood of unidentified non-compliance

Assessing the likelihood of unidentified non-compliance is the first step that is necessary to determine the risk class.

The likelihood of unidentified non-compliance should not be confused with the likelihood of occurrence of an unsafe condition as per AMC 21.A.3B(b). In fact, that AMC provides EASA's confidence level that the design organisation addresses all the details of the certification basis for the CDI concerned, and that non-compliance will not occur.

The likelihood of unidentified non-compliance is established as being in one of four categories (very low, low, medium, high), depending on the level of performance of the design organisation as assessed by EASA and on whether the CDI is novel or complex, as follows.

Step 1 — Likelihood of unintended non-compliance			
	CDI		
Performance level of the design organisation	No novel aspects, no complex aspects	No novel aspects, but complex ones Novel aspects, but no complex ones	Novel and complex aspects
High	Very low	Low	Medium
Medium	Low	Medium	High
Low or unknown	Medium	High	High

3.3. Method for determining the risk class

This second step will assess the criticality of the article, for the intended installation, as defined in the certification programme.

For the purpose of LoI class determination, the impact of an instance of non-compliance can be critical, non-critical or undefined.

Failure conditions 'hazardous' and 'catastrophic' will be considered critical.

Development assurance levels A and B for AEH and software will be considered critical.

The 'undefined' category applies to ETSO articles with undefined failure classification conditions or an undefined development assurance level. Most of the ETSO articles will fall under this category as there is limited or no knowledge of the intended installation of such articles.

Step 2 — Risk class				
Criticality	Likelihood (see Section 3.2.5)			
	Very low	Low	Medium	High
Non-critical	Class 1	Class 1	Class 2	Class 3
Critical	Class 1	Class 2	Class 3	Class 4
Undefined	Class 1	Class 2	Class 3	Class 4

The various inputs and the resulting risk class determination are of a continuous nature, rather than consisting of discrete steps. The selected risk class provides the order of magnitude of EASA's involvement and is used as a qualitative indicator for the determination of EASA's involvement described in Section 3.4 below.

Under specific circumstances, the risk class that is determined on the basis of the above criteria may be reduced or increased on the basis of justified and recorded arguments. For a reused and well-proven item of compliance demonstration meeting the following conditions, the CDI may be accepted as being similar, resulting in a reduced LoI, as the likelihood of unidentified non-compliance is low:

— the design and qualification of the ETSO article are basically the same; and

— the ETSO authorisation process is identical to the one that was used in a change already approved by EASA.

Furthermore, when an identical CDI is reused for the compliance demonstration in a new project, there is no EASA involvement in the compliance demonstration verification, as the likelihood of unidentified non-compliance is very low.

3.4. Determination of EASA's LoI (Step 3)

EASA's LoI in the verification of compliance demonstration is proposed by the applicant and determined by EASA in step 3 on the basis of the qualitative risk class identified per CDI in step 2, as well as by applying sound engineering judgement.

EASA's LoI is reflected in a list of activities and data, in which EASA retains the verification of compliance demonstration (review and acceptance of compliance data, witnessing of tests, etc.) and the depth of the verification. The depth of the verification for individual compliance reports, data, test witnessing, etc., may range from spot checks to extensive reviews. EASA always responds to those retained compliance demonstration activities and data with corresponding comments or a 'statement of no objection'.

In addition, some data that is not retained for verification may be requested for information. In this case, no 'statement of no objection' will be provided.

It is recommended that an LoI should be proposed for each of the EASA disciplines involved. Depending on the risk classes determined in Section 3.3 above, EASA's LoI in:

(a) compliance demonstration verification data; and

(b) compliance demonstration activities (witnessing of tests, audits, etc.),

may be as follows:

— Class 1: there is no EASA involvement in verifying the compliance data/activities performed by the applicant to demonstrate compliance at the CDI level;

— Class 2: EASA's LoI is typically limited to the review of a small portion of the compliance data; there is either no participation in the compliance activities or EASA participates in a small number of compliance activities (witnessing of tests, audits, etc.);

— Class 3: in addition to the LoI defined for Class 2, EASA's LoI typically comprises the review of a large amount of compliance data and participation in some compliance activities (witnessing of tests, audits, etc.); and

— Class 4: in addition to the LoI defined for Class 3, EASA's LoI typically comprises the review of a large amount of compliance data, the detailed interpretation of test results and participation in a large number of compliance activities (witnessing of tests, audits, etc.).

By default, EASA will always assess and retain the DDP, regardless of the risk class.

If the risk assessment (steps 1 and 2 above) is made on the level of a compliance demonstration activity or on the level of a document, the risk class provides an indication of the necessary depth of the involvement — that is, the verification may take place only for certain compliance data within a compliance document.

4. Documentation of the LoI

The LoI proposal in the certification programme should include the applicant's proposal regarding the compliance demonstration verification activities and data that would be retained by EASA, as well as the data on which the LoI proposal has been based. For this purpose, the applicant should appropriately document the analysis per CDI, considering the above criteria.

In cases where the rationale for the assessment is obvious, it is considered sufficient for the applicant to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

EASA documents the LoI determination by accepting the certification programme or, if it deviates from the proposal, by recording its analysis regarding the deviations from the proposal and notifies the applicant accordingly.

5. Sampling during surveillance of the applicant

It should be noted that all the previously defined risk classes may be complemented by the sampling of project files during surveillance of the DOA holder, independently of the ongoing certification project. This is necessary in order to maintain confidence in the DOA system and to constantly monitor its performance.

For the declared design organisation, no systematic surveillance activities are performed by EASA. This is reflected in the performance level determination described in Section 3.2.2. Nevertheless, issues observed during ETSO authorisation projects regarding the LoI proposal may trigger declared design organisation oversight activity and/or the raising of findings and/or observations.