

European Aviation Safety Agency

Design Organisation Handbook template	Doc #	DOH Template
Design Organisation Handbook template	Issue	18/12/2013

Design Organisation Handbook template

Log of issues		
Issue	Issue date	Change description
001	18/12/2013	Initial issue

Design Organisation Handbook

Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

This handbook template is based on AMC No.2 to 21A.243(a), taking into account the additional requirements as presented in AMC No. 1 to 21A.243(a), and is intended to assist applicants in applying for DOA and therefore demonstrating the required design capability.

The required information is to be entered <u>below</u> each text box of the handbook sections. The first page, with EASA logo and the text boxes should be deleted after the information is entered to produce the final document. Text which is already entered below the text box are examples and shall be checked if they are appropriate and be changed accordingly by the organisation.

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

However, any referenced procedures need to be listed in an Appendix at the end of this template.

The handbook 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.

This DOH template

- is no standard manual;
- does not introduce new or modified rules and does not constitute any legal obligations or right for the Agency or the organisations;
- must not be regarded as formally adopted Acceptable Means of Compliance (AMC) or Guidance Material (GM).

Design Organisation Handbook [company name]

Date	Prepared by	Date	Checked and approved by
dd/mm/yyyy	[name]	dd/mm/yyyy	[name]
	[signature]		[signature]



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0.1 Amendment History

A list of issues and revisions including affected chapter, date and short description of the reason of the new issue/revision shall be reported here.

[TEXT HERE]

Example:

Iss.	Date	chapter	Description
1	01/01/2011	all	Initial issue
1	30/09/2011	2	Editorial changes
1	05/04/2012	1.4	Editorial changes

0.2 Distribution List

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

This chapter should also describe how the staff has access to the DOH (electronically or paper) and how it is informed about new issues and revisions of the DOH including all referenced procedures.

All issues and revisions of the DOH including all referenced procedures will be supplied to the EASA Design Organisation Approval Team Leader (preferably via e-mail as a pdf-file).

[TEXT HERE]

Example:

No.	Dept.	Name	remarks
1	[xy]	[Ms Musterfrau]	[supplier 1]
2	[yz]	[Mr. Mustermann]	[supplier 2]
3	EASA	[J. Doe]	DOATL

All employees have direct access to the current issue of the handbook including the referenced documents on the [company name's] [database/intranet]. The staff is automatically informed via e-mail each time a new issue or revision is released.

EASA Design Organisation Approval Team Leader will be supplied with all issues and revision of the DOH including all referenced procedures via e-mail as pdf-file.

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Document reference:

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Part 1 - Organisation

1.1 Objective of handbook and binding statement

This chapter should provide a short explanation of the purpose of the document for the guidance of the Organisation's own personnel, and should give a statement by the Chief Executive and Head of Design Organisation (could be the same person), declaring this manual as basic working document, which has to be followed by all personnel (including design suppliers, if applicable).

[TEXT HERE]

Example for the binding statement:

This handbook and associated documents define the organisation and procedures upon which the EASA Part 21 Subpart J approval of [company name] Design Organisation is based as defined in European Commission Regulation (EC) 748/2012 including all applicable amendments. All documents referenced in this DOH are considered as part of the DOH. The DOH is approved by the undersigned.

The undersigned ensure that:

- This DOH including the referenced documents is maintained in conformity with the Design Assurance System and is used as a basic working document within the [company name] Design Organisation;
- All personnel including design suppliers are aware of the processes described in this DOH and associated documents and will comply with the requirements of this handbook;
- [company name] Design Organisation has sufficient staff in numbers, competence and experience with the appropriate authority to be able to discharge their allocated responsibilities;
- [company name] Design Organisation's accommodation, facilities and equipment are adequate to comply with EASA Part 21;
- It is accepted that these procedures do not override the necessity of complying with any new or amended regulation published by the EASA from time to time where these new or amended regulation are in conflict with these procedures;
- It is accepted that the Agency may investigate and review any report;
- It is understood that the EASA will approve this organisation whilst the EASA
 is satisfied that the procedures are being followed and work standards
 maintained;
- It is further understood that the EASA reserves the right to restrict, suspend or revoke the Part 21 Subpart J approval of the organisation if the EASA has evidence that procedures are not followed or standards not upheld.

Chief Executive
Signature:
[NAME]
Date:

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Document reference:

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1.2 Responsible person for administration of handbook

The official title and contact details of the person responsible for the administration of the handbook must be stated. The nominated person is responsible for ensuring that the handbook is distributed, controlled, and amended or reissued as necessary.

Note: The administrator is not necessarily the author of the handbook or parts of it.

[TEXT HERE]

1.3 Design Assurance System changes, handbook amendment procedure

The procedure describes which changes to the design assurance system have to be approved by the Agency and which can be approved by the DOA.

The procedure shall address also the internal approval process:

- Who will approve changes to the DOH? (Usually the Head of Design Organisation, or if properly delegated, the Head of Office of Airworthiness);
- How will this approval be formalized? (e.g. signature on the master copy (see also front page of this template)).
- etc.

[TEXT HERE]

Example:

1.3.1 Classification of changes to the Design Assurance System

All changes to the design assurance system that are significant to the demonstration of compliance or to the airworthiness end environmental protection of the product shall be approved by the Agency. For this the form EASA FO.DOA.00082 will be filled out accordingly and sent to the e-mail address placed on the form.

Significant changes to the Design Assurance System are:

Organisation

- Change in ownership
- Relocation
- Change in the industrial organisation (partnership, suppliers, design worksharing, etc.) unless it can be shown that the independent checking function of the demonstration of compliance is not affected
- Change in the parts of the organisation that contribute directly to the airworthiness or environmental protection (independent checking function, Office of Airworthiness)
- Change to the independent monitoring principles

Responsibilities:

Change of:

- the Head of the Design Organisation
- the Head of Office of Airworthiness
- the Head of the Independent Monitoring System

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- new distribution of responsibilities affecting airworthiness or environmental protection

Procedures:

Changes to the principles of procedures related to:

- type certification
- the classification of changes and repairs as "Major" or "Minor"
- the treatment of Major Changes and Major Repairs
- the approval of the design of Minor Changes and Minor Repairs
- the issue of information and instructions under the privilege of the DOA
- the approval of documentary changes to the Aircraft Flight Manual
- the approval of the design of Major repairs
- continued airworthiness (Occurrence Reporting, Airworthiness Directives)
- the configuration control, when airworthiness or environmental protection is affected
- the acceptance of design tasks undertaken by partners or design suppliers

Resources:

Substantial reduction in number, qualification and/or experience of staff.

Scope / Privileges (Terms of Approval):

Change of:

- the scope of approval
- the categories of products
- the list of products
- the privileges

1.3.2 Handbook amendment procedure

The handbook is controlled by "Issue No." which is placed on the footer on each page. Text parts of this handbook affected by the last issue will be marked by a vertical bar on the outboard side of the text.

All file of all changes to this handbook including the referenced documents are stored in the [company name] electronic document storage, retrieval and archiving system, which is accessible for all [company name] staff.

Approval of the new issue:

1. Significant change to DAS

The procedures/handbook describing and introducing the significant change will be approved by [function and/or name] after the significant change is approved by the Agency.

2. Non-significant change to DAS

The new issue of the handbook will be approved by signature of [function and/or name] on the front page of this handbook.

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1.4 Presentation of design 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]

1.4.1 Company history

[TEXT HERE]

1.4.2 Design Organisation facilities

This section should show the accommodation(s) of the design organisation including address(es) and should describe the facility in detail like:

- Design (e.g.: Computer aided design and drawing system, filling and storage, list of software used, etc.)
- Test facilities (description of what kind of tests can be performed, what kind of equipment is available, etc.)
- Various locations and their purpose, if any

[TEXT HERE] [FIGURE HERE]

1.4.3 Design Supplier List

This section should list and describe the design suppliers including the tasks performed by them:

How the company selects design supplier is described in chapter 12.1.

[TEXT HERE]

1.5 Scope of work

The information given in this section should further detail the scope provided in the Terms of Approval. A copy of the Approval Certificate and the associated Terms of Approval should also be included.

TC applicants / holder should also provide in this section a brief description of the product(s) including applied technologies and methods.

[TEXT HERE]

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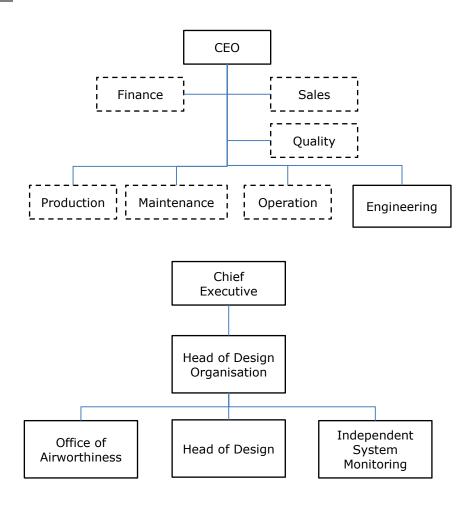
1.6 Organisation charts

This section should contain a diagram showing the position of the Design Organisation in the company and chains of responsibility of nominated design staff up to the Chief Executive within the Design Organization.

An example is shown below.

[TEXT HERE]

Example:



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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

1.7 Human resources

This section should include a description of the human resources available and give details about their responsibilities and qualification criteria if not covered by the following sections. From the description in this section the sufficient DE/CVE-ratio should become apparent.

Also the company's training policy should be defined (i.e. general framework for training plans, defining e.g. the fields of training such as "regulations", "technical training", "procedures training" etc. and its recurrences) for each affected group of staff.

[TEXT HERE]

1.7.1 Design Engineer

This section should describe the responsibilities and tasks of Design Engineers, the required minimum qualifications and a procedure for the assessment and acceptance of Design Engineers.

[TEXT HERE]

Example:

The persons nominated as a Design Engineer (DE) are listed in chapter 1.9 Authorised signatories.

DEs are assigned the following tasks:

- preparing documents like design definition documents, compliance demonstration documents, programmes and operating instructions; and filing test data, etc.;
- confirms by signing of the document that the document was prepared with best engineering practice, utmost care and to best knowledge of all facts affecting its contents and is completed.

With regard to upper mentioned tasks the DE is responsible towards the Head of Design.

1.7.1.1 Qualification and Training of Design Engineers

Each of the DE listed by name in chapter 1.9 shall have undergone adequate training to qualify for the jobs assigned and possess adequate professional experience. The DE shall be familiar with the procedures for described in this manual including project related documents affecting DE's tasks.

The minimum requirements to be eligible for a DE are:

- Basic knowledge of the relevant Certification Specification requirements;
- [text]
- [text]
- [text]

Prior to the nomination as DE, the employee shall be required to participate in a training course on airworthiness aspects and on the type certification process.

1.7.1.2 Nomination of Design Engineers

The DEs are nominated by the Head of Design. The Head of Design assures that the qualification level and experience of the persons who serve the function as DE satisfy the requirements of the respective tasks involved. The DE will be listed in this DOH chapter 1.9.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

1.7.2 Compliance Verification Engineer

This section should describe the responsibilities and tasks of Certification Verification Engineers, the required minimum qualifications for CVE applicants and a procedure for the assessment and acceptance of CVEs. It shall also indicate directly or by cross-reference to a dedicated document how each CVE has accepted his/her responsibilities (e.g. signing off a dedicated nomination sheet etc.).

[TEXT HERE]

Example:

The persons nominated as a Compliance Verification Engineer (CVE) are listed in chapter 1.9 Authorised signatories.

CVEs are assigned the following tasks:

- Independent checking of compliance demonstration documents (e.g. design definition documents, operating instructions, analysis, test programmes test data and manuals required to be approved by the Agency or under DOA privileges (e.g. AFM)) for technical accuracy and compliance with applicable airworthiness requirements;
- Confirming the independent check with his signature.

With regard to upper mentioned tasks CVEs are solely responsible towards the HDO.

1.7.2.1 Qualification and Training of Compliance Verification Engineers

Each of the CVEs listed by name in chapter 1.9 shall have undergone adequate training to qualify for the jobs assigned and possess adequate professional experience. He shall be familiar with the procedures for verification described in this manual including project related documents.

The minimum requirements to be eligible for a CVE are:

- Thorough knowledge of the relevant Certification Specification requirements;
- Thorough knowledge of the company and its design organisation
- Thorough knowledge of the chapters including referenced procedures affecting the design, approval and continued airworthiness process.
- Basic knowledge of EASA Part 21
- [text]
- [text]

Prior to the nomination as CVE, the employee shall be required to participate in a training course on airworthiness aspects and on the type certification process.

1.7.2.2 Nomination of Compliance Verification Engineers

The CVEs are nominated by the HDO. The HDO assures that the qualification level and experience of the persons who serve the function of CVE satisfy the requirements of the respective tasks involved. The HDO will be assisted by recognized experts to evaluate the competences in the related technical field. Every CVE receives a nomination which states his scope of authorization. The nomination is signed by the CVE and the HDO. Form DO-30 is used. The CVE will be listed in this DOH chapter 1.9.

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1.8 Management staff

Management staff comprises following functions:

Chief Executive, Head of Design Organisation (HDO), Head of Office of Airworthiness (HOA) and Head of Independent System Monitoring (HISM).

The credentials of the managers (HDO, HOA, HISM) are submitted to the Agency on EASA Form 4 –DOA in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities.

Nevertheless it's up to the company to choose and accept its management staff. To this end, this section should describe each manager's tasks and responsibilities and define the qualification criteria the organisation has set up to make sure management staff is competent to fulfil their respective obligations (only **minimum** qualification criteria are included in this guidance).

<u>Note:</u> In general it is possible that two or more functions are performed by the same person. As already mentioned in GM No.1 to 21.A.239(a) the Chief Executive and the Head of Design Organisation function may be thus combined.

The person performing the **Head of Design Organisation** function may also perform the **Head of Office of Airworthiness** function. This needs to be individually assessed by the DOATL taking into account e.g. the expected workload in the Organisation.

In very small organisations it may be acceptable if the Head of Design Organisation also performs the Independent System Monitoring function. This depends on the involvement of the HOD in the design processes and might require an additional independent auditor. However the organisation needs to show how independence is guaranteed.

Both Head of Design Organisation and Head of Office of Airworthiness may also act as Design Engineers and/or Certification Verification Engineers.

A list of typical responsibilities for the Office of Airworthiness is provided in GM No.1 to 21.A.239(a).

In the example are typical qualifications for the management staff (Chief Executive, Head of Design organisation, Head of Office of Airworthiness, Head of Independent System Monitoring) listed. They may be adapted to the tasks of each position and the scope of the organisation.

[TEXT HERE]

Example:

The credentials of the Head of Design Organisation, Head of Office of Airworthiness and Head of Independent System Monitoring are submitted to the Agency on EASA Form 4-DOA in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities.

1.8.1 Chief Executive

The Chief Executive Manager has the following accountabilities, tasks and responsibilities:

- Providing the necessary resources for the proper functioning of the company's Design Organisation.

1.8.2 Head of Design Organisation (HDO)

The HDO has the following tasks and responsibilities:

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

- Unlimited responsibility and liability for ensuring the satisfactory accomplishment of the design work carried out by or on behalf of company's DO;
- Determining the necessary resources for the proper functioning of the company's DO;
- Ensuring that the company's DO properly discharges its responsibilities in accordance with the appropriate regulations of EASA Part 21 and the organisation's Terms of Approval;
- Ensuring that the procedures as specified in the DOH and referenced procedures are maintained and followed;
- Overall technical responsibility for the company's Design Engineering deliverables;
- Continued airworthiness support and safety of the product designed, changed or repaired by the company's DO;
- See also table of chapter 1.9 (Authorised signatories).

Qualification of HDO:

The HDO has sufficient knowledge and authority to enable him to respond to EASA and to implement necessary improvements as:

- General knowledge of the relevant Part 21 requirements and company procedures is expected;
- Management skills.

1.8.3 Head of Office of Airworthiness (HOA)

Note:

The list below is based on the GM No 1 to 21.A.239 (a)3.1.4. Depending on the scope of the design organisation this list should be adapted accordingly.

The HOA reports directly to the HDO and has the following tasks and responsibilities:

- Liaison between the design organisation and the Agency with respect to all aspects of Type Investigation;
- Ensuring that a handbook is prepared and updated as required in 21.A.243;
- Co-operation with the Agency in developing procedures to be used for the type certification process;
- Issuing of guidelines for documenting compliance;
- Co-operation in issuing guidelines for the preparation of the manuals required by the applicable implementing rules, Service Bulletins, drawings, specifications, and standards;
- Ensuring procurement and distribution of applicable CS and environmental protection requirements and other specifications;
- Co-operating with the Agency in proposing the type-certification basis;
- Interpretation of CS and environmental protection requirements and requesting decisions of the Agency in case of doubt;
- Advising of all departments of the design organisation in all questions regarding airworthiness, environmental protection approvals and certification;
- Preparation of the Certification Programme and co-ordination of all tasks related to Type Investigation in concurrence with the Agency;
- Regular reporting to the Agency about Type Investigation progress and announcement of scheduled tests in due time;
- Ensuring co-operation in preparing test programmes needed for demonstration of compliance;

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An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate.

- Establishing the compliance checklist and updating for changes;
- Checking that all compliance documents are prepared as necessary to show compliance with all CS and environmental protection requirements, as well as for completeness, and signing for release of the documents;
- Checking the required type design definition documents described in 21.A.31 and ensuring that they are provided to the Agency for approval when required;
- Preparation, if necessary, of a draft for a type-certificate data sheet and/or type-certificate data sheet modification;
- Providing verification to the HDO that all activities required for Type Investigation have been properly completed;
- Approving the classification of changes in accordance with 21.A.91 and granting the approval for minor changes in accordance with 21.A.95(b);
- Monitoring of significant events on other aeronautical products as far as relevant to determine their effect on airworthiness of products being designed by the design organisation;
- Ensuring co-operation in preparing Service Bulletins and the Structural Repair Manual, and subsequent revisions, with special attention being given to the manner in which the contents affect airworthiness and environmental protection and granting the approval on behalf of the Agency;
- Ensuring the initiation of activities as a response to failure (accident/incident/in-service experience) evaluation and complaints from the operation and providing of information to the Agency in case of airworthiness impairment (continuing airworthiness), (see also 21.A.3A and 21.A.3B);
- Advising the Agency with regard to the issue of airworthiness directives in general based on Service Bulletins, (see also 21.A.3B);
- Ensuring that the manuals approved by the Agency, including any subsequent revisions (the Aircraft Flight Manual, MMEL, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable) are checked to determine that they meet the respective requirements, and that they are provided to the Agency for approval.

Oualification of HOA:

The HOA has sufficient knowledge and authority to enable him to respond to EASA and to implement necessary improvements as:

- Thorough knowledge of the relevant Part 21 requirements and company procedures is expected;
- Thorough knowledge of this handbook especially the procedures relevant to the classification, compliance demonstration, certification and continued airworthiness process;
- Thorough knowledge of the relevant certification specification;
- Management skills.

1.8.4 Head of Independent System Monitoring (HISM)

The HISM reports directly to the HDO and has the following tasks and responsibilities:

- Plan all activities related to the Independent System Monitoring (ISM);
- Verify efficiency of the design organisation;
- Survey any corrective actions;
- Perform audits (the HISM may not be involved directly in any activities he is auditing).

Qualification of HISM:

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- Knowledge of related Part 21 requirements;
- Knowledge of this handbook including the related procedures;
- Thorough knowledge of the "Independent Monitoring Procedure";
- Experience in auditing (for the case he his auditing himself).

1.9 Authorised signatories

This Section should contain a list of Approved Signatories, with the documents the respective personnel are authorised to sign, giving their names, positions in the company. This list should include signatories for:

- Compliance check-list
- Compliance documents (drawings, analysis, reports...)
- Manuals (or supplement)
- Classification of changes and/or repairs
- Changes and/or repairs (before submission to EASA)
- Service Bulletins, or other documentation used to issue information or instructions to owners of products
- Unintentional deviations from the approved data occurring in production (concessions or non-conformances).
- ...

The table shown below is an example only. It can be organised in another way.

[TEXT HERE]

Example:

		Authorisations		
Name	Signature	Function	prepare	check/approve
[Person 1]		Head of Design Organisation		6, 7, 8, 9, 10, 11
[Person 1]		Head of Office of Airworthiness	1, 2, 3, 5, 6, 7	1, 2
[Person 2]		Head of Independent System Monitoring	11	
[Person 1]				
[Person 2]		Design Engineer	1, 2, 3, 5, 9, 10	
[Person 3]				
[Person 1]				
[Person 2]		Compliance Verification Engineer	1, 2	3, 4, 5
[Person 3]		2.1911001		

List of documents / templates:

- 1. Application and Classification
- 2. Certification Programme
- 3. Test Plan
- 4. Statement of Conformity
- 5. Compliance Document
- 6. Declaration of Compliance
- 7. Minor Change Approval

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

- 8. Repair Approval
- 9. Service Bulletins
- 10. Concessions
- 11. Audit Plan

Part 2 - Independent System Monitoring

The procedure of performing surveillance audits at design suppliers is described in chapter 7.

- a) The procedure for the Independent System Monitoring shall include
 - Planning of monitoring activities
 - Performance of monitoring activities
 - Determination of corrective actions and acceptable timeframes
 - Follow-up of findings
 - Coverage of design suppliers
 - Reporting lines

The ISM shall cover all company processes and all Part 21 requirements in a suitable timeframe but at least within a maximum of three years. It usually consists of all or part of following activities:

- Process audits
- Product audits
- b) For very small companies it could be more practicable to review the projects which were performed by the design organisation. In this case the Head of ISM invites for a meeting after a project is closed. Within this meeting every step of the project shall be reviewed and discussed in accordance with the written procedures. The Head of ISM documents the result of this meeting including findings, and improvements. Aspects which cannot be covered by this project review (e.g. Occurrence Reporting) shall be addressed by the Head of ISM separately. The Head of the ISM has to assure that all issues of the design assurance system are covered within a suitable timeframe but at least within a maximum of three years.

[TEXT HERE]

Example for a):

How [company] performs the surveillance audits at the design suppliers is described in Part 12 -.

2.1 Scope of ISM

The efficiency of the Design Assurance System is ensured by the Independent Monitoring System (ISM). The ISM consists of an independent auditing and reporting system to monitor the compliance and effectiveness of the Design Organisation.

2.2 Audit plan

The basis for the internal audits are the relevant Part 21 requirements. The DOH including the referenced procedures describe how [company] fulfils these requirements. All procedures of the DAS will be audited/monitored in a [n] year cycle. The HISM will issue a detailed audit/monitoring plan (see form DO-40, Audit Plan) every year on the basis of the [n]year plan (see [n] year audit plan). These plans have to be approved by the HDO.

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2.3 Performance of an audit

Each audit is prepared by the auditor according to the audit plan. Following issues will be addressed:

- Purpose of the audit
- Scope of the audit
- Time frame of the audit
- Contact person of the audited party
- List of documents to be available during the audit

The auditor will perform the audit with help of interviews and check list. He can decide to perform the audit together with an expert of the field to be audited. The auditor shall ensure that this expert was not directly involved in the audited subject.

The auditor will document the results in an audit report (see form DO-41, Audit Report) which will be issued to the HDO.

Deviations will be classified as follows:

- Level 1: Any non-compliance which could lead to uncontrolled non-compliances with applicable Part 21 requirements and which could affect the safety of the aircraft.
- Level 2: Any non-compliance which is not classified as level 1.
- Level 3: Any item where it has been identified, by objective evidence, to contain potential problems that could lead to a level 2 or 1 finding.

Corrective actions have to be implemented within:

- Level 1: within 21 days
- Level 2: latest within 3 month
- Level 3: to be defined by the relevant department where the weakness or possibility of improvement has been discovered.

2.4 Determination and monitoring of findings and corrective actions

In case of deviations and findings the relevant department where the deviations or findings have been discovered is responsible for analysing the reason and suggesting a solution, determining time frames and implement the corrective actions. The time frame has to be accepted by the HISM. The HISM has to ensure that the time frame is within the frame listed in chapter 2.3.

The HISM will add this information in the audit report. He is also responsible to monitor all defined actions. For this he updates the Action and Finding List (see form DO-42, Action and Finding List). In case any findings are still open after the scheduled date the HISM will inform the HDO.

It is responsibility of HDO to define and enforce the actions to close the finding as soon as possible and inform the Agency immediately in case of finding classified as Level 1.



Document reference:

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Part 3 - New Type Certificate

A concise description is required of the Organisation's technical procedures covering all aspects of work conducted under the DOA. This should show how matters affecting airworthiness are controlled. The organisation shall be such as to ensure that, in all matters affecting airworthiness, full and efficient coordination exists between the technical disciplines.

The procedure shall define following aspects:

- Management of the project
- Application of this significant change to the Design Assurance System (EASA FO.DOA.00082)
- Application for a new TC (EASA Form 30)
- Certification programme
- Compliance Demonstration
- Tests
- Compliance summary
- Declaration of compliance
- Approval

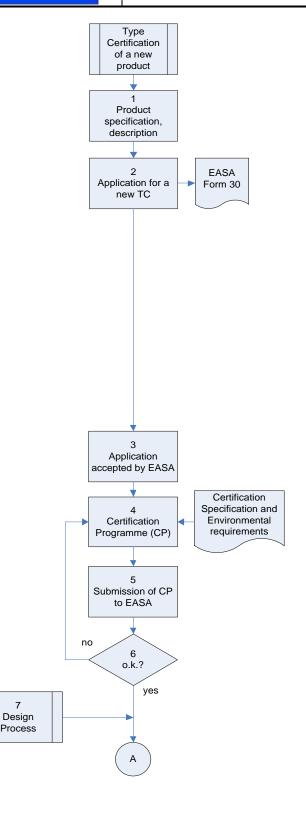
Before the application for a new TC is sent to the Agency the Office of Airworthiness applies for a significant change of the DOA. See also chapter 1.3.

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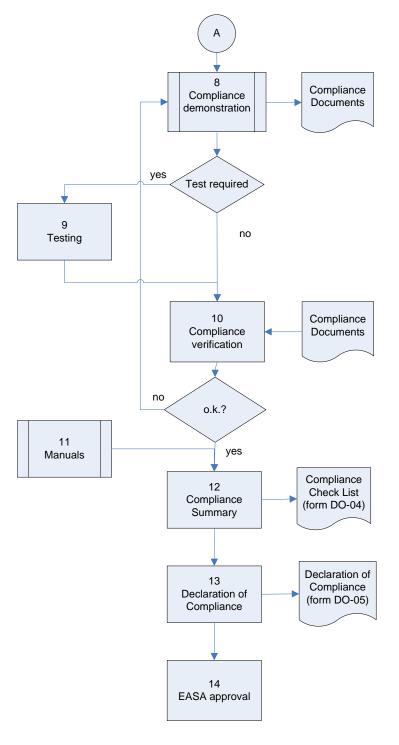
- [Describe here who in the design organisation is responsible for specifying and describing the new product to be developed.]
- 2. [Describe here who in the design organisation is filling out the application form and sending it to EASA. The application for an aircraft TC shall be accompanied by a three-view drawing of that aircraft and preliminary basic data, including the proposed operating characteristics and limitations. An application for and engine or propeller TC shall be accompanied by a general arrangement drawing, a description of the design features, the operating characteristics, and the proposed operating limitations, of the engine, or propeller. The HOD should check and sign the form] [TEXT HERE]
- EASA will allocate a Project No. and will inform the DO on the responsible PCM.
- The HOA together with the CVEs are preparing the CP. The HOA is responsible for the preparation of the CP and will approve it (form DO-02).
- The HOA is responsible for the submission of the CP to the PCM at EASA.
- The PCM checks the CP and will accept it or will ask for revision. In addition he will define the level of involvement by defining documents to be sent to EASA and tests to be witnessed by EASA.
- The design process can start at this point. See Part 6 -. The type design documents (specifications, drawings, bill of material, production and installation procedures, etc.) are prepared.

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- The design engineer prepares the compliance demonstration document according to the certification programme (analysis, compliance statements, reports, etc.).
 Refer to Part 7 -.
- For tests (ground test and flight tests) see Part 7 chapter 7.3.
- The independent checking within respect to completeness and technical content is performed by the appropriate CVE within their field and with respect to their competences.(see chapter 1.9 and 7.3.8.
- 11. Manuals see chapter 11.1
- 12. The Office of Airworthiness is summarising all compliance documents in the Compliance Summary. With his signature the HOA declares that the type investigation is finished. (see chapter 3.4)
- 13. The HOD signs the Declaration of Compliance and Office of Airworthiness sends the Declaration of Compliance including the compliance summary and all compliance documents. (See chapter 3.5)
 Note: Defined Compliance documents and manuals can be sent to the PCM after these documents are approved by the [company].
- 14. EASA will check the documents and will issue the Type Certificate in case all requirements are met.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

3.1 Application, product specification, description

Describe here who in the design organisation is responsible for specifying and describing the new product to be developed.

Describe here who is responsible to issue the application form and send it to EASA:

- The application for an aircraft TC shall be accompanied by a threeview drawing of that aircraft and preliminary basic data, including the proposed operating characteristics and limitations.
- An application for and engine or propeller TC shall be accompanied by a general arrangement drawing, a description of the design features, the operating characteristics, and the proposed operating limitations, of the engine, or propeller.
- The HOD should check and sign the form.

[TEXT HERE]

3.2 Type Certification Basis of a new product

See 21.A.17

[TEXT HERE]

Example:

The type certification basis of a new product consists of the applicable airworthiness code established by the agency that is effective on the date of application unless otherwise specified by the Agency or compliance with certification specifications of later effective amendments is chosen by the [company] or required by 21.A.17[company] or (d).

The certification specifications are published on the EASA webpage.

3.3 Certification programme

This chapter describes in general the Certification Programme. Most information should be given with the Certification Programme form being used.

The MoC used in the sample are typically used for aircraft TC. For engine and propeller they may be adapted.

[TEXT HERE]

Example:

In order to guarantee a co-ordinated and efficient course of type investigation the HOA (supported by the agency, for major only) shall develop together with the relevant CVEs the Certification Programme.

The Certification Programme includes:

- the Type Certification Basis, and
- the means of compliance including details about the activities behind

Type Certification Basis consist of:

- the applicable airworthiness code including amendment established by EASA effective on the date of application,
- any special conditions in accordance with Part 21.A.16B(a), and

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• any certification specification not complied with that is compensated for by factors that provide an equivalent level of safety.

Following MoC are defined:

Type of Compliance	МоС	Associated compliance document
-	NA	Justification for not applicability of requirement.
	NR	No Requirement – Nomenclature only
Engineering Evaluation	(0) Compliance statement	reference to Type Design documentselection of methods, factorsdefinitions
		Type Design Documents, recorded Statements
	(1) Design Review	Description, drawings
	(2) Calculation, Analysis	Substantiation Reports
	(3) Safe Assessment	Safety Analysis (FMECA)
Tests	(4) Laboratory Test	Test Programmes
	(5) Ground Test	Test Reports
	(6) Flight Test	
	(7) Simulation	
Inspections	(8) Design Inspection/Audit	Inspection or Audit Reports
Equipment Qualification	(9) Equipment Qualification	Note: Equipment qualification is a process which may include all previous MoC.

After approval by HOA and acceptance by the agency, the certification programme is the binding working paper to demonstrate compliance to the relevant CS and environmental protection requirements. The issues which are covered are defined by the certification programme form.

In case during the development it turns out that the defined MoC are not sufficient the Certification Programme shall be corrected accordingly. The new issue has to be again checked and approved by the HOA.

The Means of Compliance shall be defined for each airworthiness and environmental protection requirement.

For the certification programme the form DO-02 is used.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate.

3.4 Compliance Summary (Compliance Check List)

This chapter describes in general the Compliance Check List. Most information should be given with the Compliance Check List form being used.

This chapter shall describe:

- The scope of the Compliance Check List (CCL)
- How the CCL is managed
- Who is responsible for the CCL
- By whom and when the CCL is approved

The CCL shall cover following issues:

- Reference to the CP and project.
- The certification basis, including special conditions, equivalent safety findings and environmental protection requirements including amendment.
- Means of compliance
- List of documents which demonstrate compliance with the listed certification specification and environmental protection requirements according to the agreed CP, including their status

[TEXT HERE]

Example:

In order to guarantee at the end of the certification process that all in the Certification Programme defined tasks were performed and all related certification documents and manuals are approved by the personnel defined in chapter 1.9 Authorised signatories, a Compliance Check List is established.

The Compliance Check List is maintained by the Office of Airworthiness.

The Office of Airworthiness shall also check if the MoC being used correlate with the MoC defined in the Certification Programme.

When all related tasks are closed HOA approves the Compliance Check List. The Compliance Check List is the basis for the Declaration of Compliance.

For the Compliance Check List the form DO-04 is used.

3.5 Declaration of Compliance

This chapter describes the process when the declaration of compliance can be issued for a new TC, STC or Major Change and who is responsible for this task.

[TEXT HERE]

Example:

After completion and acceptance of all certification specification and environmental protection requirements the Office of Airworthiness issues the Declaration of Compliance. The completions is tracked with the compliance summary (compliance check list)(see chapter 3.4).

- For Minor Changes and Minor and Major (only own TC) Repairs the Declaration of Compliance is part of the Approval form (see form DO-08, DO-22).
- For STC, TC and Major Changes the form DO-09 is used.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

The signature of the Head of Design Organisation on the Declaration of Compliance confirms that:

- the type investigation is completed,
- the new/changed/repaired product complies with the applicable Certification Specification, Type Certification Basis and environmental protection requirements, and
- the applicable procedures and processes as specified in the DOH have been followed.

For new TC, STC and Major Changes the Declaration of Compliance will be provided to the Agency (PCM).

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Document reference:

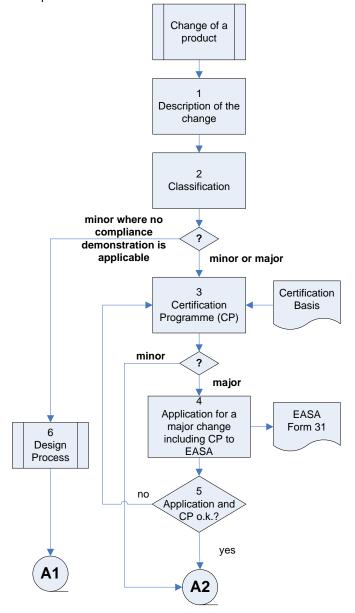
An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

Part 4 - Changes to Type Design

This chapter describes the procedure for a minor or major change of the Type Design. The procedure shall define following aspects:

- Management of the project
- Application for a change (for major only) (EASA FO.TCCH.000 31)
- Certification programme
- Compliance Demonstration
- Tests
- Compliance summary
- Declaration of compliance (for major only)
- Approval

[TEXT HERE] Example:



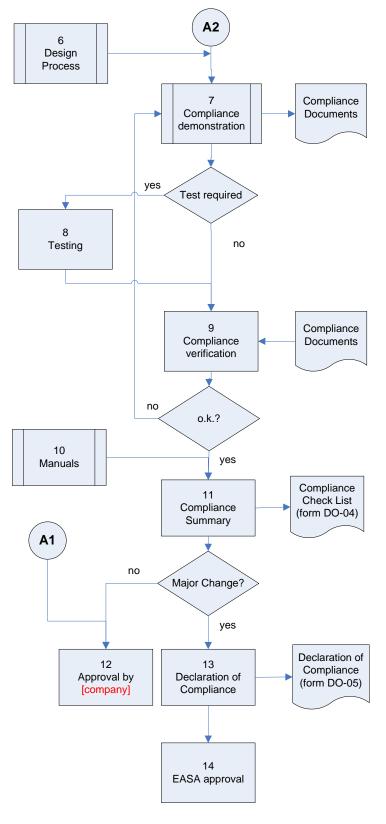
- [Describe here who in the design organisation is responsible for specifying and describing the change to be developed.] [TEXT HERE] See chapter 4.1.
- The HOA together with the CVEs are preparing the classification including the substantiation for it. The HOA is responsible for the preparation and will approve it (form DO-01). For further details see chapter 4.2.
- 3. The HOA is defining the type cert. basis (see chapter 4.3) and together with the CVEs they are preparing the CP. The HOA is responsible for the preparation of the CP and will approve it (form DO-02). For further details see chapter 4.4.
- 4. [Describe here who in the design organisation is filling out the application form and sending it to EASA. The application for a major change shall be accompanied by an overview drawing of the change including preliminary basic data like proposed operating characteristics and limitations. The HOD or HOA should check and sign the form] [TEXT HERE]
- EASA will allocate a Project No. and will inform the DO on the responsible PCM. The PCM checks the CP and will accept it or will ask for revision.

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- The design process can start at this point. See Part 6 -. The type design documents (specifications, drawings, bill of material, production and installation procedures, etc.) are prepared.
- The design engineer prepares the compliance demonstration document according to the certification programme (analysis, compliance statements, reports, etc.).
 Refer to Part 7 -
- For tests (ground test and flight tests) see Part 7 chapter 7.3
- The independent checking within respect to completeness and technical content is performed by the appropriate CVE within their field and with respect to their competences. (see chapter 1.9 and 7.3.8)
- 10. Manuals see chapter 11.1.
- 11. The Office of Airworthiness is summarising all compliance documents in the Compliance Summary. With his signature the HOA declares that the type investigation is finished. (see chapter 4.5)
- The HOD approves the Minor Change by using form DO-08. See chapter 4.7.1.
- 13. The HOD signs the
 Declaration of Compliance
 and Office of Airworthiness
 sends the Declaration of
 Compliance including the
 compliance summary and all
 compliance documents
 defined by the PCM. See
 chapter 4.6 and form DO-09.
 Note: Compliance documents
 and manuals can be sent to the
 PCM after these documents are
 approved by the [company].
- 14. EASA will check the documents and will issue the approval of the change in case all requirements are met.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate.

4.1 Specification and description of the Change

Describe here who in the design organisation is responsible for specifying and describing the change of the product to be developed.

[TEXT HERE]

4.2 Classification of Design Changes

The procedure should describe the classification criteria i.a.w. 21.A.91 and GM to 21.A.91 for changes.

Changes must be classified as:

- Major
- Minor where additional work is necessary to demonstrate compliance with the CS and environmental protection requirements.
- Minor requiring no further demonstration of compliance

[TEXT HERE]

Example:

Classification of Changes to a type design into Major or Minor is to determine the type investigation procedure and approval route to be followed.

The classification is performed by the Office of Airworthiness together with the involved CVEs and documented on the form DO-01.

The Office of Airworthiness has to be aware of the interaction between disciplines and consequences this will have when assessing the effects of a change (i.e., operations and structures, systems and structures, systems and systems, etc.).

The classification is approved by Office of Airworthiness.

In any case of doubt the Office of Airworthiness asks the Agency for further clarification.

For classification of changes in the following chapters the wording "appreciable" is used. Following provides guidance on the word "appreciable" means as applied to the areas identified at airplane level.

A. Weight - Appreciable changes are:

- a. Changes increasing the certified maximum or decreasing the certified minimum weight limits:
 - i. Max Taxi Weight
 - ii. Max Take-off Weight
 - iii. Max Zero Fuel Weight
 - iv. Max Landing Weight
 - v. Minimum Flying Weight
- b. Changes in distribution of weight and the associated moment of inertia that would affect the spin characteristics, dynamic stability or flutter characteristics of the airplane

B. Balance - Appreciable changes are:

- a. Changes in the certified center of gravity limits
 - i. Decreasing the forward limit (i.e. move it more forward of the certificated forward limit)
 - ii. Increasing the aft limit (i.e. move it further aft of the certificated aft limit)

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C. Structural Strength - Appreciable changes are:

- a. Changes to primary structure (structure that carries flight, ground, or pressure loads as defined in AC 25.571-1, Damage Tolerance and Fatigue Evaluation of Structure), that is not obviously to the conservative side
- b. Changes in loads / load paths
 - iii. Changes in material
 - iv. Changes to method of construction
 - v. Changes to stiffness
- c. Increase of structural design speeds:
 - i. VA
 - ii. VFE
 - iii. VNE
 - iv. VD
- d. Internal cabin changes:
 - i. Changes that increase floor loading limits
 - ii. Changes to increase cargo compartment loading limits
 - iii. Changes to cabin configuration resulting in relocation of major items (galleys, lavatories, etc.)
- e. Other factors:
 - i. Change of fatigue mission profile
 - ii. New required structural inspections
 - iii. Increase of control surface deflections
 - iv. Changes that affect the flutter characteristics

D. Reliability - Appreciable changes are:

a. Changes that negatively (e.g. is it in curriculum) impact the airplane level reliability with the propensity for pilot distraction or preoccupation to the extent that a reduction in safety margins or rise in the level of preoccupation of the pilot's attention (pilot workload) is likely to happen

E. Operational Characteristics: Appreciable changes are:

- a. Airplane, engine, and propeller changes that affect the performance data presented in the POH (including the approval of different take-off and landing surface conditions)
- b. Engine cooling changes
- c. Change in types of acceptable fuel
- d. Engine and / or propeller changes
- e. Changes to emergency procedures in the POH
- f. Changes to operating limits in the POH, including changes to the ambient envelope (altitudes and temperatures)
- g. Changes that affect the flight characteristics of the airplane in a manner that is perceptible to the pilot (e.g. change in control surface deflection and/or gearing; thrust/power changes; external configuration changes)
- h. System changes that increase pilot workload
- i. Changes in the certified maximum seating capacity
- j. Changes to unusable fuel supply

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F. Environmental protection such as noise, fuel venting or exhaust emission,

- a. Changes that increase the noise level
- b. Changes that reduce noise level, when the reduction shall be identified on the POH
- c. Changes in the emissions level

G. Other characteristics affecting the airworthiness of the product: Appreciable changes are:

- a. Changes as a result of a safety issue
- b. Changes to the Airworthiness Limitations Manual
- c. Interior changes that affect passenger safety (for example new items of mass in the interior, installation of air bag seat belts, changes that affect occupant injury characteristics (e.g. Head Injury Criteria (HIC)) compliance, new seats, etc.)
- d. Changes to systems or equipment that have an effect on safety or are perceptible to the pilot.

Note: When the strict application criteria results in a Major classification, the Office of Airworthiness may request re-classification, if justified, and Agency could take the responsibility in re-classifying the change. For example if a simple design change planned to be mandated by an airworthiness directive may be re-classified Minor due to the involvement of the Agency in the continued airworthiness process. Reasons for a classification decision shall be recorded by the Office of Airworthiness by using the form DO-01.

4.2.1 Minor Changes

Changes will be classified as Minor if they have no appreciable effect on

- mass
- balance
- structural strength
- reliability
- operational characteristics
- noise fuel venting
- exhaust emission
- declared life
- health (adverse effects on cabin bleed quality)
- other characteristics affecting the airworthiness

of the product, part or appliance.

For the case that with the minor change no Certification Specification and no environmental protection requirement is affected, the Office of Airworthiness will state this in the Classification form (DO-01) accordingly. A justification of this statement is necessary and is also placed in the Classification form (DO-01). This justification is checked and signed by the applicable CVE.

4.2.1.1 Minor change requiring no further demonstration of compliance

These are minor changes were no certification specification including special conditions and environmental protection requirements are applicable. This is documented on form DO-01 with a substantiation for this decision and approved by Office of Airworthiness.

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4.2.2 Major Changes

A Change with an appreciable effect on characteristics affecting the airworthiness of the product shall be classified as MAJOR, when one or more of the following conditions are met:

- Where the change requires an adjustment of the type-certification basis (such as special condition, equivalent safety finding, elect to comply, earlier certification specification (reversion), later certification specification).
- Where a new interpretation of the certification specifications used for the type type-certification basis, that has not been published as AMC material or otherwise agreed with the Agency is proposed.
- Where the demonstration of compliance uses methods that have not been previously accepted as appropriate for the nature of the change to the product or for similar changes to other products designed by the applicant.
- Where the extent of new substantiation data necessary to comply with the applicable certification specifications and the degree to which the original substantiation data has to be re-assessed and re-evaluated is considerable.
- The change alters the Airworthiness Limitations or the Operating Limitations.
- The change is made mandatory by an airworthiness directive or the change is the terminating action of an airworthiness directive (ref. 21.A.3B). The design change previously classified minor and approved prior to the airworthiness directive issuance decision needs no re-classification. However, the Agency retains the right to review the change and re-classify/re-approve if found necessary
- Where the change introduces or affects functions where the failure effect is classified catastrophic or hazardous.

Examples for Major Changes:

The Appendix A to the GM 21.A.91 shows some examples for Major Changes per discipline. It is not intended to present a comprehensive list of all major changes. Examples are categorised per discipline and are applicable to all products (aircraft, engines and propellers). However a particular change may involve more than one discipline, e.g., a change to engine controls may be covered in engines and systems (software). The example below is just for ELA 1 aircrafts. The DO has to adapt the list to its scope.

A. Structure:

- Changes sus as cargo door cut-out, fuselage plugs, change of dihedral, addition of floats;
- Changes to materials, processes or methods of manufacture of primary structural elements, such as spars, frames control surfaces, landing gear and critical parts;
- changes that adversely affect fatigue or damage tolerance or life limit characteristics;
- changes that adversely affect aeroelastic characteristics;

B. Flight:

- Changes which adversely affect the approved performance, such as high altitude operation, brake changes that affect braking performance.
- Changes which adversely affect the flight envelope.
- Changes which adversely affect the handling qualities of the product including changes to the flight controls function.

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Document reference:

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C. Systems:

For systems the classification process is based on the functional aspects of the change and its potential effects on safety.

- Aspects of the compliance demonstration use means that have not been previously accepted for the nature of the change to the system.
- The change affects the pilot/system interface (displays, controls, approved procedures).
- The change introduces complete new types of functions/systems.

D. Environment

A change that introduces an increase in noise or emissions.

E. Power plant installation

Changes which include:

- Control system changes which affect the engine/propeller/airframe interface:
- New instrumentation displaying operating limits;
- Modifications to the fuel system and tanks (number, size and configuration);
- Change of engine/propeller type;
- Appreciable effect on fuel system, cooling system, fuel venting, oil system, induction system, ...
- Appreciable effect on environmental protection characteristic such as for example noise emission.

4.3 Type Certification Basis for a Change to Type Design

The Agency wrote the GM 21.A.101 to provide guidance for establishing the type certification basis for changed products in accordance with 21.A.101 and to help identify if it will be necessary to apply for a new type certificate under 21.A.19.

The method is valid for major changes and STCs.

The procedure here shall describe how the DOA and who defines the type certification basis.

[TEXT HERE]

Example:

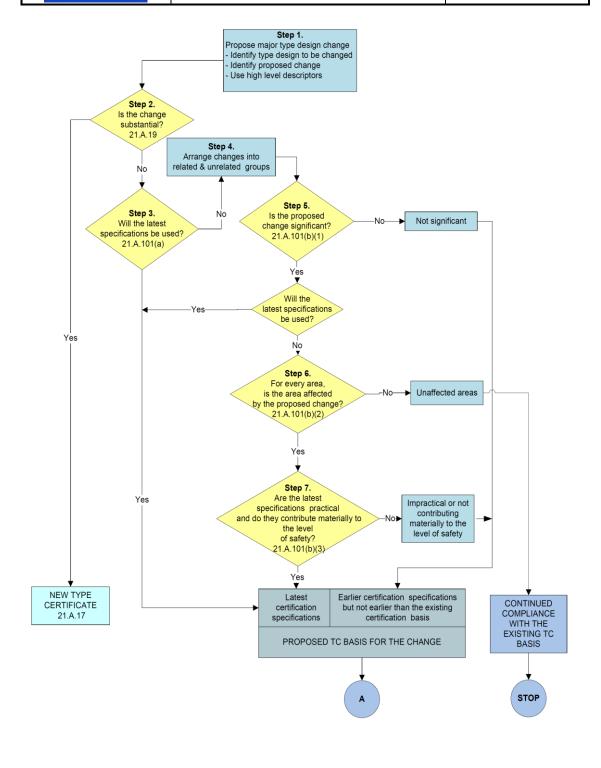
The Head of Office of Airworthiness is responsible to define the Type Certification Basis according to the procedure below (see also GM to 21.A.101). The Type Certification Basis is recorded for each major change and STC in the Certification Programme. For minor changes the type certification basis listed in the type certification data sheet is used or the newest valid certification specification. The Head of Office of Airworthiness will decide which certification basis will be used depending on practicability, safety and quality benefits.

The flow define the certification basis of a major change see flow chart below.

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Document reference:

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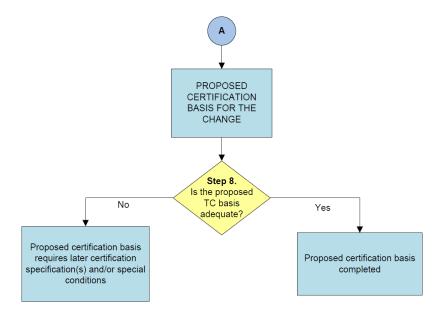


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For further explanations of each step see GM 21.A.101.

4.4 Certification Programme

See chapter 3.3.

4.5 Compliance Summary (Compliance Check List)

See chapter 3.4.

4.6 Declaration of Compliance

See chapter 3.5

4.7 Approval of Changes

This chapter describes the process how a minor or a major Design Change is approved. For minor changes most information should be given with the Design Change Approval form being used.

The basis for the approval of a minor change should be the Compliance Check List. The basis for a major change is the declaration of compliance. Minor changes can be approved by the design organisation. Major changes are approved by the Agency.

[TEXT HERE] Example:

4.7.1 Approval of Minor Changes

Example:

The approval of a Minor Change is pronounced on the basis of a completed type investigation. Therefor the Compliance Check List is used (see also chapter 4.5). The approval form (DO-08) references the Compliance Check List (DO-04). In case the Compliance Check List is approved by Office of Airworthiness the Head of Design Organisation approves the Minor Change by using the form DO-08.

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4.7.2 Approval of Major Changes

Example:

On the basis of the completed Compliance Check List (see also chapter 4.5) the Head of Design Organisation states the Declaration of Compliance (see 4.6). For this the form DO-09 is used. Office of Airworthiness sends this document to the assigned PCM. In case all type investigation documents are completed and correct the Agency will issue the approval for the Major Design Change.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

Part 5 - Repairs

This chapter describes the procedure for a minor or major repairs of the Type Design. The procedure shall define following aspects:

- Management of the project
- Application for a repair (for major only when the DOA is not the TC holder of the product or STC holder for repairs affecting STC) (EASA FO.TCCH.000 31)
- Certification programme
- Compliance Demonstration
- Tests
- Compliance summary
- Declaration of compliance (for major only when the DOA is not the TC holder of the product, or STC holder for repairs affecting STC)
- Approval

[TEXT HERE]

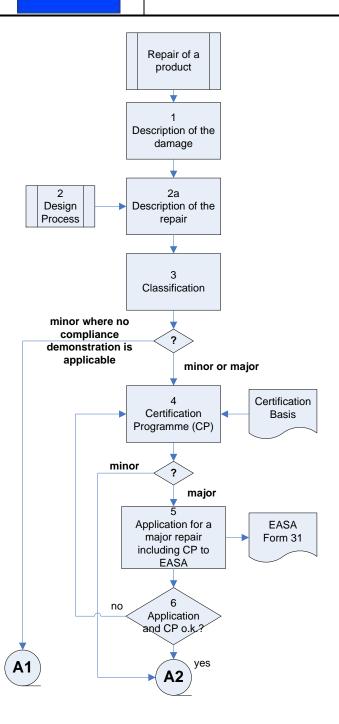
Example (for repairs on parts or products where the repair holder is not the TC/STC holder or the privilege to approve major repair design is not applicable):

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..



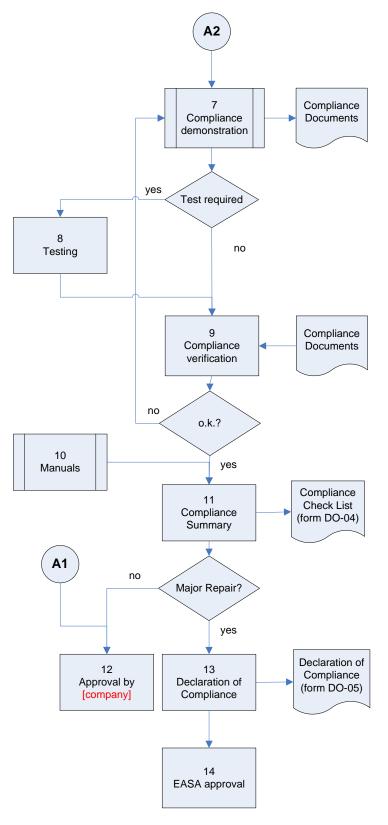
- [Describe here who in the design organisation is responsible for describing the damage to be repaired.]
 [TEXT HERE]
- The design process can start at this point. See Part 6 -. The type design documents (specifications, drawings, bill of material, production and installation procedures, etc.) are prepared. [Describe here who in the design organisation is responsible for specifying and describing the repair to be developed.] [TEXT HERE]
- The HOA together with the CVEs are preparing the classification including the substantiation for it. The HOA is responsible for the preparation and will approve it. For further details see chapter Błąd! Nie można odnaleźć źródła odwołania.
- 4. The HOA together with the CVEs are preparing the CP. The CP for repairs is part of RAS (form DO-22). The HOA is responsible for the preparation of the CP and will approve it.
- 5. [Note: This step is only necessary when the privilege to approve major repair design is not applicable.] [Describe here who in the design organisation is filling out the application form and sending it to EASA. The application for a major change shall be accompanied by an overview drawing of the change including preliminary basic data like proposed operating characteristics and limitations. The HOD or HOA should check and sign the form] [TEXT HERE]
- EASA will allocate a Project
 No. and will inform the DO on
 the responsible PCM. The
 PCM checks the CP and will
 accept it or will ask for
 revision.

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 The design engineer prepares the compliance demonstration document according to the certification programme (analysis, compliance statements, reports, etc.).
 Refer to Part 7 -

- For tests (ground test and flight tests) see Part 7 -, chapter 7.3
- The independent checking within respect to completeness and technical content is performed by the appropriate CVE within their field and with respect to their competences.
- 10. Manuals see chapter 11.1
- 11. The Office of Airworthiness is summarising all compliance documents in the Compliance Summary. With his signature the HOA declares that the type investigation is finished. (see chapter 5.7)

[NOTE: Companies designing a major repair for a product where they are also TC holders can apply for the privilege to approve the repairs by themselves.]

- The HOD approves the Minor Repair by using form DO-22.
- 13. The HOD signs the
 Declaration of Compliance
 and Office of Airworthiness
 sends the Declaration of
 Compliance including the
 compliance summary and all
 compliance documents
 defined by the PCM to the
 PCM. (see chapter 5.8)
 Note: Compliance documents
 and manuals can be sent to the
 PCM after these documents are
 approved by the [company].
- EASA will check the documents and will issue the approval.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

5.1 Damage description

Describe here who in the design organisation is responsible for specifying and describing the change of the product to be developed.

[TEXT HERE] Example:

The Design Organisation usually receives a damage report from an operator or a maintenance organisation. The engineering checks if the description is sufficient to be in the position to prepare a repair on this basis. If not the engineering will request further information from the operator or maintenance organisation. The damage description will be inserted in the Repair Approval Sheet (form DO-22).

5.2 Repair description

Describe here who in the design organisation is responsible for specifying and describing the repair to be developed

[TEXT HERE]

Example:

The engineering specifies the repair the repair on the basis of the damage description (see chapter 5.1). The repair description will be inserted in the Repair Approval Sheet (form DO-22).

5.3 Unrepaired damage

[TEXT HERE]

Example:

Also when a damaged product, part or appliance, is left unrepaired, and is not covered by previously approved data, the evaluation of the damage for its airworthiness consequences will be performed according to the procedure 0.

5.4 Classification of Repairs

The procedure should describe the classification criteria i.a.w. 21.A.435 and GM to 21.A.435(a)

Repairs must be classified as:

- Major
- Minor where additional work is necessary to demonstrate compliance with the CS and environmental protection requirements.
- Minor requiring no further demonstration of compliance

[TEXT HERE]

Example:

The form DO-22 appendix A is used to document the classification including the substantiation. The result is transferred then to the first page of the Repair Approval Sheet (form DO-22).

The classification for Repairs is similar to the classification of Changes. For classification of repairs in the following chapters the wording "appreciable" is used. The guidance on the word "appreciable" is detailed in chapter 4.2 (Classification of Design Changes).

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It is understood that not all the certification substantiation data is available to the Office of Airworthiness classifying repairs. A qualitative judgement of the effects of the repair is therefore acceptable for the initial classification. The subsequent review of the design of the repair may lead to it being re-classified, owing to early judgements being no longer valid.

5.4.1 Minor Repairs

Repairs whose effects are considered Minor and require minimal or no assessment of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements, are to be considered Minor.

Repairs will be classified as Minor if they have no appreciable effect on of the product, part or appliance:

• Weight and Balance:

The weight of the repair may have a greater effect upon smaller aircraft as opposed to larger aircraft. The effects to be considered are related to overall aircraft centre of gravity and aircraft load distribution. Control surfaces are particularly sensitive to the changes due to the effect upon the stiffness, mass distribution and surface profile which may have an effect upon flutter characteristics and controllability.

Structural performance:

This includes static strength, fatigue, damage tolerance, flutter and stiffness characteristics. Repairs to any element of the structure should be assessed for their effect upon the structural performance

Systems:

Repairs to any elements of a system should be assessed for the effect intended on the operation of the complete system and for the effect on system redundancy. The consequence of a structural repair on an adjacent or remote system should also be considered as above, (for example: airframe repair in area of a static port).

- Reliability
- Operational characteristics:

Changes may include:

- stall characteristics
- handling
- performance and drag
- vibration
- Noise fuel venting
- Exhaust emission
- Declared life
- Health:

Adverse effects on cabin bleed quality.

- Other characteristics affecting the airworthiness:
 - changes to load path and load sharing
 - fire protection / resistance

Repairs whose effects are considered minor and require minimal or no assessment of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements, are to be considered Minor

For the case that with the minor repair no Certification Specification and no environmental protection requirement is affected, the Office of Airworthiness will state this in the Classification form (DO-01) accordingly. A justification of this statement is necessary and is also placed in the Classification form (DO-01). This justification is checked and signed by the applicable CVE.

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An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

5.4.1.1 Minor repair requiring no further demonstration of compliance

Minor repairs were no compliance demonstration is required are minor repairs were no certification specification including special conditions and environmental protection requirements are applicable. This is documented on form DO-22 appendix A with a substantiation for this decision and approved by Office of Airworthiness.

5.4.2 Major Repairs

A Repair with an appreciable effect on characteristics affecting the airworthiness of the product could be classified as MAJOR, when one or more of the following conditions are met:

- After repair a permanent additional inspection to the approved maintenance programme is required.
 - Temporary repairs for which specific inspections are required prior installation of a permanent repair do not necessarily need to be classified as Major. Also, inspections and changes to inspection frequencies not required as part of the approval to ensure continued airworthiness do not cause classification as Major for the associated repair.
- Repairs to life limited or critical parts.
- A repair that introduced a change to the AFM
- Repairs which need extensive static, fatigue and damage tolerance strength justification, testing in its own right.
- Repairs which need methods, techniques or practices that are unusual (i.e. unusual material selection, heat treatment, material process, jigging diagrams, etc.).
- Repairs that require a re-assessment and re-evaluation of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements.^

5.5 Type Certification Basis for a Repair Design

See 21.A.433(a)(1)

[TEXT HERE]

Example:

The [company] will demonstrate compliance with the type certification basis and environmental protection requirements listed in the type certification data sheet or the newest valid certification specifications. The Head of Office of Airworthiness will decide which certification basis will be used depending on practicability, safety and quality benefits.

5.6 Certification programme

[TEXT HERE]

Example:

See chapter 3.3. For repairs the form DO-22 is used to document the certification programme.

5.7 Compliance Summary (Compliance Check List)

See chapter 3.4. For repairs the form DO-22 is used for the compliance check list.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

5.8 Declaration of Compliance

See chapter 3.5. For repairs the form DO-22 is used.

5.9 Approval of Repairs

This chapter describes the process how a minor or a major Repair is approved.

The basis for the approval of a minor change should be the Compliance Check List. The basis for a major change is the declaration of compliance. Minor repairs can be approved by the design organisation. In case the design organisation is also TC or STC holder it can apply for the privilege to approve also Major Repairs for their product. In case the design organisation does not have the privilege, the Major Repairs are approved by the Agency.

[TEXT HERE] Example:

5.9.1 Approval of Minor Repairs

Example:

The approval of a Minor Repair is pronounced on the basis of a completed type investigation. To demonstrate this the Compliance Check List is used (see also chapter 5.7) which is part of the form DO-22. After the Office of Airworthiness stated that the type investigation is completed the Head of Design Organisation approves the minor repair by using the form DO-22.

5.9.2 Approval of Major Repairs

Example (no privilege for major repair approval existing):

On the basis of the completed Compliance Check List (see also chapter 5.7) the Head of Design Organisation states the Declaration of Compliance (see 5.8). For this the form DO-22 is used. Office of Airworthiness sends this document to the assigned PCM. In case all type investigation documents are completed and correct the Agency will issue the approval for the Major Repair.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

Part 6 - Design Process

Detailed description required how the DO manages a design project. The design process shall also describe the tools being used.

The type design documents (specifications, drawings, bill of material, production and installation procedures, etc.) are prepared. Describe here the complete design process (who is taking the project lead, which tools are used, which kind of tasks are delegated to a supplier, etc.). A link to a separate document describing the design process could be sufficient.

[TEXT HERE]

6.1 Initiation of Design Process

A description is required how the design process is initiated within the design organisation.

[TEXT HERE]

6.2 Management of Design Project

[TEXT HERE]

6.3 Drawings, Bill of Material

[TEXT HERE]

6.4 Configuration Control

Configuration control is essential to provide identification and traceability of designed and repaired parts and products. This chapter should describe how this can be assured by the DO.

Following issues have to be addressed:

- Who is responsible for the configuration control?
- Description of the tool be used
- Part Number
- Serial Number
- Drawing Number
- Bill of Material
- Relation between drawing and part number
- How are issues and revisions handled?

[TEXT HERE]

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

6.4.1 Marking

The procedure should describe how the marking requirement of Part 21 Subpart Q is taken into account and specified in the design data:

- Information to be marked, including EPA letters, as relevant
- Size
- Place
- Type of marking

[TEXT HERE]

6.4.2 etc. [TEXT HERE]

[TEXT HERE]

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

Part 7 - Compliance Demonstration

[TEXT HERE]

7.1 Compliance Statements

[TEXT HERE]

7.2 Analysis

[TEXT HERE]

7.3 Investigation and Testing

See 21.A.33 and 21.A.35 including the GM

[Text]

Example:

[company] performs investigations and tests necessary to demonstrate compliance with the applicable type certification basis and environmental protection requirements. These tests are defined in the Certification Programme and detailed in a Test Plan.

7.3.1 Test Plan

For each compliance test a test plan which is based on the agreed certification programme shall be issued. The test plan is part of the compliance demonstration. The test plan describes in detail the scope of the test including the Certification Specification supported by the test, the test procedure including inspection requirement, the proposed test results including fail/pass criteria, the test location, test facility, etc. For the test plan the Form DO-05 shall be used. The test plan has to be checked and approved by the relevant CVE.

7.3.2 Conformity Inspection, Conformity Statement

The build standard of the test specimen must be representative of the TC / Change / Repair for the particular test. The authorized quality assurance representative of the manufacturer ensures via samples of the manufacturing and equipment documentation before the test starts that:

- the test specimen, all relevant parts, the manufacturing processes, materials, construction and assembly conform to the specifications (e.g. Test Plan, Engineering Order, etc.)
- any deviations and non-conformances were justified and approved by the relevant CVE
- qualification of the test facility set-up and their calibration

The result is summarised in a statement of conformity or in an EASA Form 1 (only for conformity, not eligible for installation on in-service type-certificated aircraft / engine / propeller) presented to the Agency if requested by the Office of Airworthiness. For the statement of conformity the Form DO-06 is used. In case the conformity statement is part of the test report, the CVE confirms with his signature the upper mentioned issues after the test was performed.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

7.3.3 Witnessing

Both Agency and Office of Airworthiness reserve the right to witness the tests performed within the certification process. All compliance tests have to be reported to the Airworthiness Office in due time (at least 2 cw before start). In case the Agency requested to witness the test the Office of Airworthiness informs the Agency as soon as possible.

The Office of Airworthiness witnesses all tests, which are:

- required by the certification specification
- delegated from the Project Certification Manager (PCM) of EASA to the Office of Airworthiness

Nevertheless the Office of Airworthiness and the Agency has right to witness any other compliance tests any time.

Witnessing of these tests can be delegated from the Office of Airworthiness to a CVF

To document the witnessing the Form DO-07 is used.

7.3.4 Laboratory Tests

The test facility and test bed equipment shall be adequate for the test performed. If the own test bed and equipment is not adequate, external test facilities support may be used when approved by the [company] or supervised by personal of the [company's] qualified personal and shall be audited regularly by the [company] (see also Part 12 -).

7.3.5 Ground Tests

[TEXT HERE]

7.3.6 Flight Tests

See appendix E to this DOH.

[TEXT HERE]

Example:

See appendix E to this DOH(chapter 13.5.)

7.3.7 Test Report

The test report is the final document for a test. The form DO-03 is used for the test report. The test report contains following information:

- reference to the project no.
- reference to the certification programme
- reference to the conformity inspection
- title of the project
- purpose of the test
- list of the certification specification requirements which are supported by the
- reference to the test plan
- detailed description of the deviations to the test plan
- test result (fail/pass criteria)
- statement that the part tested complies with the specified requirements under fail/pass criteria mentioned in the test plan

Note: The test report is a compliance demonstration document therefor see also chapter 7.3.8.

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An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

7.3.8 Compliance Demonstration Document

This chapter describes:

- The scope of a Compliance Document
- The document numbering system
- By whom a Compliance Document is issued
- By whom a Compliance Document is approved

A reference to a form which implements the main issues of a compliance document would be beneficial.

The Compliance Document shall cover following issues:

- Reference to the project
- Reference to the certification specification to which compliance is demonstrated
- Summary/conclusion which states compliance to the referenced requirements
- Author (design engineer) signature
- CVE signature (as checked)

[TEXT HERE] Example:

For all applicable certification requirements noted in the Certification Programme a Compliance Demonstration Document shall be prepared. It is also possible to merge several requirements in one Compliance Demonstration Document if reasonable. This Compliance Demonstration Document describes the Means of Compliance and summarises the compliance findings. The complete set of Compliance Demonstration Documents shall cover the defined requirements listed in the Certification Programme.

All Compliance Demonstration Documents are archived in order to provide the information necessary to ensure the continued airworthiness. See also 10.1.

The compliance demonstration documents shall be signed by:

- The Design Engineer (author)
- The CVE (checked and approved)

Note: The Design Engineer and the CVE shall not be the same person.

The Design Engineer signs the document that the:

- technical content is correct.
- technical content and the means of compliance is in accordance with the referenced Certification Programme.
- compliance demonstration fulfils the referenced certification specification.
- referenced documents are available.

The CVE signs the document that he independently:

- checked the technical content including all referenced documents despite they were already checked by other CVE.
- checked that the referenced certification specification is completely fulfilled.

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

Part 8 - Permit to Fly

8.1 Establishment (and Approval) of Flight Conditions

In case the Design Organisations wishes to obtain the privilege to approve flight conditions (21.A.263(c)(6)), a procedure in accordance with AMC 21.A.263(c)(6) shall be prepared.

Design Organisations not holding the 21.A.263(c)(6) privilege shall prepare a procedure describing the establishment and application for approval of flight conditions. This procedure shall cover following points of AMC 21A.263(c)(6):

- 2.3 Management of the aircraft configuration
- 2.4 Determination of the conditions that must be complied with to perform safely a flight
- 2.5 Documentation of flight conditions substantiations

In addition it shall include:

- description of how the addressee is identified based on the criteria specified in 21.A.709(a) (i.e. related to the safety of the design or not),
- identification of the application form to be used (EASA Form 18b) and the documents to accompany that application
- identification of the person(s) authorized to sign the application

[TEXT HERE]

8.2 Application for / Issue of Permit to Fly

In case the Design Organisations wishes to obtain the privilege to issue a Permit to Fly (21.A.263(c)(7)), a procedure in accordance with AMC 21.A.263(c)(7) shall be prepared.

Design Organisations not holding the 21.A.263(c)(7) privilege shall prepare a procedure describing the application for a Permit to Fly. This procedure shall cover following points:

- description of how the addressee is identified (i.e. competent authority nominated by the State of registry),
- identification of the application form to be used (EASA Form 21) and the documents to accompany that application
- identification of the person(s) authorized to sign the application
- identification of issues invalidating a Permit to Fly

[TEXT HERE]

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

Part 9 - Coordination between design and PO/MO

9.1 Coordination between design and production

The procedure should describe the link established between design and production. In the case where the production is made by a separate legal entity, a formal arrangement shall be signed between the two companies. A template is proposed in GM 21.A.133(b).

The procedure should cover the transfer of information from the design organisation to the production organisation. More information is given in AMC 21A.4.

The procedure should also cover the deviation and concession process. Production deviations from the approved design data should be treated through the changes approval process.

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

[TEXT HERE]

Example (for a company where the production is in the same entity as the DOA):

Coordination between the [company] design organisation and the [company]

production organisation is ensured through the [company] quality system wherein
the design organisation assures that:

- All necessary airworthiness data as drawings, specifications, dimensional data, processes, surface treatment, shipping conditions, qualification requirements are correct and up to date
- All above mentioned documents are timely transferred to the production organisation to enable the production organisation to draw up a certificate of conformity or a release note.
- All continued airworthiness aspects are supported by the production organisation.

9.1.1 Data exchange

To assure the data exchange the Office of Airworthiness provides all approved data to the production organisation in a separate folder ["approved design data"] where just approved data is collected. In case parts have to be produced for compliance demonstration or prototyping purposes the data is provided by Office of Airworthiness in the folder ["released design data"]. Both folders are protected and no changes can be made by unauthorized staff.

This arrangement enables the production organisation to verify that their deliveries conform to applicable airworthiness data.

The procedure to provide data to the production organisation comprises the major steps:

- checking of approved / release signatures requested on the authorisation record
- formal approval / release of the design documents
- provide documents to the production organisation including delivery documentation via the [company] data base.

9.1.2 Production deviations, concessions

Every unintended deviation from the design data on a part during production shall be documented with the concession form [form concession]. Following steps have to be followed:

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

- 1. The production organisation describes the deviation / non-compliance of the part.
- 2. The design engineer assesses the part. Following possibilities are available:
 - scrap
 - us as is
 - rework the part

When the decision is that the part has to be scraped the rejected part is marked unserviceable acc. to the process of the production organisation.

- 3. The deviation will be classified as major/minor acct. to chapter 4.2 by the Office of Airworthiness
- 4. In case of major the process according to chapter 4.2 has to be followed. In case of minor the Office of Airworthiness defines the affected certification specification on the concession form.
- 5. The design engineer prepares the compliance demonstration which can be directly performed on the concession form or referenced there.
- 6. The applicable CVEs checks and approve the compliance demonstration
- 7. Office of Airworthiness approves the concession direct on the concession form.
- 8. The concession including all referenced documents are archived acc. to chapter 10.1.

9.2 Coordination between design and MRO

When the first installation of a change to type design, or the design of a repair, require the assistance by a maintenance and repair organisation (MRO), the DOA Holder needs to ensure effective and efficient coordination with the MRO. This coordination is especially important when the MRO will perform some of the compliance demonstration tests.

In these cases, the DOA Holder should establish how the transfer of information will be organised, how the tasks performed by the MRO will be supervised, and how the final deliverables will be validated. Topics such as configuration management, component handling, on-aircraft development of the change or repair, etc., have to be addressed. The document EASA_S21_GP001 "Good Practices – Coordination between Design and Maintenance", published on EASA's internet pages, should be used for reference.

If described in a procedure, this document should list the responsibilities taken over by each organisation, including the involvement of the MRO in the preparation and review of design data and the related statement of conformity. In the case where the MRO is a separate legal entity, a formal arrangement shall be signed between the two companies.

[TEXT HERE]



Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

Part 10 - Document control

10.1 Record keeping

The procedure should describe the record keeping or archiving system in place in the organisation and define who is responsible for this task.

For each change or repair, all relevant design information, drawings, test reports, instructions and limitations issued, justification for classification and evidence of the design approval, shall:

- (a) be held by the design approval holder at the disposal of the Agency, and
- (b) be retained by the repair design approval holder in order to provide the information necessary to ensure the continued airworthiness of the repaired products, parts or appliances.

There is no limitation of duration. Records should be kept available as long as the modified or repaired product or part is retained in service.

[TEXT HERE]

Example:

The preparation and approvals of all certification documents has to follow the DOH procedures. Any handwritten change to the pre-filled form (e.g. editorial corrections) has to be signed by the responsible Design Engineer with date and signature.

The full design data which are produced by [company] are stored within the [company] electronic document storage/retrieval and archiving system [database]. All design data including drawings, test reports, instructions, limitations and basic documents like coordination memos are stored in [database]. All forms (templates) to be used in the design organisation are also stored in [database].

All certification documents and ICA are linked to the internal project number. The originals (signed documents) are stored in the archive by the Office of Airworthiness and will not be handed out to unauthorized persons. Copies can be made on request.

Additionally to storing them digitally in the system, the originals of documents (reports) are stored separately for long term archiving. The originals of drawings and schemes are, additionally to the storage in the system, stored as pdf-files with digital signatures. All data are stored on 2 different places.

For Type Design data the retention period is "Life of Product" plus further 3 years.

The Agency has any time access to all type investigation documents. [TEXT HERE]

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

Part 11 - Continued Airworthiness

The procedure should describe the system put in place for ensuring safe operation of the product and informing the customer and operators concerning Instructions for Continued Airworthiness.

[TEXT HERE] Example:

11.1 Manuals

The procedure should explain how the company is organized to produce, maintain and update copies of all manuals required by the applicable type certification basis and environmental protection requirements for the product and provide copies, on request, to the agency (Part 21A.57, 21A.119).

The manuals the Part 21 is referring to are:

- The aircraft flight manual (AFM) or supplement to AFM
- The aircraft maintenance manual (AMM) or supplements to AMM
- Structural Repair Manuals (SRM) or supplements to SRM
- Parts Catalogue
- ...

From this list, the documents approved by the Agency are the approved sections of aircraft flight manual and the Airworthiness Limitation section of the AMM.

The production of the manual allows to partially answering the Part 21 requirements concerning the instructions for continued Airworthiness (Part 21A.31, 21A.120, 21A.449).

11.1.1 Aircraft Flight Manual (AFM)

[TEXT HERE]

11.1.2 Aircraft Maintenance Manual (AMM)

[TEXT HERE]

11.1.3 Structural Repair Manual (SRM)

[TEXT HERE]

11.1.4 Parts Catalogue

[TEXT HERE]

11.1.5 Etc.

[TEXT HERE]

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Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate..

11.2 Instructions for Continued Airworthiness

In order to fully answer the requirements, the process describing the manual management process should be completed with specific instructions concerning the preparation and publication of accomplishment instructions to the owners, by the mean of Service Bulletins or Repair Approval Sheets. Service Bulletins can be used for describing accomplishment instructions (change implementation) but also for inspection instructions, further to an EASA Airworthiness Directive. Repair Approval Sheets are used to describe a repair but also for further inspection instructions related to a repair.

The procedure should explain that the feasibility of all instructions must be verified by the organisation before being published.

The Agency does not approve information or instructions. Statement should refer to the fact that the documentation has been produced in accordance with DOA procedures, or refer to technical data that has been approved by the Agency or by the Design Organisation.

[TEXT HERE]

Example:

Following documents are issued by [company]:

- Aircraft Maintenance Manual (AMM) (including Airworthiness Limitations like life limited parts)
- Service Bulletins (SB)
- Alert Service Bulletins (ASB)
- Repair Approval Sheets (RAS)

11.2.1 Service Bulletins (SB)

Service Bulletins (SB) are issued to provide instructions for changes/modifications of a part or product. It can be also used to provide maintenance organisations with necessary maintenance data for the performance of maintenance, including inspections. The categories of application specify the order of precedence in which Service Bulletins are incorporated.

a) <u>Customer Option</u>: The Service Bulletin will be incorporated upon costumer

reauest.

b) Recommended: The incorporation of this Service Bulletin is recommended by

the [company] Design Organisation.

c) <u>Mandatory</u>: This Service Bulletin will be sent to the Agency for approval

with the request to issue an Airworthiness Directive. The Service Bulletin must be incorporated according to the

requirements of the Airworthiness Directive.

The establishing and checking of Service Bulletins is based on the approved minor or major changes. Therefore every Service Bulletin states that "the technical content of this document is approved under the authority of DOA ref. EASA.21J.xyz".

- The Head of Office of Airworthiness will approve the Service Bulletin when, in case of major change, the change is approved by the Agency and in case of minor change when the Head of Design Organisation has approved the minor change.
- With the signature the Head of Office of Airworthiness confirms that the technical content has been checked and the change described is approved.



Document reference:

An unambiguous reference should be given (name of document) that will be referenced in the Approval Certificate...

For the Service Bulletin the form DO-20 is used.

Numbering System of Service Bulletins: SB-[company]-[sequential number] (e.g.: SB-DO-061)

11.2.2 Alert Service Bulletin (ASB)

Alert Service Bulletins are used just in case of safety-critical situations. The Alert Service Bulletin must contain at least all information required for implementing immediate measures.

In urgent cased where the safety of aircraft may be affected, an Alert Service Bulletin is produced as quickly as possible and sent to the operators and Agency. In such cases the measures defined by the [company] may be released for publication by the Design Organisation's authorised signatories only (Head of the Office of Airworthiness, Head of the Design Organisation). Usually the content of an Alert Service Bulletin is implementation of extraordinary inspections or life limitations which are not based on an approved change but on fleet experience, events or analysis results..

- Alert Service Bulletin are by definition Mandatory, therefore EASA will be requested to issue an Airworthiness Directive.
- The Head of Office of Airworthiness will approve the Alert Service Bulletin.
- In case technical changes will be introduced the Alert Service Bulletin must be based on an already approved change.
- With the signature the Head of Office of Airworthiness confirms that the technical content has been checked and the change described is approved.

For the Alert Service Bulletin the form DO-21 is used.

<u>Numbering System of Service Bulletins</u>: ASB-[company]-[sequential number]

(e.g.: ASB-DO-001)

11.2.3 Repair Approval Sheet (RAS)

The RAS is intended to provide information for maintenance stations which describes a specific repair, which is not covered in the repair manuals. It is prepared only for a component on the basis of the information supplied to the [company]. The approval procedure for Repair Approval Sheet is described in 0. For the Repair Approval Sheet the form DO-22 is used.

<u>Numbering System of Service Bulletins</u>: RAS-[company]-[sequential number]

(e.g.: RAS-DO-019)

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11.3 Failures, malfunctions and defects

The procedure should describe the system put in place for 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 the product, part or appliance covered by the STC, or repair design approval (21A.3).

The procedure should explain how the reporting to the Agency is organized.

The procedure should mention directly or by cross reference with 1.9 who is authorised to create, append, and modify the data's collected and to do the reporting to the Agency.

The procedure should also explain how the organisation carries out any required technical investigation subsequent to an occurrence.

Finally, the procedure should explain, in the case where an Airworthiness Directive is published, how the organisation is cooperating with the Agency (21A.3B).

The procedure should include airworthiness review meetings with EASA, as appropriate.

[TEXT HERE] Example:

11.3.1 Monitoring occurrences

The Head of Office of Airworthiness is responsible for the monitoring of events/occurrences on [company's] products but also other aeronautical products as far as relevant to determine their effect on airworthiness being designed by [company].

All information is collected by Office of Airworthiness. The information be received from:

- Internally
- Production Organisation
- Maintenance Organisation
- Operator, owner

The form to be used to report to [company] is provided with the aircraft manual. In addition on each Service Bulletin and on [company]'s webpage the contact address (e-mail) is distributed, so the information can be transferred in any way to the [company]. In any case the information will be evaluated and relevant actions will be introduced.

11.3.2 Classification and investigation of occurrences

Occurrences, which present definitely no flight safety risk (e.g. pure quality issues, where none of the affected parts have been delivered) will be filtered out by the Office of Airworthiness. In this case the issue will be closed at this early stage and forwarded directly to the affected department for further action.

All other occurrences will be discussed and classified with the related CVEs considering following points:

- Is all information available which enable a decision?
- Is there further information necessary from the costumer/ TC-Holder?
- Has the costumer/ TC-Holder to be informed in advance?
- Is flight safety affected?
- Are corrective actions required?
- Are immediate actions required?



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The result of this initial investigation is recorded on the "Occurrence Record Form" DO-13.

Based on the result of the investigation necessary actions are defined and initiated.

Classification	Description	Report
Catastrophic	Failure conditions, which would result or could have resulted in multiple fatalities, usually with the loss of the aeroplane.	 Immediately: Inform EASA by phone, or e-mail Inform all known operator of affected aeroplanes or affected persons. Within 72 hours:
		 Complete report to EASA. Technical Note to EASA for issuing an AD
Hazardous	 Failure conditions, which could reduce the capability of the aeroplane or the ability of the crew to cope with adverse operating, conditions to the extent that there would be: A large reduction in safety margins or functional capabilities; Physical distress or excessive workload such that the flight crew cannot be relied upon to perform their tasks accurately or completely; or Serious or fatal injury to a relatively small number of the occupants other than the flight crew. 	 Immediately: Inform EASA by phone, or e-mail Inform all known operator of affected aeroplanes or affected persons. Within 72 hours: Complete report to EASA. Technical Note to EASA for issuing an AD
Major	Failure conditions, which could reduce the capability of the aeroplane or the ability of the crew to cope with adverse operating conditions to the extent that there would be: • A significant reduction in safety margins or functional capabilities • A significant increase in crew workload or in conditions impairing crew efficiency or discomfort to the flight crew • A physical distress to passengers or crew, possibly	 In dependence of the level of a possible hazard within 72 hours: Complete report to EASA Inform all known operator of affected aeroplanes or affected persons. Technical Note to EASA for issuing an AD

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including injuries.

Minor

Failure conditions which would not significantly reduce aeroplane safety, and which involve crew actions that are well within their capabilities. Minor failure conditions may include:

- A slight reduction in safety margins or functional capabilities
- A slight increase in crew work load such as routine flight plan changes
- Some physical discomfort to passengers or cabin crew

- Treatment as complaint
- Inform all known operators or affected persons by Service Bulletin
- Only if necessary: technical note to EASA for issuing an AD

11.3.2.1 List of examples of reportable occurrences

The AMC 20-8 lists reportable occurrences. This list of examples will not be used by the [company] directly for the purpose of determining when an occurrence has to be reported to the Authority. It will rather serve as guidance for establishing a system for data collection. After receipt of reports from a primary source of information, the [company] will perform an analysis to determine whether an occurrence has resulted or may result in an unsafe condition and report it to the Agency.

11.3.3 Occurrence Report

To report an event or any other safety related issue the "Occurrence Report" form DO-13 is used. In this form all information is recorded including:

- Affected aircraft/part
- Problem description
- Immediate actions taken
- Investigations, further steps
- Information if this occurrence has to be reported to the Agency or not including justification.

This report is signed by the affected CVE and Office of Airworthiness.

11.3.4 Reporting to the Agency

To inform the Agency the EASA Occurrence Reporting Form (Form 44) is used. This form can be downloaded from the EASA web site http://easa.europa.eu/iors/index.html. Instructions for completion and where to send the form (report@easa.europa.eu) is also given on this site.

11.3.5 Airworthiness directives (AD)

An AD means a document issued by the Agency which mandates actions to be performed on the aircraft to restore an acceptable level of safety.

The Agency shall issue an airworthiness directive when:

- an unsafe condition has been determined by the Agency to exist in an aircraft, as a result of a deficiency in the aircraft, or an engine, propeller, part or appliance installed on this aircraft; and
- that condition is likely to exist or develop in other aircraft.

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The Office of Airworthiness provides all necessary information and support to define measures to be implemented to restore the level of safety. For this the [company] will issue a Service Bulletin or an Alert Service Bulletin.

See also chapter 11.2.1 and 11.2.2.

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Part 12 - Design Suppliers

Where design supplier are used, the selection and surveillance processes should be described. The procedure should address how the technical assessment of partners or design supplier is carried out by the organisation.

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

[TEXT HERE]

Example:

In case [company] sees the need to subcontract design work outside the [company] design organisation the Head of Design will select a design supplier with sufficient qualification.

It is possible to involve design suppliers

- with **own** EASA design organisation approval (with DOA), or
- without own EASA design organisation approval (without DOA), or
- as a single person

When employing design suppliers, individual "Work Share Agreements" will be signed between [company] and the design suppliers where [company]'s basic requirements towards the design suppliers are listed. The agreement contains a description of the design suppliers organisation and design activities (see 21.A.243(b)).

Following arrangements have to be defined:

- Scope of Work
- List of affected chapters of the DOH which have to be followed.
- Nomination as design engineer or CVE.
- Possibility for [company] to carry out scheduled or unscheduled audits at the design supplier.
- Agreement to allow the Agency to perform any investigations necessary to determine compliance and continued compliance with the applicable requirements of EASA Part 21, Subpart J (21.A.257(a)).
- Design suppliers are obligated to inform the Head of Design immediately, by telephone or electronic mail, of any defects that may be classified as "Reportable defects" as defined in EASA AMC 20-8.
- Should an error be found in, or a change be required to the design drawings or documentation, the supplier will raise a design query note to the [company]
- For design suppliers with DOA:
 - Information on EASA or internal level one or level two findings must be provided to [company] in case it affects the working arrangement.
 - Information of any changes to the terms of approval or limitations must be provided to [company].
 - Regular coordination and link up of ISMs from both sides.
 - Access is given to design suppliers DOH sections that are relevant for the subcontracted task.

12.1 Selection criteria for design suppliers

For completely unknown design suppliers a detail qualification assessment will be conducted at the location of the design supplier. For design suppliers with verified

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qualification from independent institutions, covering the intended scope of work, this verification can be used as selection basis. For design suppliers where work experience exists between [company] and the design supplier, based upon previous work conducted, even when outside of or prior to the existence of the [company], this experience can be considered sufficient as selection basis without further evaluation.

If the design supplier's scope of work entails test activities, the relevant test equipment as well as test procedures are verified (with regards to capacity, appropriateness, accuracy, calibration records etc.). The Work Share Agreement must show a requirement that [company] must be informed of any modification to the equipment that might have influence on the assessment, prior to usage of this changed equipment for tasks conducted on behalf of [company]. Only if the result of these assessments is satisfactory, the company may be chosen to perform the intended tasks for [company]. The assessment results will be archived in the same way as compliance demonstration reports (see chapter 10.1).

12.1.1 Subcontracting to design suppliers without DOA

Before allocating any task to a non-qualified potential design supplier, the QMS of that company, if existing, is evaluated under the responsibility of the [company] ISM, considering the specific task intended for subcontracting. In addition the qualification of the potential design supplier is verified by the Head of Design, also considering the specific task intended for subcontracting. Additional audits are instigated on request of [company]'s Head of Design Organisation or Head of Office of Airworthiness or by Head of ISM at any time. The audits are limited to those processes that are relevant to and concern the work that is performed for [company] design organisation. As single person offices typically do not have or require a quality management system, in this case only an initial assessment is required. This assessment shall confirm the qualification for the intended task. A reaudit is not required. Continuous quality and correctness of delivered data is ensured by the provisions of the deliverables acceptance.

Non-approved design suppliers or single person offices may conduct design tasks only under supervision of a design engineer of [company]'s design organisation. All design results have to be checked and signed by the design engineer of [company]. The results are further on treated as if generated by this design engineer (21A.239(c)). Upon completion and delivery, design results and compliance documentation are checked and signed by the design engineer of [company] and only then verified and approved by CVE of [company] following this DOH. (21A.243(b)).

12.1.2 Subcontracting to design suppliers with DOA

Design suppliers must verify and prove to [company] that the task they perform for [company] is covered by their DOA. For this they have to give [company] access to their DOH and associated process descriptions. In case of unclear issues the ISM of [company] may conduct an audit at the design supplier. [Company] reserves the right (refer to Work Share Agreement) to request and receive all information and results of ISM activities and EASA audits performed at design supplier level. These information are perused and evaluated by [company] and if evaluation results give reasons for concern, [company] may decide to perform an own audit on the subject area. Additional audits are instigated on request of [company]'s Head of Design Organisation, Head of Office of Airworthiness or Head of ISM. If any of the audits above provides unsatisfactory results that can not immediately be remedied with

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positive effect to the subcontracted work in order to satisfy the requirements of this DOH, then these design suppliers are treated like design suppliers without DOA.

Approved design suppliers can conduct complete design tasks within their scope of work. The design supplier must be provided with all required information regarding the Certification Programme as necessary for the task. The Design supplier runs the design activity under his approved design assurance system. Depending on the agreements defined within the individual work share agreement, deliverables from qualified design suppliers may be accepted with CVE approval from the design supplier and do not require CVE verification within [company]. In all other cases verification is done (in addition) by a CVE within [company]. (21A.239©).

12.2 Design supplier, CVE nomination

12.2.1 CVE at a design supplier without DOA

It is possible to nominate a person of the design supplier as CVE of [company] design organisation for a specific task. In this case his personal records, like Curriculum Vitae, documented evidence of qualification and experience, etc. are to be provided to [company]'s Head of Design Organisation where it is treated and stored in the same way as mentioned in chapter 1.7. The nominated person must be trained and made aware of all DOH chapters and procedures relevant to their activity. In addition they get full access to all DOH sections that are applicable to his specific task and duties. It must be ensured that the CVE reports direct to the Office of Airworthiness at [company]. This will be stated in the nomination sheet of each CVE.

12.2.2 CVE at design supplier with DOA

Nominated design engineers or CVEs of design suppliers with approved design organisation may be accepted on the basis of the approved provisions of the design supplier's DOH. In this case no personnel records for these design engineers or CVEs of approved design suppliers are kept at [company].

The Work Share agreement defines technical expertise needed to cover [company's] scope of work for the project. In addition the CVEs are identified in this agreement. The design supplier is obliged to inform [company] about any changes to its qualification requirements or to the status of nomination of the person.

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Part 13 - Appendices

Appendix A - Abbreviations

Appendix B - Definitions

Appendix C – List of referenced procedures

Appendix D – List of forms and templates

Appendix E – Flight Test Operations Manual

etc.

[TEXT HERE] Example:

13.1 Abbreviations

An appendix to this DOH can be referenced here, but could be also part of this handbook.

[TEXT HERE] Example:

13.2 Definitions

An appendix to this DOH can be referenced here, but could be also part of this handbook.

[TEXT HERE] Example:

13.3 List of referenced Procedures

An appendix to this DOH can be referenced here, but could be also part of this handbook.

[TEXT HERE] Example:

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13.4 List of forms and templates

An appendix to this DOH can be referenced here, but could be also part of this handbook.

[TEXT HERE] Example:

DOH-ref.	Title	
DO-01	Application and Classification	
DO-02	Certification Programme	
DO-03	Compliance Demonstration Report	
DO-04	Compliance Check List	
DO-05	Test Plan	
DO-06	Statement of Conformity	
DO-07	Test Witness Report	
DO-08	Minor Change Approval	
DO-09	Declaration of Compliance	
DO-20	Service Bulletin	
DO-13	Occurrence Record Form	
DO-21	Alert Service Bulletin	
DO-22	Repair Approval Sheet	
DO-30	CVE nomination sheet	
DO-40	Audit Plan	
DO-41	Audit Report	
DO-42	Action and Finding List	

13.5 Flight Test Operation Manual

An appendix to this DOH can be referenced here, but could be also part of this handbook.

[TEXT HERE] Example:

Appendix E Flight Test Operation Manual

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