**Regulatory framework**

STC applicants are required from EASA Part 21.A.112B(a) to demonstrate design capability in accordance with EASA Part 21 Subpart J; by way of derogation [ref. EASA Part 21.A.112B(b)] they can demonstrate design capability in the form of Alternative Procedures to Design Organisation Approval (AP to DOA). EASA certifies this demonstration of design capability by issuing a Finding of Compliance to the applicant. The **derogation** is acceptable to EASA, if the conditions of GM 21.A.112B are applicable to the specific STC application.

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

In accordance with GM 21.A.14(b): *The acceptance of alternative procedures, as defined in AMC 21.A.14(b), should be limited where the Agency finds it more appropriate for the conduct of …, supplemental type certification, …, approval of repair design.*

In accordance with AMC 21.A.14(b): *Alternative procedures are an acceptable means to demonstrate design capability in the cases described in 21.A.14,* ***21.A.112B*** *or* ***21.A.432B****. This concept is the implementation, in the context of specific projects, of procedures required in Subpart J DOA, to ensure that the applicant will perform relevant activities as expected by the Agency, but without the requirements on the organisation itself that can be found in Subpart J. The establishment of these alternative procedures may be seen as a starting phase for a Subpart J DOA, allowing at a later stage, at the discretion of the applicant, to move towards a full Subpart J DOA by the addition of the missing elements.*

The above reported guidance material explain also why you will find in this template some references to EASA Part 21 Subpart J.

**Additional template information**

This manual template is intended to assist applicants in applying for EASA acceptance of AP to DOA and therefore demonstrating the required design capability.

The required information is to be entered below each text box of the manual sections. The text boxes should be deleted after the information is entered to produce the final document.

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

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

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

# 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.

[TEXT HERE]

## Issue / Amendment procedure [ref. 21.A.243 (c), GM 21.A.247]

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 (e.g. new product type, 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 or the list of signatories etc) or changes, other than above, affecting the content of the previous EASA finding of compliance (e.g. company name, company address, handbook/procedures reference numbers, title or issue/date). All new issue*s* of the manual or its referenced procedures must be submitted to the Agency via EASA Form 81 for approval.

**Amendments** to the manual should cover documentary changes not impacting the showing of compliance with Part 21*.* All amendments to the manual or its referenced procedure should be provided to the Agency for information only.

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

A significant change to a procedure referenced to in the appendix (Part 3 - of this manual) shall require a reissue of the manual.

[TEXT HERE]

## List of Effective Pages

A list of pages with their individual issue and amendment status shall be reported here.

[TEXT HERE]

## Distribution List

It is the distribution list of the manual. Each holder of a controlled copy of the manual should be recorded on this page. All subsequent amendments and reissues of the manual and its referenced procedures shall be supplied to the holders of the controlled copies (including the Agency).

[TEXT HERE]

# Organisation

## Purpose of the manual

This section should provide a short explanation of the purpose of the manual for the guidance of the organisation's own personnel.

[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. 216/2008, EC Regulation No. 748/2012 and its Annex Part 21, this manual defines the organisation and procedures upon which the EASA Finding of Compliance against 21.A.112B (b) 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 approval is granted.*

[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 addresses of the various premises, should be described. Where appropriate, relationships with other organisations forming part of the same group should be mentioned.

[TEXT HERE]

## Scope of work

This section must list the CS-2X (number and title) airworthiness code(s) together with the specific disciplines for which the applicant is seeking to demonstrate design capability for; this information should be the same as that indicated on EASA Form 81.

A concise definition of the authorised scope will be subsequently published on the EASA web site.

Please remember to verify the proposed scope of work versus the guidance provided in GM 21.A.112B. The organisation will only be eligible for an AP to DOA when the scope of work is within the Group 2 cases as defined in this GM.

The Agency can be consulted any time to discuss if the organisation’s proposed scope of work is within the Group 2 cases, and will have final decision on the group allocation of the projects proposed by the organisation under AP to DOA process.

[TEXT HERE]

## Authorised Signatories

This section needs to contain a diagram showing chains of responsibility of nominated design staff (e.g. organization charts). Brief terms of reference of nominated personnel need to be provided. Eventual references to external documents are acceptable (e.g. personnel records).

This section also needs to contain a list of approved signatories and the types of document they are authorised to sign. The list should report their names, positions in the company, and sample signatures (the signatures could be reported in separate sheets, one for each person). This list should include signatories for:

- Compliance documents (see section 2.1.4 of this template)

- Classification of design changes and repairs to (supplemental) type design (see section 2.2.2 of this template)

- Approval of the implementation of minor design changes and repairs to (supplemental) type design (see section 2.2.4 of this template)

- Manuals (see section 2.3.2 of this template)

- Documentation used to issue information and instructions to owner of products (aircraft, engine, or propeller) incorporating the features of the supplemental type-certificate (see section 2.3.3 of this template)

- Classification and approval of unintentional deviations from approved design data occurring in production (see section 2.2.6 of this template).

- Declaration of Compliance (see section 2.2.4 of this template)

- Occurrence analysis and reports (see section 2.3.5 of this template)

Example of authorisations table:

|  |  |  |  |
| --- | --- | --- | --- |
| **AUTHORISATIONS** | | | |
| **Signatories** | **Prepare** | **Check** | **Approve** |
| Person 1 or job title | (1)(2)(3) |  |  |
| Person 2 or job title | (1) | (3)\*, (2)\* | (2)(5) |
| Person 3 or job title | (1) | (3) | (2)(4)(5) |
| **Type of documents**   1. Compliance document type No. 1 2. Production concessions 3. Classification of changes/repairs 4. Internal approval of changes/repairs 5. Internal approval of ICA/Manuals 6. EASA Form 33 (**please note**: only approval signature required) 7. EASA Form 31 (**please note**: only approval signature required) 8. EASA Form 32 (**please note**: only approval signature required) 9. EASA Form 36 (**please note**: only approval signature required) 10. EASA Form 37 (**please note**: only approval signature required) 11. Declaration of Compliance 12. ………… 13. …………   \* by delegation if responsible person is absent for more than three days | | | |

Delegation policy should be clearly addressed and explained. If job titles are used, a list identifying all design staff and associated job titles should be reported (alternatively all design staff and associated job titles shall be identified in the organization charts).

[TEXT HERE]

# Procedures

A concise description of the organisation's technical procedures covering all aspects of work conducted under these AP to DOA is required; this should show how matters affecting airworthiness are controlled and that full and efficient co-ordination exists between technical departments and disciplines.

[TEXT HERE]

## Management of the STC/Major Change Certification Process

### Application for Supplemental Type Certificate (Ref. 21.A.113)

The initial process of applying to EASA for an STC approval should be described.

The procedure should list the documents that are submitted at the time of the application. This should include, as a minimum, the EASA Form 33, and the certification programme as per 2.1.2.

The procedure should also indicate that all the data required by 21.A.93 as per 21.A.113(b), including a declaration of compliance; a final declaration of compliance and all technical data required by the 21.A.93, shall be submitted at later time.

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

[TEXT HERE]

#### Application for a Major Change to a Supplemental Type Certificate (Ref. 21.A.117 (b)&(c))

The initial process of applying to EASA for a Major Change to an STC for which the APtoDOA is the STC Holder should be described.

The procedure should list the documents that are submitted at the time of the application. This should include, as a minimum, the EASA Form 31, and the certification programme as per 2.1.2.

The procedure should also indicate that all the data required by 21.A.93 as per 21.A.113(b), including a declaration of compliance; a final declaration of compliance and all technical data required by the 21.A.93, shall be submitted at later time.

As per 21.A.117(c), the application for a Major Change to an STC is permitted **only** to the STC Holder itself, otherwise it will lead to a new STC application.

**At the time of the application the organization should verify if the subject application is covered by their currently 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.14(b), section 2.1)

At the commencement of a project to achieve an STC approval, in accordance with the provision of **AMC 21.A.14 (b) section 2.1**, **referring to AMC 21.A.20(b) and GM to 21.A.20(b)**, the organisation should submit a certification programme to EASA that describes the process that will be followed to ensure that requirements of the relevant CS-2X and environmental requirements will be met.

Details of the format and typical content of a certification programme need to be presented in this section.

A procedure should be provided that describes how the certification programme is kept current throughout the project and that all revised elements are submitted to the Agency. It is recommended as a good practice that all revisions of the certification programme are submitted to the Agency to seek agreement.

The procedure should set the guidelines for the certification programme, including the definition of the means of compliance that are intended to be used. (Thus, any means of compliance that will not be used should also not be defined.)

For a particular project and as part of the technical familiarisation, the applicant provides a certification programme that includes:

1. a plan containing the following information:

* description of the project and the kind of operations envisaged.
* The proposed certification specifications, special conditions, equivalent safety findings and environmental protection requirements.
* The description on how compliance will be demonstrated, with proposed means of compliance [see Appendix to AMC 21.A.20(b) for codes reported in the table below], and any selected guidance material. The description of the means of compliance should be sufficient to determine that all necessary data will be collected and compliance can be demonstrated.
* A compliance checklist addressing each paragraphs of the type-certification basis and environmental protection requirements applicable to the project, with reference to the means of compliance and to the related compliance documents.
* Identification of relevant personnel making decisions affecting airworthiness and environmental protection interfacing with the Agency, unless otherwise identified to the Agency;

2. a project schedule including major milestones.

A typical means of compliance codes follows:

|  |  |  |
| --- | --- | --- |
| **Type of compliance** | **Means of compliance** | **Assoc. compliance doc.** |
| Engineering evaluation | **MC0:** Compliance statement  - reference to Type Design documents  - election of methods, factors  - definitions | Type Design Documents  Recorded Statements |
| **MC1:** Design Review | Description, Drawings |
| **MC2:** Calculation/Analysis | Substantiation Reports |
| **MC3:** Safety Assessment | Safety Analysis |
| Tests | **MC4:** Laboratory Tests | Test Programmes  Test Reports  Test Interpretations |
| **MC5**: Ground Tests on related product |
| **MC6:** Flight Tests |
| **MC8:** Simulation |
| Inspection | **MC7:** Design Inspection/Audit | Inspection or Audit  Reports |
| Equipment  Qualification | **MC9:** Equipment Qualification | Note*: Equipment qualification is a process which may include all previous means of compliance* |

Example of Compliance Check List

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Requirement** | **DESCRIPTION** | **METHOD OF COMPLIANCE** | **REMARKS** | **Supporting Documents** |
| 2X.853(a) | Flammability Test for non-metallic material | MC4 | Vertical Test | TP-08-00X  TR-08-00Y |
| 2X.853(c) | FBL Test for Seat Cushion | MC4 | Oil Burner Test | TP-08-00X  TR-08-00Y |
|  |  |  |  |  |

[TEXT HERE]

### Design Processes (Ref. AMC 21.A.14(b), section 1)

In accordance with **AMC 21.A.14(b), 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 flows of work, is strongly encouraged (see very simple examples below). The procedure should highlight typical milestones of the organization design process, e.g. checkpoints, design reviews, showing of compliance, etc.

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

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

The control of time schedule, for the accomplishment of the tasks in due time shall be described. Responsible person for the preparation, recording, and update of the time-schedule shall be identified. Format and location of the file containing the time-schedule could be reported to assist the internal and external coordination of the team working on the project.



[TEXT HERE]

### Compliance Documents (ref. AMC 21.A.14(b) section 2.2)

In accordance with the principles of **AMC 21.A.14 (b) section 2.2**, a procedure should explain how compliance documents are created, addressing the various types to be produced, e.g. reports, analyses, drawings, etc. The procedure should also mention directly or by cross reference with section 1.5 who is authorised to create, modify and approve compliance documents.

The applicant must establish procedures for creating compliance documents [ref. AMC 21.A.20(c)] in such a way that:

1. the kind of document and the technical objectives for each document are determined at the beginning of the process; each compliance document should normally contain:

* an adequate link (e.g.: numbering system to identify the compliance documents) with the corresponding certification programme;
* the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;
* data demonstrating compliance;
* a statement by the applicant declaring that the document provides the proof of compliance for which it has been created;
* the appropriate authorised signature.

1. the production of the documents is carefully managed all along the process, in accordance with the milestones defined in the certification programme
2. Each compliance document should have a number and issue date. The various issues of a document should be controlled. The issue control system should ensure the traceability between the various issues of each compliance document (e.g. by issue number and/or log register).

If so agreed by the Agency, some compliance documentation may be produced after issuance of the final statement of compliance required by 21.A.20(d).

To ensure compliance documents are created in a consistent manner it is expected that document templates are defined for the different types of compliance documents indicating minimum content and that compiling guidelines are provided. It is recommended that compliance document templates are included in the handbook (as appendix or by reference).

If flight testing is anticipated as a means of compliance, the flight test organisation and procedures must be defined. Aspects to be addressed in the procedure are:

* Test aircraft
* Personnel
* Facilities and equipment
* Deliverables

For detailed guidance, please refer to the ‘Good practices’ as published on the EASA DOA webpage.

[TEXT HERE]

### Configuration Control of the Change (Ref. 21.A.117, 21.A.31, 21.A.95, 21.A.97, AMC 21.A.14, section 1.1 and 2.1)

The organisation’s process for configuration control of the product “subject to the change” should be described in this section:

* Configuration Identification,
* Configuration Control,
* Configuration Verification.

The process should address these aspects as applicable to any project developed by the design organisation itself.

The following diagram summarizes these three points and may be considered as the general process for the configuration management and control during the project lifetime.



The configuration control system shall be appropriate to the working methods and size/complexity of the organization. The system shall ensure that changes in the (Supplemental) Type investigation process during any phase are properly managed, so that correlated documentation is evaluated and updated as necessary. And that any design changes or document updates (especially after STC approval) will be appropriately classified and approved.

The documentation of the projects (both STC and Change Design) shall be organised in a logical structure where the document hierarchy and the correlation between documents is well defined; in particular reference with the Certification Programme (paragraph 2.1.2) shall be ensured. This concept allows an adequate control of the impacts that a modification determines on the documentation (drawings, specification, reports, manuals, etc….). The following diagram shows the fundamental structure (tree) of the documentation describing a project.



A description of the documents linked in the tree shall be provided.

[TEXT HERE]

#### Modification of Drawings: up-grade of revision index, change in drawing number or change in p/n



Description of the drawing system shall be provided (P/N system, revision index, description, etc. …).

The rules for change of the revision index shall be described.

Changes to the Product type design could be of three types:

1. a change to a component in the hierarchical structure that does not affect form, fit and function of the component itself, and therefore it triggers only an increment of the revision level of the associated drawing and a revised master drawing list (including the updated revision level of the component). New amendment of the article part number is also necessary.
2. a change to a component in the hierarchical structure that affects form, fit and function of the component and eventually of the next higher assemblies containing the component that will require a change of the component part number and, eventually, an increment of the revision level of the next higher assemblies containing the component, as well as a revised master drawing list (including the new component part number and new revision level for the next higher assemblies). New amendment of the article part number is also necessary.
3. a change to the type design that triggers the generation of new part number(s) (e.g. suffix change numbers or letters) and a new associated master drawing list.

About the interchangeability concepts, the following applies:

* Two components are considered “interchangeable” when even their physical and functional characteristic may appear different; they exhibit the same (or equivalent) performances, reliability, maintenance and safety aspects.
* It means that other than to guarantee fit, form and function, the introduction of “new components” in the existing “product” does not require any special measures aimed to guarantee the right application of the new components (retrofit is allowed).

**The obligation to classify, as per section 2.2.2 below, each of these types of changes above remains. In fact identification of changes should not be confused with classification.**

Use of parts list containing all “changed” components in a hierarchical structure and with their current revision level is an acceptable means for controlling configuration. In this section it should be described if part number and drawing number coincide, or if a drawing can illustrate more part numbers.

The control of configuration will also support the task of the production organization to properly associate to each component of the change the corresponding design configuration.

Compliance of design data with applicable requirements shall not be confused with the conformity of the changed products/parts/appliances with the design data. See the flow chart below.



[TEXT HERE]

#### Modification of Technical Specifications, Master Document List and Technical documentation



In this section the document management system shall be described (document numbering system, issue control method, etc. …). It should cover all documentation as shown in the right hand branch of the figure above, i.e.:

* Project Technical Specification
* Master Document List
* Technical Documentation
  + Technical specifications
  + Compliance reports (with cross-reference to 2.1.4)
  + Vendor Item List
  + Manuals (with cross-reference to 2.3.2)
  + ICA (with cross-reference to 2.3.3)

The descriptions in this section should especially highlight how the dependencies between correlated documents are managed. The procedure should ensure that design changes and/or changes in the Technical Documentation are properly reviewed for their impact on other documents, so that these dependent documents are updated as necessary.

Thought should also be given to record how it is justified (recorded) when documentation is not updated when changes do not affect the technical content of the dependent document. (E.g. when a design change or material specification change is introduced after the release of a flammability test report, it can be that the specific change does not affect the applicable flammability test – then the flammability test report could remain valid. For this case, the document management process must ensure that this evaluation is made, documented and appropriately approved.)

[TEXT HERE]

### Approval for Special Conditions [ref. 21.A.16(b)]

This paragraph should describe the process the organisation will follow whenever an approval to proposed equivalent level of safety from airworthiness requirements contained in a CS-2X is requested to EASA in accordance with 21.A.16(b).

The section should describe the procedure for application to the Agency that shall contain the identification of the CS-2X requirement from which deviation is proposed and appropriate documentation of the equivalent level of safety proposed.

At the following web-address the APtoDOA could find the SC under consultations or ones for which the consultations period is expired: <http://easa.europa.eu/document-library/public-consultations> .

[TEXT HERE]

## Management of Design Changes, Repair Design and Production Deviations (ref. AMC 21.A.14(b) section 3)

### Design Changes

A procedure for managing design changes to a (Supplemental) Type Certificate is required. The procedure should ensure:

- the reason for the design change is described;

- the design change is classified as Major or Minor in accordance with 21.A.91 (see section 2.2.2 of this template);

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

- that in case the design change is classified as Minor this will be documented, and a justification is given for the classification for those cases which are not straightforward;

- that compliance with the certification basis is adequately demonstrated and the change introduces no unsafe features;

- that the design change is declared compliant with the applicable requirements;

- that in case the design change/repair is classified as Minor, a proper application in accordance with 21.A.95 by using EASA Form 32 is performed;

- that in case the design change is classified as Major, a proper application in accordance with 21.A.97 by using EASA Form 33 new STC (or EASA Form 31 in case of existing STC) is performed.

- that in case of Major Repair, a proper application in accordance with 21.A.433 by using EASA Form 31 is performed.

[TEXT HERE]

### Classification of Design Changes

A procedure needs to describe in sufficient detail how proposed design changes to (S)TC will be classified as Major or Minor in accordance with 21.A.91, with supporting examples of the types of design changes that are relevant to the scope of the organisation. 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
* 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.

*Identification of changes to article design*

The procedure must indicate how the following are identified:

* major changes
* minor changes

Configuration of the product/part/appliance before and after the change shall be identified (e.g. use of master drawing list is encouraged)

*Classification*

In accordance with 21.A.91, the procedure should define the criteria for determining the classification of the changes. Please make sure to check the EASA website for FAQ / Guidance on classification.

*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 (S)TC 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 needs to describe the system used to record all initiated design changes. The system should record the following:

- the reference number allocated to the design change

- a brief description of the design change

- the design change classification

- status (Pending, Ongoing, Approved…)

- ICA/Manuals issued (if necessary)

- Flight Manual (Supplement) issued (if necessary)

- Project manager / Responsible Design Office representative

- limitations (if any)

- Effectivity of the design change (a/c type, model, etc.)

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

[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 internally approve the implementation of a minor/major design change to a (S)TC and further apply to EASA.

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 requirements is necessary, compliance documentation must be established following guidelines of paragraph 2.1.4.

*Approval process*

1. For the approval of changes to (S)TC, an application must be made to the Agency (see also 2.2.1 above) anda 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 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 the Agency*

The organisation should define here the means and methods, in addition to paragraph.2.1.2, in order to liaise with the Agency during the certification/approval process. It includes the process for preparation and submission of a **declaration of compliance** in accordance with 21.A.20(d) and (e) and 21.A.265(c).

[TEXT HERE]

### Repair Design (ref. AMC 21.A.14(b), section 3.4)

As indicated in 21.A.431, if it is necessary to issue a repair design, the repair itself must be managed similarly to a design change in accordance with 21.A.91. Therefore, such repair designs are then subject to classification as Major or Minor, recording in the design change register, etc., ref. above paragraphs 2.2.1, 2.2.2, 2.2.3 and 2.2.4.

In case of Major Repair the application form will be the EASA Form 31, as well as a certification programme could be prepared and included in the specific procedure (even if not required). Please also consider the additional reference that is available for the relevant set of substantiation data: “AMC 21.A.433(a) and 21.A.447”.

[TEXT HERE]

### Unintentional Production Deviations (ref. AMC 21.A.14(b), section 3.4)

The process for classification and 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 possible production deviations from the approved design data will be reviewed as Major (rejected) or Minor in accordance with 21.A.91, with supporting examples of possible type of production deviations. **Please note that a deviation can be seen as a design change applicable to a restricted series of production articles.**

The minimum content of the procedure should be

* identification of deviation from approved design data
* classification
* documents to justify the classification
* compliance documentation
* approval process
* authorised signatories

*Identification of deviations from the approved design data*

The procedure must indicate how the following are identified:

* major deviation (therefore rejected)
* minor deviation

*Classification*

In accordance with 21.A.91, the procedure should define detailed and practical criteria for determining the classification of the deviations.

*Documents to justify the classification*

All decisions of classification of deviations 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.

*Compliance documentation*

For major deviations and those minor deviations from type design where additional work to show compliance with the applicable requirements is necessary, compliance documentation must be established following the procedures of paragraph 2.1.4.

*Approval process*

1. For production deviations where additional showing of compliance is needed and/or additional rework is required, the procedure should define a document that supports the approval. This document must include at least:
   * identification and brief description of the deviation and its classification
   * applicable requirements
   * reference to the compliance documents and/or additional reworking instructions
   * effects, if any, on limitations and on the approved documentation
   * authorised signatory
2. For the other minor production deviations, the procedure must define a means:
   * to identify the deviation

*Authorised signatories*

The procedure must identify the persons authorised to sign the classification and internal approval of the production deviations before release to the Agency for final approval as per section 1.5 above

*Submission to the Agency*

The organisation should define here the means and methods, in addition to paragraph 2.1.2, in order to liaise with the Agency during the certification/approval process.

[TEXT HERE]

## Obligations of STC Holder (ref. 21.A.118A) and Major Repair Holder (ref. 21.A.451)

### Technical Data and Records (ref. 21.A.105 and 21.A.447)

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.105 is maintained for any design change and/or repair design for which an approval (e.g. STC) has been issued.

There is no limitation of duration. Records should be kept available as long as the change/repair 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 the Agency proper functioning of the archiving system.

[TEXT HERE]

### Manuals (ref. 21.A.119, AMC 21.A.14(b)2, section 4)

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.119 and provides copies, on request, to EASA.

[TEXT HERE]

### Issue of Information and Instructions for Continued Airworthiness to Operators (other than manuals – ref. 21.A.120, 21.A.449, AMC 21.A.14(b)2, section 4)

In accordance with the principles of AMC 21.A.14(b) section 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 effectivity, description, effects on airworthiness, especially when limitations are changed

- Verification of the feasibility of the information and practical instructions

- Authorised Signatories for internal approval as mentioned in paragraph 1.5.

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 organisation should include a statement that “The technical content of this document is approved under the Authority of EASA ref. approval number xxx and have been produced in accordance with alternative procedure to DOA nr. EASA.APxyz” (where APxyz is the AP number assigned by the Agency to the organisation). **Note: EASA does not approve information or instructions.**

[TEXT HERE]

#### Issue of Flight Manual Supplement

Similarly with previous paragraph, the organisation should identify a proper procedure in accordance with the principles of AMC 21.A.14(b) section 4; the procedure needs to describe the different kinds of documents to be produced by the organisation to issue (when necessary) Flight Manual Supplement.

Flight Manual Supplement approval implies anytime the EASA approval.

In case of STC/Major Repair process the FMS is approved by the PCM during the certification process.

The approval statement will be the same of previous paragraph: “The technical content of this document is approved under the Authority of EASA ref. approval number xxx and have been produced in accordance with alternative procedure to DOA nr. EASA.APxyz” (where APxyz is the AP number assigned by the Agency to the organisation).

[TEXT HERE]

### EPA Marking (ref. 21.A.804(a))

Products/Parts/Articles associated to the change must be marked in accordance with 21.A.804(a). The format in which articles will be marked to comply with 21.A.804 needs to be described.

Exceptions are foreseen in 21.A.804(b); specific procedure should describe the process to manage this derogation.

Samples of possible markings and associated reference on drawings should be reported in this section. Marking should also include blank fields to include future changes implemented via service bulletins.

[TEXT HERE]

### Failures, Malfunctions and Defects (ref. 21.A.3A)

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 STC affected products/parts/appliances.

The procedure needs to explain how reporting to EASA is organised, particularly with regard to the 72 hours 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 and to report to EASA. The procedure should also explain how the organisation carries out any required technical investigation subsequent to an occurrence.

[TEXT HERE]

### Airworthiness Directives (ref. 21.A.3B)

In the case where EASA is required to issue an Airworthiness Directive relating to an STC, a procedure needs to explain how the organisation will develop and propose to EASA appropriate corrective actions and/or required inspections in accordance with 21.A.3B(c).

[TEXT HERE]

### Coordination between Design and Production (ref. 21.A.4)

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.

The procedure should also address the production deviation process. Production deviations from the approved design data should be treated through the design change process.

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 proposed in GM 21.A.133(b)).

[TEXT HERE]

### Arrangement with the TC/STC Holder (ref. 21.A.115(c) and 21.A.433(b))

Organisation should explain whether it will identify any reinvestigation necessary to show compliance of the changed product with the applicable certification basis process using its own resources or through an arrangement with the type certificate holder (21.A.93 - 21.A.113).

Where the organisation is not capable to use its own resources and has entered into an arrangement with the TC holder, the modification dossier must include (21.A.115, 21.A.433(b)):

- A statement of non technical objection from the (S)TC holder

- A statement from the (S)TC holder that he has agreed to collaborate with the STC/Major Repair applicant to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with 21.A.44, 21.A.118A, 21.A.433(b).

[TEXT HERE]

## Control of Design Subcontractors

Where design sub-contractors are used, the selection and surveillance processes need to be described. The procedure should address how the technical assessment of partners or subcontractors is carried out by the organisation. Design subcontractors also include those providing testing capabilities.

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

Subcontractors shall be properly identified (e.g. a register of approved subcontractors should contain name, location, scope of work, focal points contact details, qualifications references, etc – it should be stated in the manual what is the document name for the register, and where it is kept).

[TEXT HERE]

Appendixes

## Procedures List

Any procedures referenced within this manual need to be listed below along with their revision level.

Example:

Procedure 1 Issue 1

Procedure 2 Issue 2

Procedure 3 Issue 0

[TEXT HERE]

## Compliance Check List to Part 21

The organisation shall propose its own compliance to applicable requirements of Part 21 through the template offered below filling the column “Procedure Reference” as applicable.

EASA will verify the proposed compliance during the investigation, asking for procedures adequacy improvement as necessary.

[TEXT HERE]

|  |  |  |
| --- | --- | --- |
| **References** | **Subject** | **Procedure reference** |
| **AMC 21.A.14(b), 1.1 & 1.2** | **Manual of procedures** |  |
| **AMC 21.A.14(b), 2.1**  TC case: ref. to AMC 21.A.20(b) and GM 21.A.20(b)  STC case: ref. to AMC 21.A.114 | **Certification programme** |  |
| **AMC 21.A.14(b), 2.2**  Ref. to AMC 21.A.20(c) | **Compliance documents** |  |
| Ref. to GM 21.A.20(d) | **Final statement** |  |
| **AMC 21.A.14(b), 3.2** | **Classification of changes:** | |
| 3.2.2 | *Identification of changes to type design* |  |
| 3.2.3 | *Airworthiness classification* |  |
| 3.2.4 | *Control of changes to type design initiated by subcontractors* |  |
| 3.2.5 | *Documents to justify the classification* |  |
| 3.2.6 | *Authorised signatories* |  |
| **AMC 21.A.14(b), 3.3** | **Approval of changes:** | |
| 3.3.2  Ref. to AMC 21.A.20(c) | *Compliance documentation* |  |
| 3.3.3  Ref. to AMC 21.A.97 | *Approval process* |  |
| 3.3.4 | *Authorised signatories* |  |
| **AMC 21.A.14(b), 3.4** | **Repairs (including production deviations from the approved design data)**  *(See Note 1)* | |
| 3.2.2 | *Identification of repairs to type design* |  |
| 3.2.3 | *Airworthiness classification* |  |
| 3.2.4 | *Control of repairs initiated by subcontractors* |  |
| 3.2.5 | *Documents to justify the classification* |  |
| 3.2.6 | *Authorised signatories (related to classification proposal)* |  |
| 3.3.2 | *Compliance documentation* |  |
| 3.3.3 | *Approval process* |  |
| 3.3.4 | *Authorised signatories (related to approval proposal)* |  |
| **AMC 21.A.14(b), 4** | **Issue of information and instructions to owners** | |
| 4.1 | *General* |  |
| 4.2 | *Data related to changes* |  |
| 4.3 | *Procedure* |  |
| 4.4 | *Statement (see Note 2)* |  |
| **AMC 21.A.14(b), 5** | **Obligations addressed in 21.A.44 (TC holder), 21.A.118A (STC holder) or 21.A.451 (repair design approval holder)** | |
| Ref. to 21.A.3A | *Failures, malfunctions and defects* |  |
| Ref. to 21.A.3B | *Airworthiness directives* |  |
| Ref. to 21.A.4 | *Coordination between design and production* |  |
| Ref. to 21.A.55 (TC), 21.A.105 (STC) or 21.A.447 (Repairs) | *Recordkeeping* |  |
| Ref. to 21.A.57 (TC), 21.A.119 (STC) | *Manuals* |  |
| Ref. to 21.A.61 (TC), 21.A.120 (STC) or 21.A.449 (Repairs) | *Instructions for continued airworthiness* |  |
| Ref. to 21.A.14 (TC), 21.A.112B (STC) or 21.A.432B (Repairs) | *Demonstration of capability (See Note 3)* |  |
| Ref. to Part 21 Subpart Q (TC), 21.A.804(a) (STC and Repairs) | *Markings* |  |
| Ref. to 21.A.115(d) (STC) or 21.A.433(b) (Repairs) | *Collaboration with the TC holder* |  |
| Ref. to 21.A.443 (Repairs) | *Limitations* |  |
| **AMC 21.A.14(b), 6** | **Control of design subcontractors** |  |

Note 1: Production deviations must always be addressed under this section.

Note 2: The Agency does not approve information or instructions.

Statement of AP to DOA Holder should:

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

2) provide reference to EASA approvals of related changes or repairs, when applicable.

Note 3: The manual of procedures should contain a statement from the Chief Executive of the organisation for continued commitment to agreed procedures.