Applicants for ETSO authorisations are required by EASA Part 21.A.602B (b) 2 to demonstrate design capability in the form of Alternative Procedures to Design Organisation Approval (AP to DOA) or by holding an appropriate EASA Part 21 Subpart J Design Organisation Approval – (see dedicated guidance material). EASA certifies this demonstration of design capability by issuing a Finding of Compliance to the applicant.

**These procedures must be concise and limited to the information needed for quality and proper control of activities by the applicant/holder, and by EASA.**

This Manual template is intended to assist applicants in applying for EASA acceptance of its AP to DOA and therefore demonstrating the required design capability. The guidance is assuming the applicant is based in an EASA member state and holds a Part 21G Production Organisation Approval. If the applicant’s situation differs from these assumptions, certain guidance may not apply in full, and such peculiarities should be discussed with EASA on a case-by-case basis.

Each section contains guidelines (blue text) explaining what content is expected in that specific chapter. Below the guideline is placed [TEXT HERE] to highlight that the applicant should develop its own content. The blue text should be deleted as it is not intended to be part of the final document.

The required information can be entirely presented in this manual, or in external procedures appropriately identified and referred to in this document.

However, to ensure proper control of approved alternative procedure revision levels, any referenced procedures need to be listed (along with their revision level) in the Appendix at the end of this document.

The Manual and the referenced procedures should be written in the most suitable language for people dealing with it. An English translation is welcome and helps in speeding up the process.

A cover page should be established for this document, capturing as minimum the following information:

* AP to DOA approval number;
* document title;
* document reference number;
* overall issue/amendment status;
* document approval signatory flow (if applicable)

# Manual Administration

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##  Manual Administrator

The official title and contact details of the person responsible for the administration of the manual must be stated. The nominated person is responsible for ensuring that the manual is distributed, controlled, and amended or reissued as necessary. Any need for amending this manual should be notified to the Manual Administrator, to be identified in this section:

**Forename SURNAME:**

Position/Title within the Organisation:

Address / location:

Phone number:

Email:

[TEXT HERE]

##  Issue / Amendment procedure (ref. 21.A.609 (g))

The Issue/Amendment procedure must describe the update mechanism of the manual and related procedures, in relation with the nature of changes, impacting or *not* impacting the showing of compliance with Part 21.

A **new** **issue** is necessary when the manual is introducing changes which are impacting the showing of compliance with Part 21, like a **change to the scope of work** of the AP to DOA Holder (e.g. a new ETSO Authorisation (ETSOA), or additional technical fields, such as the introduction of composite materials, etc.), or **changes to the design practices, resources, sequence of activities** (e.g. the organization structure, or a procedure principle, etc.) or **changes, other than above, affecting the content of the previous EASA Finding of Compliance** (e.g. company name, company address, manual/procedures reference numbers, title or issue/date). All **new issues** of the manual or its referenced procedures must be submitted to EASA (Form FO.DOA.00081) for approval.

**Amendments** to the manual are all ‘*documentary changes’* not impacting the showing of compliance with Part 21, including changes to the list of Authorised Signatories (see section 1.5.2). All **amendments** to the manual or its referenced procedure should be provided to EASA for information only.

This section should explain how these kind of changes are managed (explanation concerning the issue/amendment policy) and are identified in the content of the manual (e.g. vertical side-bars and amendment level of the page).

Also a significant change to a procedure referenced to in the Appendix 3.1 of this manual shall require a new issue of both the procedure and this manual.

EASA is requesting the company to put in place this dual index system (Issue & Amendment) to avoid too frequent changes of the EASA AP Finding of Compliance. Indeed, this Finding of Compliance only retains the Issue number of the Handbook. Therefore, in case of Amendment, no re-issue of the EASA AP Finding of Compliance is needed.

***Note****: Although this dual index system is not required for associated documents (procedures or forms), it is however recommended for the traceability of the revision classification (significant vs. not significant) of these documents, which must also be ensured in the relevant log of procedure.*

Below is an example of a decision flow chart, showing how an update procedure could be presented.

[TEXT HERE]



## List of Effective Pages

If applicable (see 0.5 Log of Revisions below), a list of pages, with their individual issue and amendment status, should be incorporated here.

Example (the actual list must state each and every page)

|  |  |  |
| --- | --- | --- |
| **Page** | **Issue** | **Amendment** |
| 1 | 2 | 3 |
| 2 | 2 | 2 |
| … | … | … |
| 45 | 2 | 0 |

[TEXT HERE]

## Log of Revisions

This chapter shall describe in details how new issues/amendments are indicated on each and every page. If each and every page always share the same issue/amendment status as the overall manual status, it is recommended to maintain just the Log of Revisions, and delete the List of Effective Pages in 0.4 above.



The Log of Revisions shall provide a listing of the manual issues & amendments including a short but complete description of all the changes to the manual. The sample table below can be used to summarise the issue/amendment evolution, tracing the changes in the affected paragraphs.

|  |
| --- |
| **Log of Revisions** |
| **Issue** | **Amendment** | **Date** | **Description** |
| 1 | 0 | DD/MM/YYYY | Initial Issue (ref. Form 81 dated) |
| 1 | 1 | DD/MM/YYYY | Documentary changes, affected paragraphs: … |
| 2 | 0 | DD/MM/YYYY | New Form 81 dated ….: changed scope of work by adding ETSO CYY, affected paragraphs: … |
| … | … | … | … |

[TEXT HERE]

## Distribution List

This paragraph should address the distribution of the manual. Holders of a controlled copy of the manual should be identified. The manual should describe how all subsequent amendments and re-issues of the manual and its referenced procedures will be supplied to the holders of the controlled copies. Please also make sure that the EASA focal point for your AP to DOA (DOA Team Leader) and the National Aviation Authority focal point for your POA (POA Team Leader) are included in this list.

Furthermore, it should be described where the master hard copies and/or the master electronic copies are stored, and how design organisation staff are provided access to the manual. If the manual is published in a company intranet or equivalent, the manual should describe how employees are made aware of changes to the manual or associated documents (procedures/forms).

[TEXT HERE]

# Organisation

## Purpose of the Manual

This chapter should describe the purpose of the manual, as the inherent procedures are meant to provide guidance for the company’s personnel. Furthermore, a short introduction to the company’s ETSO articles (to which this manual applies) should be given.

[TEXT HERE]

## Statement of Commitment

This section must contain a statement by the organisation’s Chief Executive, declaring that the organisation will comply with the AP to DOA.

**Example**: W*ith reference to EC Regulation No. 2018/1139, EC Regulation No. 748/2012 and its Annex Part 21, this manual defines the organisation and procedures upon which the EASA AP Finding of Compliance against 21.A.602B (b) 2 is based.* *These procedures are approved by the undersigned and must be adhered to as applicable when the organisation is performing the functions for which the AP Finding of Compliance is granted.*

In case of a new Issue of the Manual, this Statement of Commitment has to be dated and signed again by the organisation’s Chief Executive.

[TEXT HERE]

## Details of the Organisation

This section should give brief general information about the organisation's structure, staff numbers, premises and history. The scope of the organisation undertakings, at the address(es) of the (various) premises, should be described. Where appropriate, relationships with other organisations forming part of the same group should be mentioned.

[TEXT HERE]

### Organisational chart(s)

Please provide here charts of:

* the **overall company** (including also the link and reporting lines between the company’s Design Organisation and Production Organisation); and
* the **design organisation** (AP to DOA) showing chains of responsibility of nominated design staff. (Optional link with the Quality function, only if applicable)

Depending on the size and (non-)complexity of the organisation, these charts may be combined or presented separately (as appropriate).



[TEXT HERE]

### Interface with the Production Organisation

The interface between design and production should be introduced. Highlight whether the design and production are within the same company or separate entities. Provide the document reference number(s) for the DO-PO arrangement(s), if applicable, and identify the POA approval number(s). Please shortly describe who is in charge of implementing the DO-PO procedures (as described in chapter 2.3.7 of this manual).

[TEXT HERE]

### Nominated Personnel

Key positions in the design organisations should be introduced, as well as an overview of all the functions within the design organisation. Brief terms of reference of nominated personnel need to be provided; tasks & responsibilities and internal\* qualification requirements. Eventual references to external documents are acceptable (e.g. job descriptions in personnel records).

*\** ***Note****: it is suggested to make use of the existing internal quality management system to define the above mentioned qualification requirements.*

A listing of all nominated personnel, their positions in the company and their names should be available. It is recommended **not** to include this list in the manual itself but as a separate list, to have a more flexible documentation system – see Appendix 3.2.

[TEXT HERE]

## Scope of work

This section must list the CS-ETSO (number and title) standards for which the applicant is seeking to demonstrate design capability for; this information should be the same as indicated on form FO.DOA.00081.

***Note****: In general it is not necessary to indicate the revision status of the CS-ETSO, as otherwise each revision of the CS-ETSO standard would trigger a Significant Change to the AP to DOA. However for some ETSO standards (e.g. ETSO-C127) it might be necessary to identify in this section also the Revision letter of the ETSO standard, due to the significant evolution of the ETSO standard. Please consult with your DOA Team Leader for your specific Scope of Work.*

Example

|  |
| --- |
| ETSO Scope of Work |
| ETSO-C1 | Cargo compartment fire detection instruments |
| ETSO-C2 | Airspeed instruments |
| … |  |

[TEXT HERE]

## Authorised Signatories

This section needs to contain an overview of the kinds of documents (to be) created by the design organisation, and the identification of all personnel authorised to sign those documents. The listing of these Approved Signatories may be included directly within this section or as a separate list (see the example template in Appendix 3.2). The list should report their names, function in the company, and sample signatures.

[TEXT HERE]

### List of documents

For the list of documents should be considered:

* **Classification of design changes and repairs** to an ETSO article (see section 2.2.2 of this template)
* **Classification and approval of unintentional deviations** from approved design data occurring in production (see section 2.2.6 of this template).
* **Certification Programme** (see section 2.1.2 of this template).
* Compliance Matrix (if not included in the Certification Programme; see section 2.1.2 of this template)
* **Approval of the implementation of minor design changes and repairs** to an ETSO article (see section2.2.4 of this template)
* **Compliance documents** (see section 2.1.4 of this template)
* **Declaration of Design and Performance (DDP)** as per 21.A.605(b) (see section 2.1.4 & DDP template published as separate guidance material)
* Documentation used to issue **Information and Instructions** to users of ETSO articles, e.g. ICA and Service Bulletin (see section 2.3.3 of this template)
* **(Component Maintenance) Manual** (see section 2.3.2 of this template)
* **Statement of Calibration** for testing equipment (see section 2.1.6 of this template)
* **Statement of Conformity** for test article / specimen (and test set-up, if applicable) (see section 2.1.6 of this template)
* **Classification of failures, malfunctions, or defects** (see section 2.3.5 of this template)

**Example** of authorisations table:

|  |
| --- |
| **AUTHORISATIONS** |
| **Signatories** | **Prepare** | **Check** | **Approve** |
| Head of Engineering |  |  | (1), (3-7) |
| Certification Engineer | (1), (5), (7) | (1), (3-7) |  |
| Design Engineer | (1), (3-7) |  |  |
| Function X | (2), (8), (9) | … | … |
| **Type of documents (to be made consistent with the list above)**1. Compliance document type No. 1
2. Certification Programme and Compliance Matrix
3. Classification and approval of anticipated changes and production deviations
4. (Component Maintenance) Manual and other ICA
5. DDP
6. Classification of failures, malfunctions, or defects
7. Service Bulletins
8. Statement of Conformity
9. Statement of Calibration
10. .......
 |

As good practice, it is recommended to define such an authorisation policy, that a person preparing a document cannot check the same document, known as the ‘***four-eye principle’***.

In case of ‘delegations’, a policy should be clearly addressed and explained. A delegation policy may be used to ensure continuity of the design activities in case of temporary absence of responsible staff.

[TEXT HERE]

### Change of Authorised Signatories

Each Nominated Person (clearly identified in the organisation description) could act as Authorised Signatory for one or more type(s) of document(s). The Company should define the process for the appointment of any nominated person who has an Authorised Signatory role. (See section 1.3.3)

Changes in the List of Authorised Signatories should not trigger a Significant Change (see section 0.3); however, the DOATL and the PCM should be formally notified before implementation of new or changed authorizations; usually by providing the updated list (Appendix 3.2) via e-mail.

[TEXT HERE]

# Procedures

The **technical and administrative procedures, covering all aspects of work conducted under these AP to DOA,** should be provided, to show how matters affecting airworthiness are controlled and that full and efficient coordination exists between technical departments and disciplines.

## Management of the ETSO Authorisation Process

### Application for ETSO Authorisation (ref. AMC 21.A.602B(b)(2), section 2)

The initial process of applying to EASA for an ETSO Authorisation should be described, including the proper identification of the EASA communication tools.

1. The application for an ETSO Authorisation shall be filed in the EASA Applicant Portal
[<https://portal.easa.europa.eu>].
2. The exchange of technical data should be managed through SEPIAC.

The procedure should identify which documents are submitted at the time of the application, or shortly hereafter (e.g. the Certification Programme - per section 2.1.2 – with as minimum the elements a. through d.), and which documents will be submitted at a later stage of the ETSO Application process (e.g. DDP).

The procedure should indicate the timing for submittal to EASA, for all the (technical) data required by 21.A.605 and the ETSO standard.

**At the time of the application the organisation should verify if subject application is covered by their current approved scope of work**. Appropriate provisions should be put in the procedure, to enable the staff in checking the scope of work.

[TEXT HERE]

### Certification Programme (ref. AMC 21.A.602B(b)(2), section 2)

The certification process to obtain an ETSO Authorisation (ETSOA) should be described. It starts with the submission of a Certification Programme to EASA describing the process that will be followed to ensure that requirements of the relevant CS-ETSO will be met.

Details of the format and typical content of a Certification Programme need to be presented in this section, [see additional guidance below \*].

All revisions of the Certification Programme must be submitted to EASA for acceptance.

The procedure should set guidelines for the Certification Programme to:

1. describe the ETSO article and the certification basis, identifying the expected deviations and limitations;
2. provide information for EASA to define its involvement in the verification of the compliance demonstration process (e.g. review of compliance documents or data, witnessing of tests, audits, etc. …), [see additional guidance below \*\*];
3. include a time-schedule, defining the main milestones and the decision process, especially the key-points where an Agency decision/involvement is needed before further action. Keep in mind, that i.a.w. Part 21.A.615, the EASA PCM or Expert has the right to witness any test and inspect any technical data file; and that therefore, the opportunity should be offered within the project schedule and through proper advance notification. Such a schedule should be controlled and updated as necessary throughout the project;
4. define the information or data to be delivered to EASA along the project;
5. record (the reference to a document describing) the product characteristics and intended performances (including the ETSO standard number). This document (e.g. product technical specification) shall be provided to EASA;
6. define means of compliance to the ETSO requirements (e.g. Compliance Checklist / Matrix), [see additional guidance below \*\*\*];
7. identify associated compliance documentation and give relevant due dates for its submission in the time-schedule.

\* **Certification Programme template**

A template for the Certification Programme may be found on EASA website: <https://www.easa.europa.eu/easa-and-you/aircraft-products/alternative-procedures-design-organisation-approval-adoa>

**\*\* EASA’s Level of Involvement (LOI)**

Through the Commission delegated Regulation (EU) 2019/897 has been introduced into EASA Part 21 the process for determining EASA’s Level of Involvement. For ETSOA projects is applicable AMC No 2 to 21.B.100(b).

EASA’s Level of Involvement will be determined by the PCM & Experts based on the following criteria:

1. the applicant’s level of experience in the ETSO process and scope of work;
2. the applicant’s level of performance in the ETSO scope of work;
3. the use of novelties in the technology/design or in the means of compliance; and
4. the complexity of the ETSO article.

In order to support this assessment, the applicant is invited in particular to highlight aspects of novelty & complexity applicable to the ETSOA application in the Certification Programme. This should be captured in the procedure for preparing the Certification Programme as well as in the Certification Programme template.

The procedure shall also state, that unexpected difficulties / events during the compliance demonstration (refer to 21.A.605(b) & GM 21.A.605(b)) must be communicated to EASA as it may lead to a re-assessment of the LOI.

***Note****: Recent modification in the Authorised Signatories List (see section 1.5.2) might affect the PCM evaluation of the applicant’s level of experience in the ETSO process and lead to a reassessment of the LOI.*

**\*\*\* Compliance Checklist/Matrix**

The Compliance Checklist could be embedded within the Certification Programme or can be compiled as a separate document (then to be provided together with the Certification Programme). The purpose of the Compliance Checklist is to create a single overview of all the **certification requirements**, (as defined in the minimum performance requirements of the ETSO standard), and to identify for each requirement the **Means of Compliance** and the reference to the relevant **compliance document(s)** for each specific requirement and the compliance status. This document serves to capture (define) the agreement between the applicant and EASA on the proposed Means of Compliance per certification requirement, and helps to identify any possible source for disagreement at an early stage of the application. An example of a Compliance Checklist/Matrix is presented below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ETSO requirement reference (2) | Requirement title | Means of Compliance/ procedure ref. | Evidence Report | Compliance statement(1) | Comments |
| *CS-ETSO Cxxx §3.1.1 Minimum Performance Standard*🡪detail here the MOPS requirements for example: |
| ED-72A §3.1.5.1 | Tracking through Normal Manoeuvres | HVP § 2.1.3 | HVR §4.3.2 | C |  |
| AS 8034A §4.2.1 | Viewing angle | QTP §3.2.5 | QTR §4.2.3 | C |  |
| … |  |  |  |  |  |
| *CS-ETSO Cxxx §3.1.2 Environmental standard**CS-ETSO Subpart A §2.1* 🡪detail here the applicable DO-160 requirements for example: (3) |
| DO-160F §4.5.2 | Operating Low temperature | QTP §3.5.3.1 | QTR §5.6.3.3 | C |  |
| … |  |  |  |  |  |
| *CS-ETSO Cxxx §4 Marking*  |
| 4.1 | General Marking requirement | P/N xxx Labelling procedure | P/N xxx Nameplate drawing issue 01  | C |  |
| 4.2 | Specific | … |  |  |  |

(1) Compliance statement can be either: Compliant (C), Partially Compliant (PC),
 Not Compliant (NC), Deviation (D), or Not Applicable (N/A).

(2) Demonstration of compliance with ETSO-Cxxx requirements in §3.1.3, Software, §3.1.4, Airborne Electronic Hardware, and §3.2.1, Failure Conditions Classification, is not part of this ETSO Compliance Checklist/Matrix, but a specific, separate chapter is to be included in the Certification Programme and also in the DDP.

(3) It is not permissible to mix DO-160 revisions within a given qualification programme.

[TEXT HERE]

### Design Processes (ref. AMC 21.A.602B(b)(2), section 1)

In accordance with **AMC 21.A.602B(b)(2), section 1**, this section should give an overview of the design processes used by the organisation. The steps of the process and the associated logic and time sequence shall be described. References to already existing organisation procedures and use of flowcharts to graphically illustrate work-flows, are strongly encouraged (see some simple examples below). The procedure should highlight typical milestones of the organization design process, e.g. checkpoints, design reviews, certification steps (demonstration of compliance), etc.

The organization of the work, interfaces between departments and multi-disciplinary subjects shall be described (e.g. design engineers vs certification engineers, design engineers vs production engineers, electrical systems vs mechanical systems, etc.).

The use of standard forms/templates and registers/databases is encouraged, especially for the circulation of data/information between different departments (e.g. a form for the classification of changes, a register of on-going and approved projects, and a register of design staff, with the identification of job title/function, etc.)

The use of a time-schedule to plan and control the accomplishment of the design related tasks in due time, shall be described. Responsible persons for the preparation, recording and update of this time-schedule shall be identified. Format and location of the file containing this time-schedule should be incorporated to assist the internal and external coordination of the team working on the project.

|  |  |  |
| --- | --- | --- |
| “Design process flow” |  | “Certification steps” |
|  |  |  |

[TEXT HERE]

### Compliance Documents (ref. AMC 21.A.602B(b)(2), section 2)

This procedure should explain how compliance documents are created, addressing the various kind of documents to be produced, e.g. reports, analyses, drawings, statements, etc. The procedure should also mention (directly or by cross reference with section 1.5) who is authorised to create, modify or approve certain compliance documents. It should also be made clear, that ‘draft’ documents should *not* be sent to EASA; only properly checked and approved documents should be forwarded outside the company.

The applicant must establish the procedure in such a way that:

* the kind of compliance document and the technical objectives for each document are determined at the beginning of the process;
* the preparation, verification and approval of the documents is carefully managed all along the process, in accordance with the milestones defined in the certification programme;
* the various issues of compliance documents are controlled.

Each compliance document must contain:

* the reference of the requirements covered by the document,
* data demonstrating compliance and
* a statement by the applicant declaring compliance with these requirements.

A numbering system to identify the compliance documents must be defined, in order to have an adequate link with the Compliance checklist, or as defined in the Certification Programme (see section 2.1.2).

All compliance documents must be produced before issuance of the final statement of compliance, as required by 21.A.605(a) and included in the DDP.

Templates for the different types of compliance documents, indicating minimum content and compiling guidelines, are encouraged.

[TEXT HERE]

### ETSO article identification (ref. 21.A.603, 21.A.611)

The part numbering system for ETSO articles shall comply with the requirement of 21.A.611 and should be described in this section. When **a series of minor design changes to** ETSO articles **is anticipated**, the applicant should set forth the basic model number and the associated part number with *‘open brackets’* after it, to denote that different, to be defined, ‘suffix change’ letters and/or numbers will be added from time to time. Amendments to the top assy part numbers of the ETSO articles could also be used as per 21.A.611 (a) to introduce anticipated changes or to submit for approval to EASA changes that have *not* been anticipated.

The applicant is also encouraged to define a range in basic model numbers to ease the management of changes which are Major ETSO changes (i.e. new ETSOA), but which are resulting in interchangeable parts at installation level.

**Before** the application for an ETSOA, the applicant should identify possible minor changes to the ETSO article. Such identification has to be based on classification criteria which are incorporated in this manual at section 2.2.2.

The ‘suffix change’ letters and/or numbers, and the amendment levels, if used, shall be added/updated from time to time in the Product Technical Specification or in an equivalent document that is referenced to in the Declaration of Design and Performance (DDP); see paragraph 2.3.4 for further details.

The Technical Specification, or an equivalent document, reporting the ‘suffix change’ letters and/or numbers used, and the current amendment levels, shall be submitted to EASA (ETSO Section) periodically.

Eventual procedure updates introducing additional minor anticipated changes via the introduction of new open brackets or modified significance of the ‘suffix change’ letters and/or numbers, effecting the part numbering system, shall be forwarded to EASA (DOA Section) for approval via EASA form FO.DOA.00081.

On the next page is an example given of *‘applying the open bracket system’* for an **anticipated series of minor changes** in the format of a flowchart, providing further clarification.

***Note:*** *Each time additional open brackets with new suffix change letters and/or numbers significance are added for the introduction of new anticipated minor design changes to the ETSO article, EASA will verify if the applicant has properly classified the type of change, and that the appropriate demonstration of compliance, associated with that type of change, has been carried out and documented.*

*If the part numbering system is updated over time, the description of the ‘old’ part numbering system should also still be kept, as long as it would still apply to existing (still flying) ETSO Authorisations. The procedure should then clearly describe the applicability of the different part numbering systems.*

 

**Example (continued):**

Basic Model Number: 21F123

Part Number Structure: 21F123-(XX)-(YY)-(ZZ)

 customer minor options

 software minor changes

 hardware minor changes

The part numbering system shall define:

* the logic for the basic model number (e.g. “21F” is fixed for ETSO product line 1;
“123” is a running number for different main configurations), including a description of how different product lines would be numbered,
* the meaning of each bracket (definition of the kind of anticipated changes for which each open bracket will be used (e.g. a running number, or which specific meaning a certain bracket or digit has),
* the number and type of digits within a bracket (alphabetic, numeric or alphanumeric)

[TEXT HERE]

### Configuration Control (ref. 21.A.603, 21.A.611, AMC 21.A.602B(b)(2), section 2)

The process for configuration control of ETSO articles should be incorporated in this section; the procedure for identification of the article design and of changes to the article, on assembly and on sub-component level of the article, shall be described.

ETSO article design configuration is defined via the drawings, schematics, configuration of the (complex) electronic hardware and the software (if any), specifications, and a listing of those data in a hierarchical structure. Each (part of) the ETSO article and its configuration shall be adequately and uniquely identified (reference numbers, revision levels, etc.) with a numbering system. The configuration of the article design is controlled by the recording and maintenance of the traceability of the design data of all the parts and sub-components that build up the article with the appropriate use of a defined issue/revision policy for each document that defines the design.

Use of a parts list, containing all article (sub-)components in a hierarchical structure, with their current revision level, is an acceptable means for controlling the configuration.

In terms of configuration control, changes to the ETSO article could be of three types:

1. a change to a component of the article that does *not* affect form, fit or function of the component itself;
2. a change to a component of the article that affects form, fit or function of the component and eventually of the next higher assembly containing the component;
3. a change to the ETSO article that triggers the generation of a new article Part Number.

**The identification of the change should not be mixed with the necessary classification; in other words, changes of each of the 3 identified types can lead to either a minor or major classification, depending on the change itself and how it affects the compliance demonstration and the need for investigation (as per 21.A.611 – see section 2.2.2). All 3 types of change described above can be performed on a certain ETSO article and under the same ETSO Authorisation, provided they are classified minor. If a change, independent of its defined type, is classified as major a new application for ETSO Authorization is required and a new Basic Model Number is expected.**

Control of the configuration will also support the task of the production organization to associate to each produced ETSO article a S/N corresponding with the specific article design configuration.

**Compliance** of design data with applicable ETSO standard requirements shall not be confused with the **conformity** of a produced ETSO article with the design data; (see the flow chart below).



***Note:*** *for the compliance demonstration activity, control of the configuration of the prototype or test article/specimen (and also of the adequacy and calibration of test and measuring equipment), is needed, in order to document that the tests performed are representative for the actual design of the ETSO article. This can be achieved through Statements of Conformity for the prototype or test article/specimen (and test set-up, if applicable) and Statements of Calibration for the measuring and test equipment. In case of production deviations, these must be listed on the Statement of Conformity for the prototype or test article.*

The flow chart on the next page is an example of how the traceability of the design configuration could be achieved.

**TRACEABILITY OF DESIGN CONFIGURATION**

 

***Note****: in this example the revision levels of the Article Part Numbers always coincide with the Top Assy Drawing revision levels and with the revision levels of the associated Master Drawing Lists, since a change to a component will always trigger an update of the Master Drawing List and an increment of its revision level, that consequently will require an update of the Top Assy Drawing and an increment of its revision level.*

[TEXT HERE]

### Problem reporting process

Applicant needs to have in place a system to collect problem reports (for issues identified during design/development), capture their investigation, and to address resolution and rationales for closure hereof.

Open Problem reports have to be assessed for their impact on the intended function (ETSO and Non-ETSO). Open Problem reports impacting the equipment intended functions have to be documented in the DDP and communicated to ETSO article installer/user for final impact analysis at aircraft level.

Open Problem reporting related documentation shall be referenced in the DDP and, when applicable, entries shall be made in the paragraph ‘limitations’.

***Note 1:*** *for Software related Problem reports guidance may be found in ED-12C, and more specifically into its associated supporting information ED-94C (§4.9); for Airborne (Complex) Electronic Hardware related Problem reports guidance may be found in ED-80 and EASA CM-SWCEH-001, Development Assurance of Airborne (Complex) Electronic Hardware’, published on the EASA website [*[*http://easa.europa.eu/certification/certification-memoranda.php*](http://easa.europa.eu/certification/certification-memoranda.php)*].*

***Note 2:*** *See also AMC 20-189 – subject to publication (NPA 2018-09)*

***Note 3:*** *The Problem reporting process should not be mixed-up with the processes dealing with:*

*- unintended production deviations, for which a dedicated procedure should be provided; see section 2.2.6;*

*- reported occurrences with regard to failures, malfunctions and defects; see section 2.3.5.*

[TEXT HERE]

### Approval for Deviation (ref. 21.A.610)

This paragraph should describe the process the organisation will follow whenever an *‘Approval to deviate from a performance standard contained in a CS-ETSO’* is requested to EASA in accordance with 21.A.610.

In the ETSO application the proper box shall be flagged when the project includes deviations;
***do not forget*** to make reference to the document explaining the compensating factors or the design features providing an equivalent level of safety. That document ***shall*** be sent as soon as possible to start the deviation publication and consultation phase; since the ETSO certification process ***cannot*** be completed without the deviation approval.

Alternatively state *‘None’* if the ETSO article is fully compliant with the requirements.

Deviation requests will be reviewed by a panel of experts and be subject to a public consultation for a period of at least 3 weeks, except if the deviation has been previously agreed upon and published on EASA website. The final decision on all deviation requests is published on the EASA website.

Based on the proposal of the Applicant, EASA PCM will finalise a Deviation Information Paper which does capture the original requirement, a summary of the deviation and the equivalent level of Safety.

A summary of deviations approved before January 1st 2013 (with embedded links to the Deviation Information Paper) is available on EASA website here:

<https://www.easa.europa.eu/sites/default/files/dfu/certification-docs-etso-authorisations-ETSO.Dev_.pdf>

The list of ETSO deviation requests, published after January 1st 2013, can be found here: <https://www.easa.europa.eu/document-library/product-certification-consultations?search=&date_filter%5Bmin%5D%5Bdate%5D=&date_filter%5Bmax%5D%5Bdate%5D=&field_easa_consultation_type_tid%5B%5D=1425>

[TEXT HERE]

## Management of Design Changes, Repair Designs and Production Deviations (ref. AMC 21.A.602B(b)(2) section 3)

### Design Changes

A procedure for managing design changes to ETSO articles is required. The procedure should ensure, that:

- the reason for the design change is described

- the design change is classified as Major or minor, in accordance with 21.A.611 (see section 2.2.2 of this template)

- all technical documents associated with the change (drawings, reports, etc.) are identified

- in case the design change is classified as minor, a justification is given for the classification, and that the design change is declared compliant with the relevant CS-ETSO, and that EASA is informed about related updates to the DDP and of the suffix change numbers or letters that are in use for each part number or of the updated amendment levels of the Article Part Numbers.

- that in case the design change is classified as minor, but it is **not** of the same type of the **anticipated** minor changes, as per section 2.1.5 / 2.2.2, (1) a modified significance of the suffix change letters/numbers is introduced, an application for an update of the Manual (reporting the new system in 2.1.5) is submitted via FO.DOA.00081 to EASA together with an updated DDP (and eventually an updated Product Technical Specification); or (2) the amended Product Part Number, the associated Master Drawing List and all the technical document associated with the change (including classification substantiation) is submitted to EASA (ETSO Section) for approval through the EASA Applicant Portal;

- that in case the design change is classified as Major, a new ETSO authorisation for the article is applied for as required by 21.A.611(b).

[TEXT HERE]

### Classification of Design Changes

A procedure needs to describe in sufficient detail how proposed design changes to ETSO articles will be classified as Major or minor in accordance with 21.A.611, with supporting description of the types of design changes that are **anticipated**. The procedure should mention, directly or by cross reference with section 1.5, who in the organisation is authorised to classify design changes.

The minimum content of the procedure should be:

* identification of changes to article design
* classification
* changes to article design initiated by subcontractors
* documents to justify the classification
* authorised signatories

Use of forms to record technical information related to the design change is strongly encouraged. **The classification of types of changes that are not anticipated shall be submitted to EASA (ETSO Section) for approval prior to any implementation action by the ETSOA holder.**

*Identification of changes to article design*

The procedure must indicate how the following are identified:

* Major changes
* minor changes

The ETSO Authorisation number subject to change shall be identified. Part and/or function of the ETSO article subject to change shall be identified. Article design configuration before and after the change shall be identified (e.g. use of master drawing list is encouraged)

*Classification criteria and changes Impact Analysis*

In accordance with 21.A.611(a), the procedure should define detailed and practical criteria for determining the classification of the changes.

It shall describe the change and identify all the related life cycle data and configuration management aspects.

It shall also address how the classification of the change will be determined by the applicant.

This process should produce a configuration record that under the form of a Change Impact Analysis, which will describe the change and identify the impact of change on:

1. The article performance regarding
	1. ETSO performance, including deviations,
	2. Non-ETSO functions,
	3. The article specifications,
	4. The article environmental qualification.
2. The article design regarding
	1. Architecture,
	2. Software,
	3. Electronic Hardware.
3. The article use:
	1. Installation,
	2. Operation,
	3. Maintenance,
	4. Limitations.

For each of these aspects, the impact analysis needs ultimately to consider the impact on compliance demonstration.

The Change Impact Analysis shall identify criteria from which 3 categories of change can be determined:

1. Major changes
2. minor changes
3. Changes for which the classification may be questionable, because the change impact is on the frontier zone, and potentially the criteria are not accurate enough, not adapted or conduct to an unexpected classification.

In this last case, the applicant should coordinate with EASA to validate the change classification in order to limit the risk of post implementation re-classification. EASA will provide a feedback, which will prevent later re-classification and associated consequences (re-demonstration, certification basis changes, Part Numbering issues, etc.).

Because the criteria are often driven by the technology and/or specific to the domain, each applicant should develop/refine more detailed criteria to classify the minor/Major addressing the specificities of its Scope of work (for instance change of sensor for AHRS, change of LCD panel for display, etc.). By establishing its own decomposition of classification criteria closely linked to its scope of work, the applicant encourages an internal, uniform and repetitive evaluation and classification process within its company , which ensures compliance to 21.A.611 and reduces the risk of wrong classification that could lead to severe impact (when a classified minor is later assessed Major by EASA).

The applicant should provide its detailed classification criteria related to its scope of work/equipment type (i.e. for each type of equipment covered by the ETSO standards within the APDOA scope of work), developing qualitative and quantitative criteria for minor/Major classification – always establishing the link to the extent of compliance demonstration needed in relation to the design change.

*Note 1: The change classification governed by 21.A.611 is different than the one used for installation change classification as required per 21.A.91. This is a reason why change at ETSO level and at aircraft level may not have the same classification.*

*Note 2: Unchanged Form, Fit, Function should not be used as criterion, since such a design change could still ‘require a substantially complete investigation to determine compliance’.*

*Note 3: Inserting or modifying non-ETSO function is not necessarily minor, as it may for example require a substantially complete investigation to determine compliance for instance to ED-14 when adding a board.*

The experience shows that establishing adequate classification criteria is a continuously improving process with potential refinements/iterations. It is therefore recommended to keep close contact with EASA focal points (DOA Team Leader & Project Certification Manager) for updating the classification criteria.

The Change Impact Analysis should, in the case of software and electronic hardware, provide a qualitative impact indication of the modification (for example: real time scheduling, interfaces, internal logics, graphical aspects, upgrading a DAL…) as well as a quantitative indication of the change impact (modified requirements, modified lines of code, tests modified and tests performed, re-generated life cycle data).

The change impact analysis shall in all cases refer to the last approved configuration and in cases of successive minor changes, the basis for the comparison remains the initial approval.

While this guidance highlights that criteria for change classification must be linked to the extent of compliance demonstration, it is not intended to encourage the applicant to reduce their testing to meet the criteria of a minor change. It is therefore recognized that the applicant can performed additional testing on top of the minimum testing strictly required (including non-regression testing) to cover for the changed requirements/design, in particular for development purpose.

Below an example flowchart of the classification process is given.



*Control of changes to type design initiated by subcontractors*

The procedure must indicate, directly or by cross-reference to written procedures, how changes to article design initiated by subcontractors are controlled.

*Documents to justify the classification*

All decisions of classification of changes to article design must be recorded, and for those which are not straightforward, also documented. All supporting documents must be signed by an authorised signatory. It may be in the format of meeting notes or register.

*Authorised signatories*

The procedure should identify the persons authorised to sign the proposed classification. See section 1.5 above.

[TEXT HERE]

### Design Change Register

The procedure used to record all design changes implemented to ETSO articles must be described. It should include a register to record the following:

- ETSOA number(s) subject to change

- the reference number allocated to the design change

- a brief description of the design change

- the design change classification (Major, minor not anticipated, minor anticipated)

- status (Pending, Ongoing, Approved…)

- Project manager / Responsible Design Office representative

- limitations (if any)

The procedure should mention directly or by cross reference with section 1.5 who is authorised to access and modify the register.

The procedure should also define the frequency of transmittal of the above document to EASA even when no changes are performed.

***Note****: The frequency shall be at least once per year, but could be more frequent depending on the volume of changes being implemented by the applicant.*

[TEXT HERE]

### Approval of Implementation of Design Changes

The approval process for the implementation of design changes needs to be described. The procedure should mention, directly or by cross reference with section 1.5, who is authorised within the organisation to approve the implementation of a minor design change to an ETSO article or to apply for a Major design change.

The minimum content of the procedure should be:

* compliance documentation
* approval process
* authorised signatories

*Compliance documentation*

For Major changes and those minor changes to type design where additional work to show compliance with the applicable ETSO requirements is necessary, compliance documentation must be established following guidelines of paragraph 2.1.4.

*Approval process (see also 2.2.1 above)*

1. For the approval of Major changes to article design, a certification programme as defined in paragraph 2.1.2 must be established.
2. For Major changes and those minor changes to article design where additional work to show compliance with the applicable ETSO requirements is necessary, the procedure should define a document to support the approval process.

 This document must include at least:

* + identification and brief description of the change and its classification
	+ applicable requirements
	+ reference to the compliance documents
	+ effects, if any, on limitations and on the approved documentation
	+ authorised signatory

1. For the other minor changes, the procedure must define means:
	* to identify the change

*Authorised signatories*

The procedure must identify the persons authorised to sign the change.

*Submission to EASA*

Except for changes that are not anticipated as per 2.1.5 above, the organisation should define the means and the periodicity of notification of minor design changes/repairs to EASA – in-line with section 2.2.3 (design change register).

[TEXT HERE]

### Repair Design

As indicated at 21.A.431A(e), if a repair to an ETSO article requires associated design activity, the repair must be managed as a design change in accordance with 21.A.611. Therefore, such repair designs are then subject to classification as Major or minor, recording in the design change register, etc.

If the concept of repair to the ETSO articles in question is not relevant, this should be indicated as non-applicable and an explanation given. (e.g. a system of ‘repair by replacement’ is used).

[TEXT HERE]

### Production Deviations (ref. AMC 21.A.602B(b)(2) section 3.2)

The process for approval of unintentional deviations from the approved design data occurring in production needs to be described. A procedure needs to describe in sufficient detail how production deviations from the approved ETSO-authorised articles design data will be assessed and approved/rejected by the design organisation.

**A production deviation can be seen as an unintentional design change applicable to a restricted series of production articles; they should be listed in a dedicated register available on request.**

A product deviation that would be intentional should be processed as a design change (see section 2.2.2).

The minimum content of the procedure should be

* identification of deviation from approved design data
* impact analysis on performance and ETSOA compliance
* compliance documentation
* approval process
* authorised signatories

Please consider for the content of this procedure the associated guidance already provided within this template, e.g. classification of design changes (section 2.2.2), compliance documentation (section 2.1.4), approval process / authorised signatories (section 2.2.4).

*Impact analysis on performance and ETSOA compliance*

The procedure should clearly indicate the criteria for approving the production deviation, taking into account its impact on the article performance to fulfil its specification. In any case, the production deviation shall not jeopardise the ETSO article compliance with the ETSO MOPS.

Specific consideration should be given in the procedure for dealing with production deviations affecting test articles. An assessment should be made by the design organisation to confirm that the deviations are acceptable (w.r.t. the test purpose) and do not affect representativeness of the test article for the serial production. (See also the note on this topic within Configuration Control; section 2.1.6)

*Submission to EASA*

The organisation should define here the means and the periodicity of notification of production deviations to EASA (see also sections 2.2.3 and 2.24).

[TEXT HERE]

## Obligations of ETSO Authorisation Holders (ref. to 21.A.609)

### Technical Data and Records

A procedure should describe the record keeping and archiving system in place in the organisation to ensure that a current file of complete technical data and records in accordance with 21.A.613 is maintained for each model of article for which an ETSO authorisation has been issued.

There is no limitation of duration. Records should be kept available as long as the article is retained in service.

All forms of recording media are acceptable (paper, film, magnetic ...) provided they can meet the required duration for archiving under the conditions provided.

The procedures should:

- Identify records to be kept.

- Describe the organisation of and responsibility for the archiving system (location, format) and conditions for access to the information (e.g., by product, subject).

- Control access and provide effective protection from deterioration or accidental damage.

- Ensure continued readability of the records.

- Demonstrate to EASA proper functioning of the archiving system.

[TEXT HERE]

### Manuals

A procedure should explain how the company produces, maintains, updates and distributes copies of the manuals required by the applicable airworthiness specifications for the article as required by 21.A.609(c) and provides copies, on request, to EASA.

See also the guidance in section 2.3.3 below, as it extends to Manuals.

[TEXT HERE]

### Issue of Information and Instructions to Operators (other than manuals) [ref. AMC 21.A.602B(b)(2) section 4]

In accordance with the principles of AMC 21.A.14(b) paragraph 4, a procedure needs to describe the different kinds of documents to be produced by the organisation to issue information and instructions to operators. For example, these documents could include:

- Service Bulletins

- Service Letters

Preparation of information and instructions involves design, production and inspection, and these three aspects need to be properly addressed in the procedure. The procedure should take into account:

- Preparation

- Verification of technical consistency with corresponding approved design data or approved design changes, including effectiveness, description, effects on airworthiness, especially when limitations are changed

- Verification of the feasibility of the information and practical instructions

The procedure should explain that the feasibility of all information and instructions must be verified by the organisation before being issued. The procedure also should mention, directly or by cross reference with section 1.5, who is authorised to create, modify and approve information or instructions.

The procedure should include specific instructions concerning the preparation and publication of accomplishment instructions to operators. For example, the use of Service Bulletins to implement minor design changes, and also for inspection instructions further to an EASA Airworthiness Directive.

Information and instructions issued by the APDOA Holder should include a statement that:

1) refers to the fact that the documentation has been produced in accordance with an alternative procedure to DOA;

2) provides reference to EASA ETSO Authorisation number and P/N (with open brackets) under which the minor change or repair to the article is covered, as applicable

Statement example:

1. “The technical content of this document has been produced in accordance with Alternative Procedure to DOA ref. EASA.APxyz”
2. “The technical content of this document refer to EASA ETSO Authorisation number XYZ and P/N ABC-()()() under which the minor change or repair is covered”

***Note:*** *EASA does not approve information or instructions.*

The statements above apply also to Manuals like, for example, the Component Maintenance Manual.

[TEXT HERE]

### Marking of ETSO Articles

ETSO articles must be marked in accordance with 21.A.807. The format in which articles will be marked to comply with 21.A.807 needs to be described. The procedure should also consider that additional marking requirements could be mandated through the CS-ETSO.

A sample marking placard drawing should be incorporated in this section in accordance with minimum information introduced in 21.A.807(a) and section 4 of applicable ETSO standards. Marking should also include blank fields to include future changes implemented via service bulletins. This may be provided by an additional placard.

The process should describe the way to comply to 21.A.807(b) when necessary; only if listed in the procedures, the cases of impractical markings will be considered agreed by EASA.

If APDOA and POA are separate entities, it is recommend to have also the APDOA name on the placard/label.

[TEXT HERE]

### Failures, Malfunctions and Defects

A procedure needs to describe the system required by 21.A.3A that the organisation has for the **collection, investigation and analysis** of data related to failures, malfunctions, defects or other occurrences which cause or might cause adverse effects on the continued airworthiness of ETSO articles.

For the definition of “potential unsafe condition” refer to guidance to AMC 21.A.3B(b), to GM 21.A.3B(b) and to AMC 20-8.

The procedure needs to explain how reporting to EASA is organised, particularly with regard to the 72 hour timeframe required for such reporting. The procedure should mention directly or by cross reference with section 1.5 who is authorised to manage the data collected, to classify the occurrences and to report to EASA. The procedure should also explain how the organisation carries out any required technical investigation subsequent to an occurrence.

Explicit reference to the appropriate website ([www.aviationreporting.eu](http://www.aviationreporting.eu)) should be included.

The procedure should consider not only the initial report, but also the follow-up reports.

***Note 1****: In addition to the requirements within EASA Part 21, should also be considered EU Regulation No 376/2014 on the reporting, analysis and follow-up of occurrences in civil aviation.*

***Note 2****: The APDOA is encouraged to include with the periodic report of the design change register (see section 2.2.3) also the information about failures, malfunctions and defects, even in the case of non-reportable occurrence.*

The flowchart below shows a possible workflow for the occurrence reporting system.



[TEXT HERE]

### Airworthiness Directives

In the case where EASA is required to issue an Airworthiness Directive relating to an ETSO-authorised article, a procedure needs to explain how the organisation will develop and propose to EASA appropriate corrective actions and/or required, and also make available the appropriate descriptive data and accomplishment inspections in accordance with 21.A.3B(c).

[TEXT HERE]

### Coordination between Design and Production

A procedure should describe the link established between design and production. The procedure should cover the transfer of information from the design organisation to the production organisation. Detailed guidance is given in AMC 21.A.4.

For aspects already described in this Manual (e.g. production deviation process) or in a dedicated company procedure (as listed in Appendix 3.1) this chapter should provide the appropriate reference.

The procedure should mention directly or by cross reference with section 1.5 who is authorised to sign associated documents.

Where design and production are undertaken by separate legal entities, a formal arrangement should be signed between the two organisations – a template is available in AMC No. 2 to 21.A.133(b)&(c). Irrespective whether design and production are separate legal entities or not, the arrangements need to be documented. When design and production are the same entity, the arrangements could be document direct in the handbook (addressing the responsibilities as mentioned in the AMC No 2 to 21.A.133(b)&(c)).

[TEXT HERE]

## Control of Design Partners or Subcontractors [ref. AMC 21.A.602B(b)(2), section 5]

Where design partners or subcontractors are used, the selection and surveillance processes need to be described. The procedure should address how the technical assessment of design partners or subcontractors is carried out by the organisation in order to guarantee that the ETSO article complies with its certification basis. Design subcontractors also include those organisations providing testing capabilities and suppliers of ETSO article (sub-)components.

The procedure should also address the specific case of design changes initiated by partners or subcontractors and should explain how these changes are notified and accepted by the organisation.

Design partners or subcontractors shall be properly identified (e.g. a register of design partners and approved subcontractors, which should contain name, location, scope of work, focal points contact details, qualifications references, etc. The location of this register should be incorporated in this manual.

[TEXT HERE]

Appendices

Information necessary to be linked to the manual may be captured in (separate) appendices if considered practical. A listing of the appendices should be provided (here – or as part of the Table of Contents).

Typical examples of information to be captured in an Appendix are:

Appendix 3.1 Associated Documents List (Procedures & Forms)

Appendix 3.2 Authorised Signatories List

## Associated Documents List (Procedures & Forms)

Procedures and Forms/Templates referenced within this manual need to be listed, along with their issue/amendment level – see examples below.

**Procedures**

|  |  |  |
| --- | --- | --- |
| **Document Nr.** | **Title** | **Issue/amendment** |
| Procedure XY1 | Coordination between Design and Production | Issue 1/2 |
| Procedure XY2 | Supplier Control procedure | Issue 2/0 |
| … |  |  |

**Forms / Templates**

|  |  |  |
| --- | --- | --- |
| **Document Nr.** | **Title** | **Issue** |
| Form ZY1 | Certification Programme | Issue 1 |
| Form ZY2 | Compliance checklist / matrix | Issue 3 |
| Form ZY3 | Declaration of Design and Performance | Issue 2 |
| … |  |  |

[TEXT HERE]

## Authorised Signatories List

|  |  |  |
| --- | --- | --- |
| Function | Name | Sample signature |
| Head of Engineering | … |  |
| Function X |  |  |
| … |  |  |

[TEXT HERE]