DEPARTMENT OF CIVIL AVIATION MALAYSIA

Airworthiness Sector

Design Organisation Approval

Handbook

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The expression "DCA" in this handbook shall mean Director General of Civil Aviation or any persons authorised by the Director General of Civil Aviation, whichever is applicable in accordance with Civil Aviation Regulations 1996.

1.0 INTRODUCTION.

1.1 This handbook is issued by Airworthiness Sector, Department of Civil Aviation (DCA), Malaysia and contains information about standards, practices and procedures acceptable to the DCA in relation to Design Organisation Approval (DOA).

2.0 SCOPE.

2.1 Civil Aviation Regulation (CAR) 1996, Regulation 38, makes provision for the approval of design organisation and provides the regulatory basis for the Certificate of Approval. The Regulation 38 requires any organisation engaging or intending to engage with any design activities of aircraft and its associated products to hold a DOA in respect of those activities.

2.2 DCA Airworthiness Notice (AN) No. 96 is developed to provide the requirements in respect of DOA, which establishes the ***procedures*** and ***rules*** governing the rights and obligation of applicants for, and holders of, such approvals.

2.3 This handbook is issued to provide additional Means of Compliance (AMC) and Interpretative/Explanatory Material (IEM) to assist the industry on the Malaysian airworthiness requirements in relation to DOA as published in AN No. 96.

3.0 DESIGN ORGANISATION APPROVAL (DOA).

3.1 **DOA** is an approval granted to a design organisation to perform certification and airworthiness activities on behalf of DCA through the following granted privileges;

i). Release certification documents without verification by DCA.

ii). Classify modifications, repairs and manufacturing concessions of changes and repairs.

iii). Approve minor modifications, repairs and manufacturing concessions.

iv). Issue information or instructions stating that the technical content is approved (e.g. Service Bulletins).

3.2 Granting a **"DOA certificate"** means:

i). Recognition of the capability of the design organisation to release design data after validation and verification of the compliance with airworthiness and environmental protection requirements by authorised and qualified staff;

ii). All responsibilities of the design organisation are properly discharged top down;

iii). The design organisation, it's functioning and associated procedures are properly documented and referred to in Design Organisation Manual (DOM);

iv). Roles and responsibilities, capability, capacity and authority are in accordance with the DOM;

v). Effectiveness of the functioning of the organisation and the adequacy and application of documented procedures are verified continuously;

vi). Results of surveillance satisfy DCA and maintain confidence.

3.3 Effectively the granting of a DOA certificate and **"associated privileges"** is the recognition by DCA of the

i). **demonstrated capability** of the design organisation;

ii). confidence given to the **design assurance** activities.

4.0 APPLICATION.

4.1 Applicant is strongly recommended to seek a preliminary discussion with DCA to discuss the approval process and application requirements prior to the application submission.

4.2 The formal application package for a grant of a DOA should consist of the following ;

i) Letter of application;

ii) JPA AP7(DOA) - Application form;

iii) JPA AP7(A) - resume for key personnel and design signatories;

iv) Draft copies of DOM which must include the scope of work limitations;

v) Company registration or equivalent;

vi) Documentary evidence showing that the applicant has and can obtain the use of appropriate facilities for the scope of work (e.g. lease agreement);

vii) Any proposed manual, as applicable;

viii) Personnel training programmes, as applicable;

ix) Statement of Compliance against the applicable paragraphs of AN No. 96;

x) A Schedule of Events detailing the anticipated timescales for the approval process.

4.3 As required under paragraph 7 of AN No. 96, the applicant should provide the draft DOM, or an outline, including company flow-charts and, as relevant, description and information on design activities and organisation of partners or subcontractors.

4.4 **DOA Categories** are as follows :

	Nature:	***Cases:***
1A	Type Certificate applicant or holder of highly complex or large product(s)	• Large Aeroplanes • Small and Large Rotorcraft • UAVs (Large) • Turbine Engines
1B	Type Certificate applicant or holder of complex or small-medium product(s) TSOA, APU (large)	• Small Aeroplanes • Very Light Rotorcraft • Gyroplanes • UAVs (small - medium) • Piston Engines • Large APU
1C	Type Certificate applicant or holder of less complex or very small product(s) TSOA, APU (small)	• Sailplanes, powered Sailplanes • Very Light Aeroplanes • Airships • Balloons • Propeller • Small APU
2A	Design Changes / Repairs, unrestricted	Scope including at least structure, installation of avionics, hydro-mechanical systems, electrical systems, cabin interiors,
2B	Design Changes / Repairs, restricted (technical fields)	Scope with restricted technical fields

2C	Design Changes / Repairs, restricted (aircraft size)	Scope limited to one category of product only
3A	Minor Changes / Repairs, unrestricted	Scope including at least structure, installation of avionics, hydro-mechanical systems, electrical systems, cabin interiors,
3B	Minor Changes / Repairs, restricted (technical fields)	Scope with restricted technical fields
3C	Minor Changes / Repairs, restricted (aircraft size)	Scope limited to one category of product only

4.5 **Scope of Design** should identify the product type, the activity(ies) for each product type and the related technical field(s) for each activity, such as :

i) ***Product types :***

- Large aeroplane
- Small aeroplane
- Sailplane/powered Sailplane
- Very light aeroplane
- Small rotorcraft
- Large rotorcraft
- Very light rotorcraft
- Gyroplane
- Airship
- Balloon
- Turbine engine
- Piston engine
- Auxiliary Power Unit
- Propeller

ii) ***Activity***

- Type Certificates/TSOA for APU
- Supplemental Type Certificates/TSOA for APU
- Changes to type design by TC holders and continued airworthiness
- Repairs
- Minor changes only
- Minor repairs only

iii) ***Technical fields***

- All (in case of Type Certificates)
- Avionics
- Installation of avionics equipment
- Structure
- Performance
- Environmental systems
- Hydro mechanical systems
- Electrical systems
- Cabin interiors
- Galleys or other interiors equipment
- Powerplant/Fuel system
- Software
- Transmissions
- Noise
- FADEC (Full Authority Digital Engine Control)
- Non critical engine parts
- Thrust reversers

4.6 Applications to the DCA for a variation to an existing DOA should be made in the same manner as an application for a new DOA with the exception that unchanged documentation need not be resubmitted.

4.7 The DCA is required to charge a fee for the investigations required by DCA in granting a DOA in accordance with the Twelfth Schedule of CAR 1996. The application should include a payment of RM2,000.00 to cover the initial work to be carried out by the DCA. Any additional costs will be invoiced to the applicant.

DESIGN ASSURANCE SYSTEM

5.0 DESIGN ASSURANCE SYSTEM.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 6.0.

5.1 Definitions

5.1.1 *Design Assurance System* is the organisational structure, responsibilities, procedures and resources to ensure the proper functioning of the design organisation. It is described in the DOM directly or by cross reference to relevant procedures.

5.1.2 *Design Assurance* means all those planned and systematic actions necessary to provide adequate confidence that the organisation has the capability:

i). to design products or parts in accordance with the applicable airworthiness requirements and environmental protection requirements,

ii). to show and verify the compliance with the applicable airworthiness requirements and environmental protection requirements.

iii). to demonstrate this compliance to the DCA.

5.1.3 *Type Investigation* means the task of the organisation in support of the Type Certificate or other design approval processes necessary to show and verify and to maintain compliance with the applicable airworthiness and environmental protection requirements.

5.2 Design Assurance.

5.2.1 The complete process, starting with the airworthiness requirements, environmental protection requirements and product specifications, and culminating with the issuing of a type-certificate, is shown in the diagram on **Figure 1**. This identifies the relationship between the design, the Type Investigation and design assurance processes.

5.2.2 Effective Design Assurance demands a continuing evaluation of factors that affect the adequacy of the design for intended applications, in particular that the product, or part, complies with applicable airworthiness and environmental protection requirements and will continue to comply after any change.

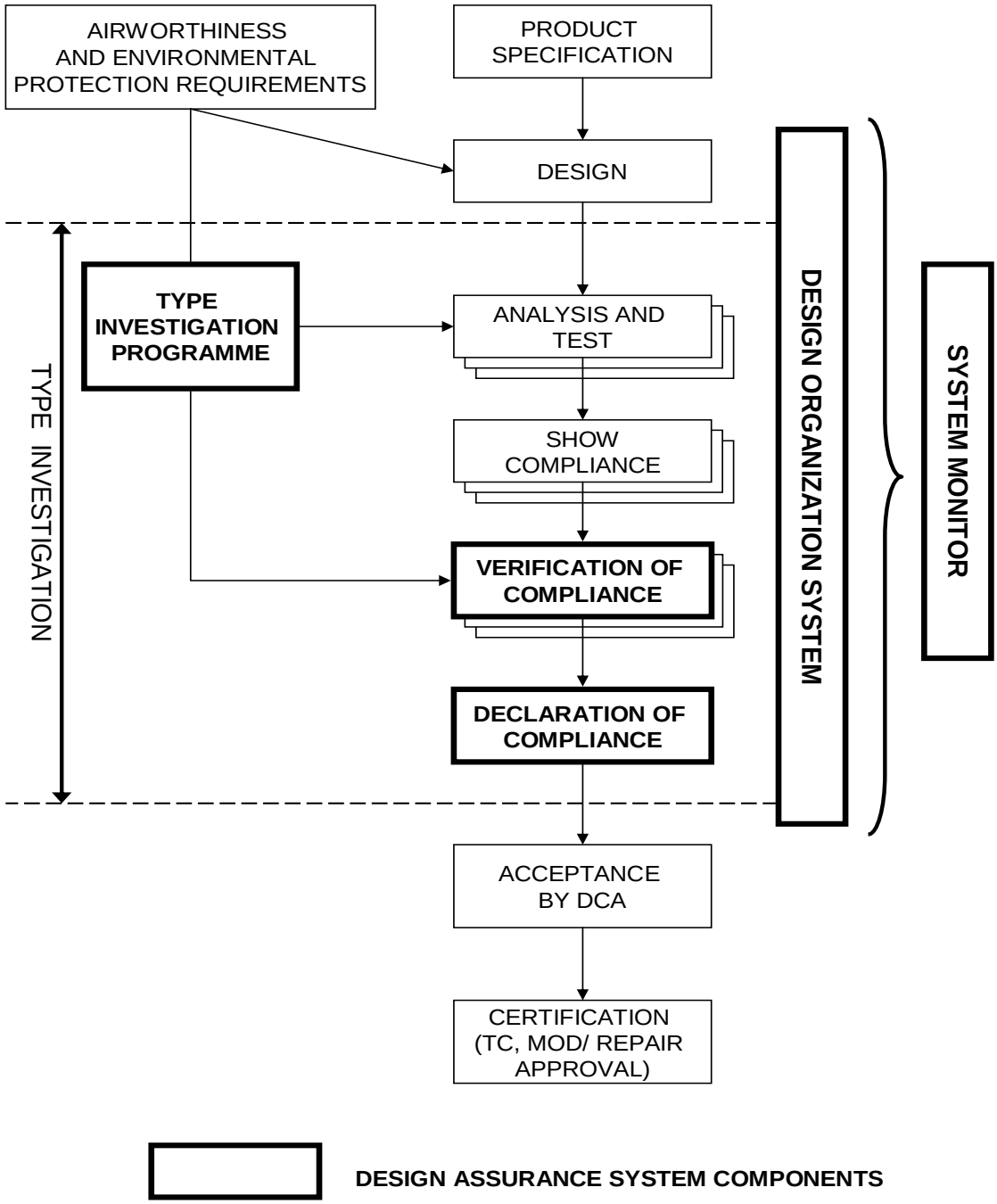


FIGURE 1 - RELATIONSHIP BETWEEN THE DESIGN, THE TYPE INVESTIGATION AND THE DESIGN ASSURANCE

5.2.3 Two main aspects should therefore be considered;

i). How the **planned and systematic actions** are defined and implemented, from the very beginning of design activities up to continued airworthiness activities.

ii). How these actions are **regularly evaluated** and corrective actions implemented as necessary.

5.3 **Planned and systematic actions**.

For design organisations carrying out type investigation of products, the planned and systematic actions should cover the following tasks and procedures should be defined accordingly:

5.3.1 General.

i) To issue or, where applicable, supplement or amend the DOM in accordance with AN No. 96 paragraph 7.0, in particular to indicate the initiation of design activities on a product.

ii) To ensure that all instructions of the DOM are adhered to.

iii) To conduct type investigation.

iv) To nominate staff as “Compliance Verification Engineers” responsible to approve compliance documents as defined in paragraph 5.3.4.

v) To nominate personnel belonging to the Office of Airworthiness responsible as defined in paragraph 5.3.5.

vi) To ensure full and complete liaison between the type design organisation and related organisations having responsibility for products manufactured to the type-certificate.

vii) To provide the assurance to the DCA that prototype models and test specimens adequately conform to the type design.

5.3.2 **Chief Executive.**

i) The **Chief Executive** is accountable to the DCA and shall ensure that all production of design documents are performed to the required standards and that the design organisation is continuously in compliance with the data and procedures identified in the DOM.

ii) The **Chief Executive** should provide the necessary resources for the proper functioning of the design organisation.

iii) The **Chief Executive** needs to have sufficient knowledge and authority to enable him or her to respond to the DCA regarding major issues of the design approval and implement necessary improvements.

iv) The **Chief Executive** needs to be able to demonstrate that he or she is fully aware of and supports the design assurance policy and maintains adequate links with the Chief of the Office of Airworthiness.

5.3.3 **Head of Design Organisation** (or deputy)**.**

i) The **Head of the Design Organisation**, or an authorised representative, should sign a declaration of compliance with the applicable airworthiness and environmental protection requirements after verification of satisfactory completion of the type investigation. The signature by the Head of the Design Organisation on the **Declaration of Compliance** confirms that the procedures as specified in the DOM have been followed.

ii) The functions of Chief Executive and Head of the design organisation may be performed by the same person.

5.3.4 **Compliance Verification.**

i) Approval by signing of all compliance documents, including test programme and data, necessary for the verification of compliance with the applicable airworthiness and environmental protection requirements as defined in Type Investigation programme.

ii) Approval of the technical content (completeness, technical accuracy….), including any subsequent revisions, of the manuals approved by the DCA (Aircraft Flight Manual, the Airworthiness Limitation section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirement (CRM) document, where applicable).

5.3.5 **Office of Airworthiness.**

Of the three mandatory elements of DOA (Design, Airworthiness and Independent Monitoring Functions), Office of Airworthiness is responsible for the Airworthiness and Independent Monitoring Functions. Some of its functions are :

i) Liaison between the design organisation and the DCA with respect to all aspects of Type Investigation.

ii) Ensuring that a DOM is prepared and updated as required in AN No. 96 paragraph 7.0.

iii) Co-operation with the DCA in developing procedures to be used for the type certification process.

iv) Issuing of guidelines for documenting compliance.

v) Co-operation in issuing guidelines for the preparation of the manuals required by the applicable implementing rules, Service Bulletins, drawings, specifications, and standards.

vi) Ensuring procurement and distribution of applicable airworthiness and environmental protection requirements and other specifications.

vii) Co-operating with the DCA in proposing the type-certification basis.

viii) Interpretation of airworthiness and environmental protection requirements and requesting decisions of the DCA in case of doubt.

ix) Advising of all departments of the design organisation in all questions regarding airworthiness, environmental protection approvals and certification.

x) Preparation of the Type Investigation programme and co-ordination of all tasks related to Type Investigation in concurrence with the DCA.

xi) Regular reporting to the DCA about Type Investigation progress and announcement of schedule tests in due time.

xii) Ensuring reporting to the DCA about Type Investigation programmes needed for demonstration of compliance.

xiii) Establishing the compliance checklist and updating for changes.

xiv) Checking that all compliance documents are prepared as necessary to show compliance with all airworthiness and environmental protection requirements, as well as for completeness, and signing for release of the documents.

xv) Checking the required type design definition documents in accordance with DCA requirements and ensuring that they are provided to the DCA for approval when required.

xvi) Preparation, if necessary, of a draft for a type-certificate data sheet and/or changes to type-certificate data sheet.

xvii) Providing verification to the head of design organisation that all activities required for Type Investigation have been properly completed.

xviii) Approving the classification of changes in accordance with DCA requirements in AN No. 78 and granting the approval for minor changes in accordance with DCA requirements in AN No. 78.

xix) 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.

xx) 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 content affect airworthiness and environmental protection.

xxi) 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 DCA in case of airworthiness impairment (continuing airworthiness).

xxii) Advising the DCA with regard to the issue of Airworthiness Directives in general based on Service Bulletins.

xxiii) Ensuring that the manuals approved by the DCA, including any subsequent revisions (the Aircraft Flight Manual, MMEL, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certificate Maintenance Requirements (CMR) document, where applicable) are checked to determine that they meet the respective requirements, and that they are provided to the DCA for approval.

5.3.6 Maintenance and Operating Instructions.

i). Ensuring the preparation and updating of all maintenance and operating instructions (including Service Bulletins) needed to maintain airworthiness (continuing airworthiness) in accordance with relevant airworthiness requirement. For that purpose, the applicant should:

a) establish the list of all documents it is producing to comply with the requirements for 'Instructions for Continued Airworthiness' such as the Appendix referred to in FAR/CS 23.1529, 25.1529, 27.1529 or 29.1529;

b) define procedures and organisation to produce and issue these documents, using where applicable and so elected AN No. 96 paragraph 16.3 iii) privilege.

ii). Ensuring all these documents are provided to all affected operators and all involved authorities.

5.4 **Continued effectiveness of the design assurance system.** – The organisation should establish the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective.

5.5 **Design Assurance System for Small Organisations Designing Only Minor Changes to Type Design or Minor Repairs to Products.**

Appendix 1 outlines some basic principles and objectives in order to comply with the AN No. 96 paragraph 6.0 for **small organisation** designing only minor changes to type design or minor repairs to products.

5.6 **Design Assurance System – Independent System Monitoring.**

The system monitoring function required in the AN No. 96, paragraph 6.1(c) may be undertaken by the existing quality assurance organisations when the design organisation is part of a larger organisation.

5.7 **Design Assurance System – Independent Checking Function of the Showing of Compliance.**

5.7.1 The independent checking function of the showing of compliance, as required by AN No. 96 paragraph 6.2, should consist of the verification by a person not creating the compliance data. Such person may work in conjunction with the individuals who prepare compliance data.

5.7.2 The verification should be shown by signing compliance documents, including test programmes and data.

5.7.3 For a product, there is normally only one compliance verification engineer nominated for each relevant subject.

Note: A procedure should cover the non-availability of nominated persons and their replacement when necessary.

5.8 Design Assurance System – Partners/Sub-contractors.

In meeting the requirement of AN No. 96 paragraph 6.3, the applicant for a DOA may adopt the following policy in working/controlling their partners/sub-contractors.

i). The satisfactory integration of the partners/sub-contractors and applicant's design assurance systems should be demonstrated for the activities covered under the applicant's terms of approval.

ii). In the event that a partners/sub-contractor holds a design organisation approval (DOA), then in accordance with AN No. 96, paragraph 6.3, the applicant may take this into account in demonstrating the effectiveness of this integrated system.

iii). When partners/sub-contractors does not hold a DOA then the applicant will need to establish to its own satisfaction and the satisfaction of the DCA, the adequacy of that partner's/sub-contractor's design assurance system in accordance with DOM.

DATA

6.0 DESIGN ORGANISATION MANUAL (DOM).

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 7.1.

6.1 Contents of DOM.

AN No. 96, paragraph 7.1 requires the applicant to produce a DOM or equivalent to establish a system to integrate the three mandatory elements of DOA (Design, Airworthiness and Independent Monitoring Functions). The DOM should provide the following information for each product covered by the design organisation approval.

i). A description of the tasks which can be performed under the approval, according to the following classification:

a). General areas, like subsonic turbojet aeroplanes, turbopropeller aeroplanes, small aeroplanes, rotorcraft.

b). Technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.).

c). A list of types and models for which the design approval has been granted and for which privileges may be exercised, supported by a brief description for each product.

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

ii). A general description of the organisation, its main departments, their functions and the names of those in charge; a description of the line management and of functional relationships between the various departments.

iii). A description of assigned responsibilities and delegated authority of all parts of the organisation which, taken together, constitute the organisation's design assurance system together with a chart indicating the functional and hierarchical relationship of the design assurance system to Management and to other parts of the organisation; also the chains of responsibilities within the design assurance system, and the control of the work of all partners and sub-contractors.

iv). A general description of the way in which the organisation performs all the design functions in relation to airworthiness and environmental protection approvals including:

a). The procedures followed and forms used in the Type Investigation process to ensure that the design of, or the change

to the design of, the product as applicable is identified and documented, and complies with the applicable airworthiness and environmental protection requirements, including specific requirements for import by importing authorities.

b). The procedures for classifying design changes as “major” or “minor” and for the approval of minor changes.

c). The procedures for classifying and approving unintentional deviations from the approved design data occurring in production (concessions or non-conformance’s).

d). The procedure for classifying and obtaining approval for repairs.

v). A general description of the way in which the organisation performs its functions in relation to the continuing airworthiness of the product it designs, including co-operation with the production organisation when dealing with any continuing airworthiness actions that are related to production of the product, part or appliance, as applicable.

vi). A description of the human resources, facilities and equipment, which constitutes the means for design, and where appropriate, for ground and flight testing.

vii). An outline of a system for controlling and informing the Staff of the organisation of current changes in engineering drawings, specifications and design assurance procedures.

viii). A description of the recording system for:

a). The type design, including relevant design information, drawings and test reports, including inspection records of test specimens.

b). The means of compliance.

c). The compliance documentation (compliance check list, reports...).

ix). A description of the record keeping system to retain all relevant design information, drawings and test reports, including inspection records for the product in order to provide the information necessary to ensure the continued airworthiness and compliance with applicable environmental protection requirements of the changed product.

x). A description of the means by which the organisation monitors and responds to problems affecting the airworthiness of its product during design, production and in service in particular to comply with the requirement related to failures, malfunctions and defects.

xi). The names of the design organisation authorised signatories. Nominated persons with specific responsibilities.

xii). A clear definition of the tasks, competence and areas of responsibility of the Office of Airworthiness.

xiii). A description of the procedures for the establishment and the control of the maintenance and operating instructions.

xiv). A description of the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective.

6.1.1 **Appendix 10** provides the Model content of a DOM.

6.1.2 Standardised evaluation criteria for DOA as provided in **Appendix 11**, should also be used in developing the DOM.

6.2 Structure of DOM

The propose structure of DOM is reflected in **Figure 2.**

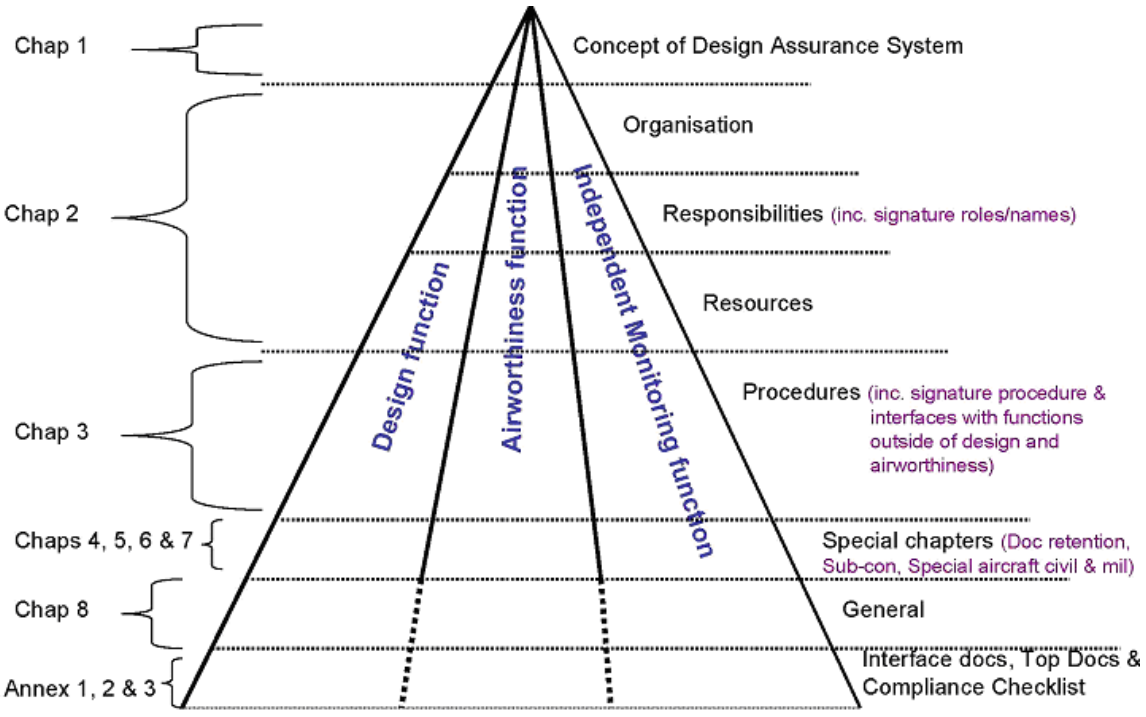


FIGURE 2 – Design Organisation Manual – Structure Concept

6.3 **DOM for Small Organisations Designing Only Minor Changes to Type Design or Minor Repairs to Products.**

Appendix 2 provides the Model content of a DOM for **small organisation** designing minor changes to type design or minor repairs to products.

7.0 STATEMENT OF QUALIFICATIONS AND EXPERIENCE.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 7.4.

7.1 **Purpose** of this paragraph is to provide the guidelines on the following points;

i). Who are the persons covered by AN No. 96, paragraph 7.4 ?

ii). What are requested from the applicant for these persons ?

7.2 **Who are the persons?**

Three different types of functions are named or implicitly identified in the requirements of AN No. 96, using qualified and experienced personnel:

i). the Chief Executive (see paragraph 5.3.2).

ii). the other management staff:

a). the Head of the Design Organisation (see paragraph 5.3.3).

b). the Chief of the Office of Airworthiness, (see paragraph 8.4.3ii).

c). the Chief of the independent monitoring function of the design assurance system (see AN No. 96 paragraph 6.1c).

iii). the personnel making decisions affecting airworthiness and environmental protection:

a). compliance verification engineers (see paragraph 5.3.4).

b). personnel of the Office of Airworthiness making decisions affecting airworthiness and environmental protection, especially those linked with the AN No. 96 paragraph 16.0 privileges (see paragraph 5.3.5).

7.3 **Kind of statement.**

7.3.1 **Chief Executive.**

i). The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.

ii). A statement of the qualification and experience of the Chief Executive is normally not required.

7.3.2 **Other management staff.**

i). The person or persons nominated should represent the management structure of the organisation and be responsible through the Head of Design Organisation to the Chief Executive for the execution of all functions as specified in AN No. 96. Depending on the size of the organisation, the functions may be subdivided under individual managers (and in fact may be further subdivided) or combined in a variety of ways.

ii). The nominated managers should be identified and their credentials furnished to the DCA on JPA AP7(A) form 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 as performed by the organisation.

iii). The responsibilities and the tasks of each individual manager should be clearly defined, in order to prevent uncertainties about the relations, within the organisation. Responsibilities of the managers should be defined in a way that all responsibilities are covered.

iv) In cases where the Chief of the independent monitoring function of the design assurance system does not directly report to the Chief Executive, he or she should have a formally established direct access to the Chief Executive.

7.3.3 **Personnel making decisions affecting airworthiness and environmental protection.**

i). For these personnel, no individual statement is required. The applicant should show to the DCA that there is a system to select, train, maintain and identify them for all tasks where they are necessary.

ii). The following guidelines for such a system are proposed.

a). These personnel should be identified in the DOM, or in a document linked to the DOM. This, and the corresponding procedures, should enable them to carry out the assigned tasks and to properly discharge associated responsibilities.

b). The needs, in terms of quantity of these personnel to sustain the design activities, should be identified by the organisation.

c). These personnel should be chosen on the basis of their knowledge, background and experience.

d). When necessary, complementary training should be established, to ensure sufficient background and knowledge in the scope of their authorisation. The minimum standards for new personnel to qualify in the functions should be established. The training should lead to a satisfactory level of knowledge of the procedures relevant for the particular role.

e). Training policy forms part of the design assurance system and its appropriateness forms part of investigation by the DCA within the organisation approval process and subsequent surveillance of persons proposed by the organisation.

f). This training should be adapted in response to experience gained within the organisation

g). The organisation should maintain a record of these personnel which includes details of the scope of their authorisation. The personnel concerned should be provided with evidence of the scope of their authorisation.

h). The authorisation document must be in a style that makes its scope clear to these personnel and any authorised person who may require to examine the authorisation. Where codes are used to define scope, an interpretation document should be readily available.

i). These personnel are not required to carry the authorisation document at all times but should be able to make it available within a reasonable time of a request from an authorised person. Authorised persons include the DCA.

j). The following minimum information should be kept on record:

Name
Date of birth
Experience and training
Position in organisation
Scope of the authorisation
Date of first issue of the authorisation
If appropriate, date of expiry of the authorisation
Identification number of the authorisation.

Note: The record may be kept in any format and should be controlled.

k) Persons authorised to access the system should be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner or that such confidential records do not become accessible to unauthorised persons.

l) Personnel should be given access to their own record.

m) Under the provision of AN No. 96, paragraph 13.0 the DCA has a right of access to the data held in such a system.

n) The organisation should keep the record for at least two years after a person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

7.4 Statement of Qualifications and Experience for Small Organisations Designing Only Minor Changes to Type Design or Minor Repairs to Products.

For **small organisations** designing minor changes to type design or minor repairs to products, the statement of the qualifications and experience required by AN No. 96, are provided in **Appendix 3**.

Approval Requirements

8.0 REQUIREMENTS FOR APPROVAL.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 8.0.

8.1 General.

The data submitted in accordance with AN No. 96 paragraph 7.0 should show that sufficient skilled personnel are available and suitable technical and organisational provisions have been made for carrying out the Type Investigation defined by paragraph 5.1.3.

8.2 Personnel.

The applicant should show that the personnel available to comply with AN No. 96 paragraph 8.1 are, due to their special qualifications and number, able to provide assurance of the design or modification of a product, as well as the compilation and verification of all data needed to meet the applicable airworthiness and environmental protection requirements while taking into account the present state of the art and new experience.

8.3 Technical.

The applicant should have access to:

i). Workshops and production facilities which are suitable for manufacturing prototype models and test specimens.

ii). Accommodation and test facilities which are suitable for carrying out tests and measurements needed to demonstrate compliance with the airworthiness and environmental protection requirements. The test facilities may be subjected to additional technical conditions related to the nature of tests performed.

8.4 Organisation.

8.4.1 Design Organisation should consist of three distinct functions; Design Functions, Airworthiness Functions and Independent Monitoring Functions as reflected in **Figure 3**.

8.4.2 The efficiency of the Design Assurance System shall be ensured by the Independent Monitoring Function (DOA Management) covering:

i) Design Assurance activities.

ii) Design Management Review.

iii) Design Assurance Reviews of Third Parties.

iv) Programmed audits.

v) Ad hoc audits after significant deficiencies.

vi) Day to day monitoring of routine tasks.

vii) Report Design Assurance System deficiencies and propose DOA solution to Head of Design Organisation and DCA.

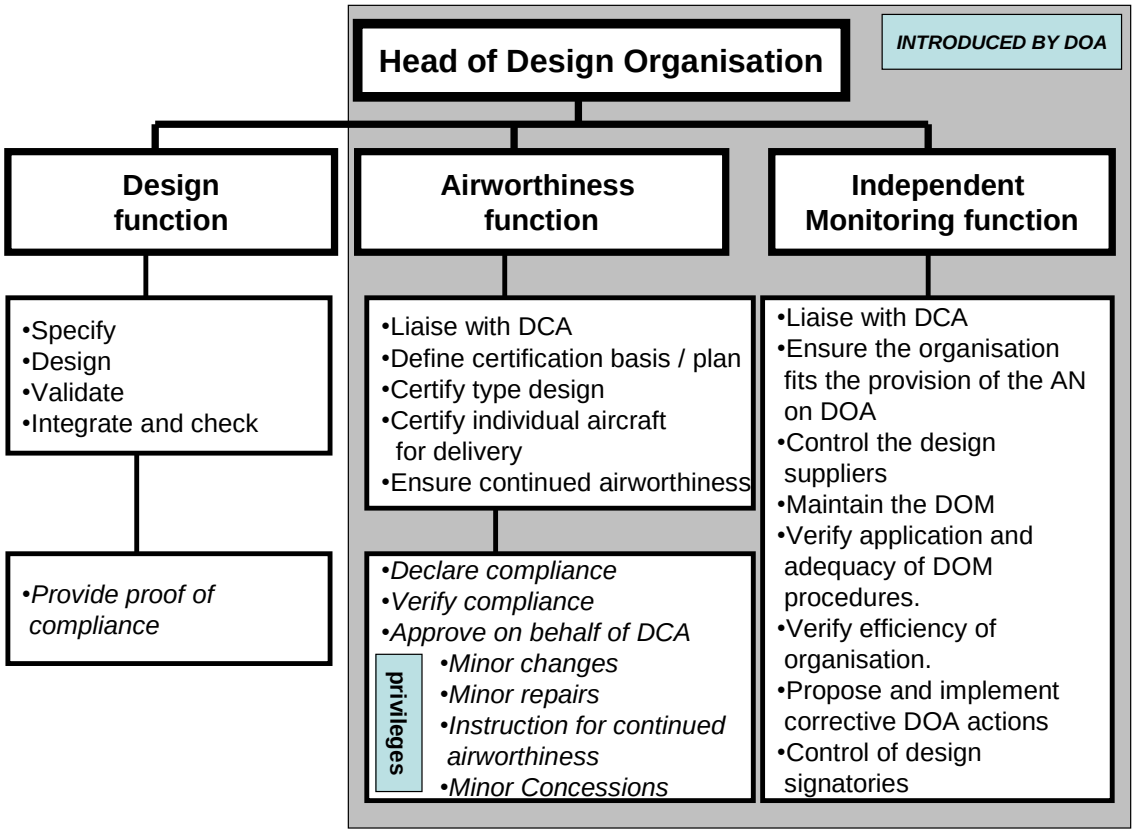


FIGURE 3 – Organisational Structure of DOA

8.4.3 The data submitted in accordance with AN No. 96 paragraph 7.0 should show that:

i). The Head of the Design Organisation for which an application for approval has been made, has the direct or functional responsibility for all departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the Head of the Design Organisation still carries the ultimate responsibility for compliance of the organisation with DCA requirements (AN No. 96).

ii) An Office of Airworthiness, or equivalent function, has been established and staffed on a permanent basis to act as the focal point for co-ordinating airworthiness and environmental protection matters (see paragraph 5.3.5); it reports directly to the Head of the Design Organisation or is integrated into an independent quality assurance organisation reporting to the Head of the Design Organisation.

iii) All documents produced by the Design Organisation for the purpose of certification, airworthiness and design assurance shall be signed by authorised person in the steps reflected in **Figure 4**.

a). The design organisation produces mainly three kinds of documents:

- The technical documents produced by the design function;
- The documents produced by the airworthiness function;
- The documents produced by the DOA management function.

b). Validation of their content shall be done by authorised signatories.

c). For documents produced and approved by the Airworthiness Function, the documents shall be signed for :

- Showing compliance;
- Independent checking;
- Approval (Authority signature and / or stamp).

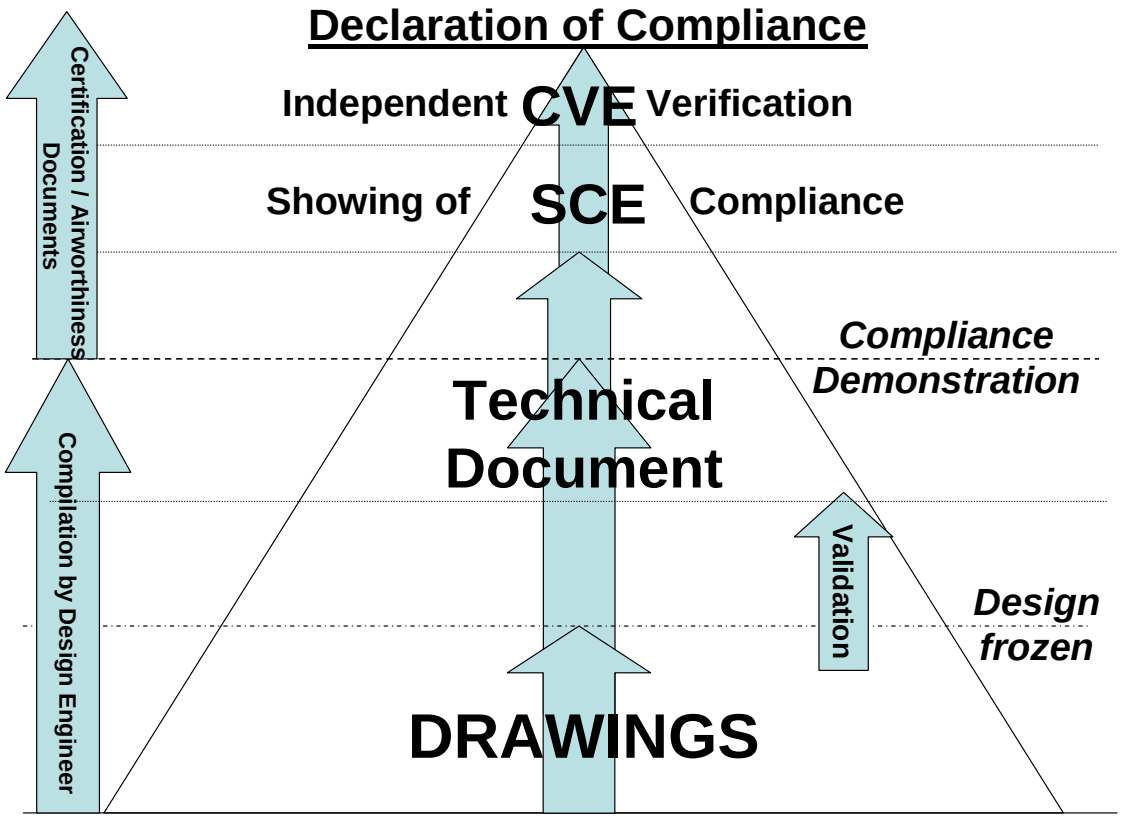


FIGURE 4 – APPROVAL OF DESIGN DOCUMENTS

8.4.4 Responsibilities for all tasks related to Type Investigations are assigned in such a way that gaps in authority are excluded.

8.4.5 The responsibility for a number of tasks as in paragraph 8.4.4 may be assigned to one person especially in the case of simple projects.

8.4.6 Co-ordination between technical departments and the persons in charge of the system monitoring required by AN No. 96 paragraph 6.1(c) has been established:

i). to ensure quick and efficient reporting and resolution of difficulties encountered using the handbook and associated procedures;

ii). to maintain the design assurance system;

iii). to optimise auditing activities.

8.5 **Requirements for Approval for Small Organisations Designing Only Minor Changes to Type Design or Minor Repairs to Products.**

Appendix 4 provides details of requirements for approval for **small organisations** designing minor changes to type design or minor repairs to products.

CHANGES IN THE DESIGN ASSURANCE SYSTEM

9.0 SIGNIFICANT CHANGES IN THE DESIGN ASSURANCE SYSTEM.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 9.0.

In addition to a ***change in ownership*** (see AN No. 96 paragraph 10.0), the following changes to the design assurance system should be considered as “significant” to the showing of compliance or to the airworthiness or environmental protection of the products.

9.1 Organisation.

i). Relocation to new premises.

ii). Change in the industrial organisation (partnership, suppliers, design worksharing) unless it can be shown that the independent checking function of the showing of compliance is not affected.

iii). Change in the parts of the organisation that contribute directly to the airworthiness or environmental protection (independent checking function, office of airworthiness [or equivalent]).

iv). Change to the independent monitoring principles (see AN No. 96 paragraph 6.1 c).

9.2 Responsibilities.

i) Change of the management staff.

- the Head of the design organisation;
- the Chief of the Office of Airworthiness;
- the Chief of the independent monitoring function of the design assurance system.

ii) New distribution of responsibilities affecting airworthiness or environmental protection.

iii) For organisations designing minor changes to type design or minor repairs to products, change of the persons identified in paragraph 7.4.

9.3 Procedures.

Change to the principles of procedures related to :

i) the type certification;

ii) the classification of changes and repairs as "major" or "minor";

iii) the treatment of major changes and major repairs;

iv) the approval of the design of minor changes and minor repairs;

v) the issue of information and instructions under the privilege of DOA;

vi) the approval of documentary changes to the Aircraft Flight Manual;

vii) continued airworthiness;

viii) the configuration control, when airworthiness or environmental protection is affected;

ix) the acceptability of design tasks undertaken by partners or subcontractors.

9.4 **Resources.**

Substantial reduction in number and/or experience of staff.

10.0 TRANSFERABILITY.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 10.0.

10.1 Transfer of the approval would normally only be agreed in cases where the organisation itself remains substantially unchanged.

10.2 An acceptable transfer situation could be for example a change of company name (supported by the appropriate certificate from the ROC) but with no changes to site address or CEO. However, if the same legal entity were to relocate to new premises with a new CEO and/or new departmental heads, then substantial investigation by the DCA would be necessary such that the change would be classified as a re-approval.

10.3 In the event of receivership there may be good technical justification for continuation of the approval provided that the company continues to function in a satisfactory manner. It is likely that at a later stage the approval might be surrendered by the receiver or transferred to another legal entity in which case the former paragraphs apply.

11.0 TERMS OF APPROVAL.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 11.0.

11.1. The terms of approval are stated on the certificate of approval issued by the DCA. The certificate states the scope of work and the products,

changes or repairs thereof, with the appropriate limitations for which the approval has been granted. For design organisation approval covering type certification or TSO authorisation for APU, the list of product types covered by the design assurance system would be included.

11.2 Approval of a change in the terms of approval in accordance with AN No. 96 paragraph 12.0 will be confirmed by an appropriate amendment of the certificate of approval.

11.3 The certificate references the DOM of the approved design organisation, provided in accordance with AN. No. 96 paragraph 7.0. The DOM defines the tasks which may be performed under the approval.

11.4 Scope of work identifies the product types, the activity(ies) for each product type and the related technical field(s) for each activity, in accordance with paragraph 4.5.

11.5 For repair design activities, the certificate states the scope of work with the appropriate limitations for which the approval has been granted.

11.6 The terms of approval issued for small organisations designing minor changes to type design or minor repairs to products are reflected in **Appendix 5.**

12.0 INVESTIGATION.

This Chapter outlines some basic principles and objectives of AN No. **96** paragraph 13.1.

12.1 Arrangements that allow the DCA to make investigations include the complete design organisation including partners, sub-contractors and suppliers, whether they are in the state of the applicant or not, assisting and co-operation with the DCA in performing inspection and audits conducted during initial assessment and subsequent surveillance.

12.2 Assistance to the DCA includes all appropriate means associated with the facilities of the design organisation to allow the DCA to perform these inspections and audits, such as a meeting room and office support.

DOA PRIVILEGES

13.0 DOA PRIVILEGES.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 16.2.

13.1 Privilege related to **compliance documents.**

i). A compliance document is the end result of a certification process, where the showing of compliance is recorded.

ii). For each specific certification process, the DCA is involved in the process itself at an early stage, especially through the establishment of the certification programme.

iii). The inspection or tests under AN No. 96 paragraph 13.0 may be performed at various stage of the whole process, not necessarily when the compliance document is presented.

iv). Therefore, according to the scheduled level of involvement, the DCA should agree with the DOA holder documents to be accepted without further DCA verification under the DOA privilege of AN No. 96 paragraph 16.0.

13.2 **Classification of changes to type design and repairs as minor and major.**

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 16.3 (i) and provides means to develop a procedure for the classification of changes to type design and repairs.

13.2.1 Each DOA applicant must develop its own internal classification procedure following, in order to obtain the associated AN No. 96 paragraph 16.3 (i) privilege.

i) **Content.** The procedure must address the following points:

a) the identification of changes to type design or repairs;

b) classification;

c) justification of the classification;

d) authorised signatories;

e) supervision of changes to type design or repairs initiated by subcontractors.

For changes to type design or repairs, criteria used for classification must be in compliance with AN No. 78.

ii) **Identification of changes to type design or repairs.** The procedure must indicate how the following are identified:

a) major changes to type design or major repairs;

b) those minor changes to type design or minor repairs where additional work is;

c) necessary to show compliance with the airworthiness and environmental protection requirements;

d) other minor changes to type design or minor repairs requiring no further showing of compliance.

iii) **Classification.**

a) The procedure must show how the effects on airworthiness and environmental protection are analysed, from the very beginning, by reference to the applicable requirements.

b) If no specific airworthiness or environmental protection requirements are applicable to the change or repairs, the above review must be carried out at the level of the part or system where the change or repair is integrated and where specific airworthiness or environmental protection requirements are applicable.

iv) **Justification of the classification.**

All decisions of classification of changes to type design or repairs as “major” or “minor” must be recorded and, for those which are not straightforward, also documented. These records must be easily accessible to the DCA for sample check.

v) **Authorised signatories.**

a) All classifications of changes to type design or repairs must be accepted by an appropriate authorised signatory.

b) The procedure must indicate the authorised signatories for the various products listed in the terms of approval.

c) For those changes or repairs that are handled by subcontractors, it must be described how the DOA holder manages its classification responsibility. The procedure must indicate, directly or by cross-reference to written procedures, how changes to type design or repairs may be initiated and classified by subcontractors and are controlled and supervised by the DOA holder.

vi) **Supervision of changes to type design or repairs initiated by subcontractors.**

The procedure must indicate, directly or by cross-reference to written procedures, how changes to type design or repairs may be initiated and classified by subcontractors and are controlled and supervised by the DOA holder.

13.3 **Classification of Changes to Type Design or Minor Repairs to Products for Small Organisations.**

Appendix 6 provide procedure for the classification of changes to type design and repairs as minor for **small organisations** designing minor changes to type design or minor repairs to products.

13.4 **Approval of minor changes to type design and minor repairs.**

This Chapter outlines some basic principles and objectives of AN No. **96** paragraph 16.3(ii) and provides means to develop a procedure for the approval of minor changes to type design or minor repairs.

13.4.1 Each DOA applicant must develop its own internal procedures, in order to obtain the associated privilege.

i) **Content.** The procedure must address the following points:

a) compliance documentation;

b) approval under the DOA privilege;

c) authorised signatories;

d) supervision of minor changes to type design or minor repairs handled by subcontractors.

ii) **Compliance documentation.**

a. For those minor changes to type design or minor repairs where additional work to show compliance with the applicable airworthiness and environmental protection requirements is necessary, compliance documentation must be established and independently checked.

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

iii) **Approval under the DOA privilege.**

For those minor changes to type design or minor repairs where additional work to show compliance with the applicable airworthiness and environmental protection requirements is necessary, the procedure must define a document to formalise the approval under the DOA privilege. This document must include at least :

a) identification and brief description of the change or repair and reasons for change or repair;

b) applicable airworthiness or environmental protection requirements and methods of compliance;

c) reference to the compliance documents;

d) effects, if any, on limitations and on the approved documentation;

e) evidence of the independent checking function of the showing of compliance;

f) evidence of the approval under the privilege of DOA by an authorised signatory;

g) date of the approval.

For the other minor changes to type design or minor repairs, the procedure must define a means to identify the change or repair and reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function may be delegated by the Office of Airworthiness but must be controlled by the Office of Airworthiness, either directly or through appropriate procedures of the DOA holder's design assurance system.

iv) **Authorised signatories.**

The persons authorised to sign for the approval under the privilege must be identified (name, signature and scope of authority) in appropriate documents that maybe linked to the DOM.

v) **Supervision of changes to type design or repairs initiated by subcontractors.**

The procedure must indicate, directly or by cross-reference to written procedures, how changes to type design or repairs may be initiated and classified by subcontractors and are controlled and supervised by the DOA holder.

13.5 **Approval of minor changes to type design and minor repairs for small organisation.**

Appendix 7 provide procedure for the approval of minor changes to type design and minor repairs for **small organisations** designing minor changes to type design or minor repairs to products.

13.6 **Issue of information or instructions.**

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 16.3 (iii) and provides guidelines to address the various aspects the DOA should cover in order to have a comprehensive procedure for the issue of information or instructions.

i) **SCOPE.**

a) The information or instructions are issued by a DOA holder to make available to the owners or operators of a product with all necessary data to implement a change on the product or a repair, or to inspect it. Some are also issued to provide maintenance organisations and other interested persons with all necessary maintenance data for the performance of maintenance, including implementation of a change on the product or a repair, or inspection, in accordance with the requirements for Instructions for Continued Airworthiness (ICA).

b) This information or instructions may be issued in a format of a Service Bulletin as defined in ATA 100 system, or in Structural Repair Manuals, Maintenance Manuals, Engine and Propeller Manuals etc. The preparation of this data involves design, production and inspection. As the overall responsibility, through the privilege, is allocated to the DOA holder, the three aspects should be properly handled under the DOA to obtain the privilege "to issue information or instructions containing a statement that the technical content is approved", and a procedure should exist.

ii) **PROCEDURE.**

For the information and instructions issued under AN No. DCA paragraph 16.3 (iii), the DOA holder should establish a procedure addressing the following points :

a) Preparation;

b) verification of technical consistency with corresponding approved change(s) , repair(s) or approved data, including effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;

c) verification of the feasibility in practical applications;

d) authorised signatories.

The procedure should include the information or instructions prepared by subcontractors or vendors, and declared applicable to its products by the DOA holder.

iii) **STATEMENT.**

a) The statement provided in the information or instructions should also cover the information or instructions prepared by subcontractors or vendors and declared applicable to its products by the DOA holder.

b) The technical content is related to the design data and accomplishment instructions, and its approval means that:

- the design data has been appropriately approved ; and
- the instructions provide for practical and well defined installation/inspection methods, and, when accomplished, the product is in conformity with the approved design data.

Note : Information and instructions related to required actions under requirements related to Airworthiness Directive, are submitted to the DCA to ensure compatibility with Airworthiness Directive content and contain a statement that they are, or will be, subject to an Airworthiness Directive issued by the DCA.

13.7 Approval of documentary changes to the Aircraft Flight Manual.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 16.3 (iv) and provides guidelines to develop a procedure for the approval of documentary changes to the Aircraft Flight Manual (AFM).

13.7.1 Each DOA applicant should develop its own internal procedure, based on these guidelines, in order to obtain the associated privilege.

13.7.2 **Examples of documentary changes to the AFM that may be approved under the DOA privilege**:

i) For AFM Issued By The Type-Certificate Holder

a) Editorial changes or corrections to the AFM.

b) Changes to weight limitations that are within all previously DCA approved limitations (e.g., structural, noise, etc.).

c) The addition of compatible and previously DCA approved AFM Temporary changes, appendices or Supplements.

d) Conversions of previously DCA approved combinations of units of measurement added to the AFM in a previously approved manner.

e) The addition of aircraft serial numbers to an existing AFM where the aircraft configuration, as related to the AFM, is identical to aircraft already in that AFM.

f) The removal of reference to aircraft serial numbers no longer applicable to that AFM.

ii) For AFM Supplements Issued by the DOA

a) Editorial changes or corrections to the AFM Supplement.

b) Changes to weight limitations that are within all previously DCA approved limitations (e.g., structural, noise, etc.).

c) Conversions of previously DCA approved combinations of units of measurement added to the AFM Supplement in a previously approved manner.

d) The addition of aircraft serial numbers to an existing AFM Supplement where the aircraft configuration, as related to the AFM Supplement, is identical to aircraft already in that AFM Supplement.

e) The removal of reference to aircraft serial numbers no longer applicable to that AFM Supplement.

13.7.3 **Procedure For The Approval Of Documentary Changes.**

i) **Content.** The procedure should address the following points:

a) preparation of all AFM changes,

b) classification as documentary AFM change,

c) verification by the airworthiness function, especially regarding the classification of the AFM change,

d) approval of AFM changes,

e) approval statement and authorised signatories,

f) distribution.

ii) **Preparation.**

The procedure should indicate how AFM changes are prepared and how the co-ordination with people in charge of design changes is performed.

iii) **Classification.**

The procedure should indicate how AFM changes are classified as documentary changes, in accordance with the criteria of paragraph 13.7.2.

Changes to the AFM of an editorial nature should be non-technical and should normally only affect existing approved data.

iv) **Verification by Office of Airworthiness function.**

The procedure should indicate how people in charge of Office of airworthiness function will :

a) verify the classification as documentary changes

b) review the content of the AFM changes.

v) **Approval.**

Any change to the AFM should be approved, either by the DCA, or under the privilege of DOA for documentary AFM changes.

For documentary AFM changes, the procedure should indicate how the approval under the privilege will be formalised.

vi) **Approval statement and authorised signatories.**

a) Revisions of the AFM containing only documentary changes should be issued with the approval statement AN No. DCA paragraph 16.3

b) When approval status is shown on each page, a simplified statement such as "Approved under the authority of DOA Approval No. xxx " may be used.

c) The authorised signatories should be identified (name, signature), together with the scope of authorisation, in a document that can be linked to the DOA DOM.

vii) **Maintaining, updating and distribution.**

The procedure should indicate how the master copy of the AFM is maintained and updated, and how approved revisions are distributed.

OBLIGATION OF THE HOLDER

14.0 OBLIGATION OF THE HOLDER.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 17.0.

14.1 Administration of DOM.

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 17.1 (i).

14.1.1 The DOM of the applicant must be in the language which will permit the best use of it by all personnel charged with the tasks performed for the purpose of the design organisation.

14.1.2 The DOM must be produced in a concise form with sufficient information to meet AN No. 96 paragraph 7.0 relevant to the scope of approval sought by the applicant. The DOM must include the following:

i). Organisation name, address, telephone, telex and facsimile numbers.

ii). Document title, and company document reference No (if any).

iii). Amendment or revision standard identification for the document.

iv). Amendment or revision record sheet.

v). List of effective pages with revision/date/amendment identification for each page.

vi). Contents list or index.

vii). A distribution list for the DOM.

viii). An introduction, or foreword, explaining the purpose of the document for the guidance of the organisation's own personnel. Brief general information concerning the history and development of the organisation and, if appropriate, relationships with other organisations which may form part of a group or consortium, must be included to provide background information for the DCA.

ix). The certificate of approval must be reproduced in the document.

x). Identification of the department responsible for administration of the DOM.

NOTE: In the case of an initial or revised approval it is recognised that certificate will be issued after DCA agreement to the DOM content in draft form. Arrangements for formal publication in a timely manner must be agreed before the certificate of approval is issued.

14.1.3 An updating system must be clearly laid down for carrying out required amendments and modifications to the DOM.

14.1.4 The DOM may be completely or partially integrated into the company organisation manual. In this case, identification of the information required must be provided by giving appropriate cross references, and these documents must be made available, on request, to the DCA.

14.2 **Use of the DOM.**

This Chapter outlines some basic principles and objectives of AN No. 96 paragraph 17.1 (ii).

14.2.1 The DOM should be signed by the Chief Executive and the Head of the design organisation and declared as a binding instruction for all personnel charged with the development and type investigation of products.

14.2.2 All procedures referenced in the DOM are considered as parts of the DOM and therefore as basic working documents.

14.3 **The system for collection, investigation and analysis of data.**

In the context of that requirement the word “Collection” means, the setting up, of systems and procedures which will enable relevant malfunctions, failures and defects to be properly reported when they occur.

14.4 **Reporting to the DCA.**

Within the overall limit of 72 hours the degree of urgency for submission of a report should be determined by the level of hazard judged to have resulted from the occurrence.

Where an occurrence is judged by the person identifying the possible unsafe condition to have resulted in an immediate and particularly significant hazard the DCA expects to be advised immediately and by the fastest possible means (telephone, fax, email, telex, etc.) of whatever details are available at that time. This initial report must be followed up by a full written report within 72 hours. A typical example would be an uncontained engine failure resulting in damage to aircraft primary structure.

Where the occurrence is judged to have resulted in a less immediate and less significant hazard, report submission may be delayed up to the maximum of three days in order to provide more details.

14.5 **Defect correction – Sufficiency of proposed corrective action.**

Appendix 8 provides guidelines to assist in establishing rectification campaigns to remedy discovered defects.

14.6 **Unsafe condition.**

An unsafe condition exists if there is factual evidence (from service experience, analysis or tests) that:

(a) An event may occur that would result in fatalities, usually with the loss of the aircraft, or reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be:

(i) A large reduction in safety margins or functional capabilities, or

(ii) Physical distress or excessive workload such that the flight crew cannot be relied upon to perform their tasks accurately or completely, or

(iii) Serious or fatal injury to one or more occupants unless it is shown that the probability of such an event is within the limit defined by the applicable airworthiness requirements, or

(b) There is an unacceptable risk of serious or fatal injury to persons other than occupants, or

(c) Design features intended to minimise the effects of survivable accidents are not performing their intended function.

Note 1: Non-compliance with applicable airworthiness requirements is generally considered as an unsafe condition, unless it is shown that possible events resulting from this non-compliance do not constitute an unsafe condition as defined under paragraphs (a), (b) and (c).

Note 2: An unsafe condition may exist even though applicable airworthiness requirements are complied with.

Note 3: The above definition covers the majority of cases where the DCA considers there is an unsafe condition. There may be other cases where overriding safety considerations may lead the DCA to issue an airworthiness directive.

Note 4: There may be cases where events can be considered as an unsafe condition if they occur too frequently (significantly beyond the applicable safety objectives) and could eventually lead to consequences listed in paragraph (a) in specific operating environments. Although having less severe immediate consequences than those listed in paragraph (a), the referenced events may reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be, for example, a significant reduction in safety margins or functional capabilities, a

significant increase in crew workload, or in conditions impairing crew efficiency, or discomfort to occupants, possibly including injuries.

14.7 **Determination of an unsafe condition.**

Appendix 9 provides guidelines to assist in the determination of an unsafe condition.

It is important to note that these guidelines are not exhaustive. However, this material is intended to provide guidelines and examples that will cover most cases, taking into account the applicable certification requirements.

14.8 **Transferring of information on eligibility and approval status from the design holder to production organisations.**

Where there is a need to provide (normally outside the design organisation) a visible statement of approved design data or airworthiness or environmental protection data associated with the approved design data, the following minimum information must be provided. The need for a visible statement may be in relation to Company holding a production organisation approval (POA).

The procedures related to the use of forms or other electronic means to provide this information must be agreed with the DCA.

Information to be provided:

Company Name: the name of the responsible design organisation issuing the information.

Date: the date at which the information is released.

Eligibility: indicate the specific products or articles, in case of TSO authorisation, for which data have been approved.

Identification: the part number of the part or appliance. Preference should be given to the use of the Illustrated Parts Catalogue (IPC) designation. Alternatively the reference to the instruction for continued airworthiness (e.g., SB, AMM, etc.) could be stated. Marking requirements (Identification Of Products, Parts And Appliances) should be taken into account.

Description: the name or description of the part or document should be given. In the case of a part or appliance preference should be given to use of IPC designation. The description is to include reference to any applicable TSO authorisation or marking, or previous approvals still valid.

Purpose of data: the reason for the provision of the information should be stated by the design approval holder.

Examples:

a) Provision of approved design data to a production organisation to permit manufacture.

b) Information regarding eligibility for installation (replacement parts, repair, modification, etc.).

c) Direct Delivery Authorisation.

If the data is in support of a change or repair, then reference to the aircraft level approval should be given (make reference to the approved SOC, change or repair).

Limitations/Remarks: state any information, either directly or by reference to supporting documentation that identifies any particular data or limitations (including specific importing requirements) needed by a production organisation to complete Block 13 of the DCA ARC/AAT.

Approval: provide reference information related to the approval of the data (DCA document or DOA privilege).

Authorised signature: name and hand-written normal or electronic signature of a person who has written authority from the design organisation, as indicated in the procedures agreed with the DCA.

APPENDIX 1 : Design Assurance System For Small Organisations Designing Minor Changes To Type Design Or Minor Repairs To Products.

1 Purpose.

This Appendix outlines some basic principles and objectives in order to comply with the AN No. 96 paragraph 6.0 for small organisations designing only minor changes to type design or minor repairs to products.

2 Design Assurance System.

The design assurance system should include the following:

a) An organisation structure to:

i) Control the design.

ii) Show compliance with applicable airworthiness and environmental protection requirements.

iii) Independently check showings of compliance.

iv) Liaise with DCA.

v) Continuously evaluate the design organisation.

vi) Control of sub-contractors.

b) Procedures and responsibility associated with the functions listed above, taking due account of DCA requirements applicable to design and approval of minor changes to type design or minor repairs to products.

APPENDIX 2 : Model Content Of A DOM For Small Organisation Designing Minor Changes To Type Design Or Minor Repairs To Products.

Part 1. Organisation.

1.1 Objective of handbook and binding statement.

1.2 Responsible person for administration of handbook.

1.3 Amendment procedure.

1.4 List of effective pages.

1.5 Distribution list.

1.6 Presentation of design organisation (including locations).

1.7 Scope of work (with identification of type and models of products).

1.8 Organisation charts.

1.9 Human resources.

1.10 Management staff.

1.11 Certifying personnel (see AN No. 96 paragraph 7.4).

1.12 Independent system monitoring.

Part 2. Procedures.

2.1 Management of changes to type design and design of repairs.
- i) configuration control;
- ii) classification;
- iii) approval of minor changes to type design and minor repairs.

2.2 Control of design subcontractors.

2.3 Collecting/Investigating of failures, malfunctions and defects.

2.4 Co-ordination with production.

2.5 Documentation control;
- i) in relations with the changes and repairs;
- ii) in relation with failures, malfunctions and defects (i.e. Services - Bulletins).

2.6 Record keeping.

APPENDIX 3 : Statement Of The Qualification And Experience For Small Organisations Designing Minor Changes To Type Design Or Minor Repairs To Products.

For small organisations designing minor changes to type design or minor repairs to products, the statement of the qualifications and experience required by AN No. 96 paragraph 7.4, should be addressed as follows :

i). The nominated managers should be identified and their credentials submitted to the DCA on JPA AP7(A) form 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 as performed by the organisation.

ii). The persons responsible to the following should be selected by the organisation in accordance with a procedure and criteria agreed with the DCA:

a). classify changes to type design or repairs in accordance with AN No. 96, paragraph 16.3 i).

b). verify compliance in accordance with AN No. 96, paragraph 6.2.

c). approve minor changes to type design and minor repairs in accordance with AN No. 96, paragraph 16.3 ii).

d). issue information or instructions in accordance with AN No. 96, paragraph 16.3 iii).

APPENDIX 4 : Requirements For Approval For Small Organisations Designing Minor Changes To Type Design Or Minor Repairs To Products

The data submitted in accordance with AN No. 96 paragraph 7.0 should show that:

i). The manager responsible for design has the direct or functional responsibility for all departments of the organisation which are involved in the design of minor changes to type design or minor repairs to products.

ii). Person(s) have been nominated to liaise with the DCA and to co-ordinate airworthiness and environmental protection matters. Their position in the organisation should allow direct report to the manager responsible for design.

iii). Responsibilities for all tasks related to the design and approval of minor changes to type design or minor repairs to products are assigned to ensure that all areas are covered.

iv). The responsibility for a number of tasks as in paragraph (iii) may be assigned to one person especially in the case of simple projects.

APPENDIX 5 : Terms Of Approval For Small Organisations Designing Minor Changes To Type Design Or Minor Repairs To Products.

The terms of approval issued for small organisations designing minor changes to type design or minor repairs to products should contain:

i). **Scope of work –** the design organisation approval has been granted for:

a). designing minor changes to type design or minor repairs to (aircraft, engine, propeller) in accordance with the applicable airworthiness and environmental protection requirements.

b). Showing and verifying the compliance with these airworthiness and environmental protection requirements.

ii). **Category of products –** any other indication if the DCA has found a limitation related to aircraft systems or technologies and reducing the scope as defined in paragraph (i).

iii). **Privileges –** list of the privileges granted with the approval, pursuant AN No. 96 paragraph 16.0, to the holder of the approval.

APPENDIX 6 : Classification Procedure For Small Organisations Designing Minor Changes To Type Design Or Minor Repairs To Products.

1). **Content.**

The procedure must address the following points:

i) configuration control rules, especially the identification of changes to type design or repairs;

ii) classification, in compliance with AN No. 78 for changes and repairs;

iii) justification of the classification;

iv) authorised signatories.

2). **Identification of changes to type design or repairs.**

The procedure must indicate how the following minor changes to type design or minor repairs are identified:

i) those minor design changes to type design or minor repairs where additional substantiation data is necessary to show compliance with the airworthiness or environmental protection requirements.

ii) other minor design changes to type design or minor repairs requiring no further showing of compliance.

3. **Classification.**

3.1 The procedure must show how the effects on airworthiness and environmental protection are analysed, from the very beginning, by reference to the applicable requirements.

3.2 If no specific requirements are applicable to the change or the repair, the above review must be done at the level of the part or system where the change or repair is integrated and where specific airworthiness or environmental protection requirements are applicable.

4. **Justification of the classification.**

4.1 All decisions of classification of changes to type design or repairs as "minor" must be recorded and, for those which are not straightforward, also documented. It may be in the format of meeting notes or register. These records must be easily accessible to the DCA for sample check.

4.2 It may be in the format of meeting notes or register.

5. Authorised signatories.

5.1 All classifications of changes to type design or repairs must be accepted by an appropriate authorised signatory.

5.2 The procedure must indicate the authorised signatories for the various products listed in the terms of approval.

APPENDIX 7 : Procedure For The Approval Of Minor Changes To Type Design Or Minor Repairs For Small Organisations Designing Minor Changes To Type Design Or Minor Repairs To Products.

1. **Content.**

The procedure must address the following points :

i) compliance documentation;

ii) approval under the DOA privilege;

iii) authorised signatories.

2. **Compliance documentation.**

2.1 For those minor changes to type design or minor repairs where additional work to show compliance with the applicable airworthiness and environmental protection requirements is necessary, compliance documentation must be established and independently checked.

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

3. **Approval under the DOA privilege.**

3.1 For those minor changes to type design or minor repairs where additional work to show compliance with the applicable airworthiness or environmental protection requirements is necessary, the procedure must define a document to formalise the approval under the DOA privilege.

This document must include at least :

i) identification and brief description of the change or the repair and reason for change or repair;

ii) applicable airworthiness or environmental protection requirements and methods of compliance;

iii) reference to the compliance documents;

iv) effects, if any, on limitations and on the approved documentation;

v) evidence of the independent checking function of the showing of compliance;

vi) evidence of the approval under the privilege of DOA by an authorised signatory;

vii) date of the approval.

3.2 For the other minor changes to type design or minor repairs, the procedure must define a means to identify the change or repair and reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function must be controlled through appropriate procedures of the DOA holder's design assurance system.

4. **Authorised signatories.**

The persons authorised to sign for the approval under the privilege of DOA must be identified (name, signature and scope of authority) in appropriate documents that may be linked to the DOM.

APPENDIX 8 : Defect Correction – Sufficiency Of Proposed Corrective Action.

This Appendix provides guidelines to assist in establishing rectification campaigns to remedy discovered defects.

1. STATUS.

This document contains guidelines of a general nature for use in conjunction with engineering judgement, to aid airworthiness engineers in reaching decisions in the state of technology at the material time.

While the main principles of this guidelines could be applied to small private aeroplanes, helicopters, etc. the numerical values chosen for illustration are appropriate to large aeroplanes for public transport.

2. INTRODUCTION.

2.1 Over the years, target airworthiness risk levels underlying airworthiness requirements have developed on the basis of traditional qualitative airworthiness approaches; they have been given more precision in recent years by being compared with achieved airworthiness levels (judged from accident statistics) and by the general deliberations and discussions which accompanied the introduction of rational performance requirements, and more recently, the Safety Assessment approach in requirements. Although the target airworthiness risk level tends to be discussed as a single figure (a fatal accident rate for airworthiness reasons of not more than 1 in 10,000,000 flights/flying hours for large aeroplanes) it has to be recognised that the requirements when applied to particular aircraft types will result in achieved airworthiness levels at certification lying within a band around the target level and that thereafter, for particular aircraft types and for particular aircraft, the achieved level will vary within that band from time to time.

2.2 The achieved airworthiness risk levels can vary so as to be below the target levels, because it is difficult if not impossible to design to the minimum requirements without being in excess of requirements in many areas; also because aircraft are not always operated at the critical conditions (e.g., aircraft weight, cg position and operational speeds; environmental conditions - temperature, humidity, degree of turbulence). The achieved level may vary so as to be above the target level because of undetected variations in material standards or build standards, because of design deficiencies, because of encountering unforeseen combinations of failures and/or combinations of events, and because of unanticipated operating conditions or environmental conditions.

2.3 There is now a recognition of the need to attempt to monitor the conditions which tend to increase the level and to take appropriate corrective action when the monitoring indicates the need to do so in order to prevent the level rising above a predetermined "ceiling".

2.4 The DCA also has a duty in terms of providing the public with aviation services and therefore would consider the penalties associated with curtailment or even removal (by "grounding") of aviation services when establishing the acceptability of any potential variation in airworthiness level.

2.5 Thus, the purpose of this guideline is:

(a) To postulate basic principles which should be used to guide the course of actions to be followed so as to maintain an adequate level of airworthiness risk after a defect has occurred which, if uncorrected, would involve a potential significant increase of the level of risk for an aircraft type.

(b) For those cases where it is not possible fully and immediately to restore an adequate level of airworthiness risk by any possible alleviating action such as an inspection or limitation, to state the criteria which should be used in order to asses the residual increase in risk and to limit it to an appropriate small fraction of the mean airworthiness through life risk.

3. DISCUSSION.

3.1 Several parameters are involved in decisions on safety matters. In the past the cost of proposed action has often been compared with the notional 'risk cost', i.e. the cost of a catastrophe multiplied by its probability of occurrence.

3.2 This can be a useful exercise, but it should be held within the constraint of acceptable airworthiness risk levels, i.e., within airworthiness risk targets which represent the maximum levels of risk with which an aircraft design must comply, i.e., in the upper part of the 'band'. Currently for large aeroplanes the mean airworthiness risk level is set at a catastrophe rate for airworthiness reasons of not more than one in every ten million flights/flying hours. The constraint is overriding in that any option, which could be permitted on risk cost considerations, or other grounds, is unacceptable if it leads to significant long-term violation of this safety requirement.

3.3 While it should clearly be the objective of all to react to and eliminate emergency situations, i.e., those involving a potentially significant increase of airworthiness risk levels, without unreasonable delay, the DCA should be able finally to rule on what is a minimum acceptable campaign programme. It has therefore seemed desirable to devise guidelines to be used in judging whether a proposed campaign of corrective actions is sufficient in airworthiness terms, and clearly this ought to be based on determining the summation of the achieved airworthiness risk levels for the aircraft and passengers during any periods of corrective action and comparing them with some agreed target.

3.4 As the period of corrective action will not be instantaneous (unless by grounding), there is potentially an increase in the achieved airworthiness risk level possibly to and, without controls, even above the higher part of the 'band', and the amount by which the level is above the mean target figure, and the period for which it should be allowed to continue, has been a matter of some arbitrary judgement.

3.5 It would appear desirable to try to rationalise this judgement. For example, if an aircraft were to spend 10% of its life at a level such that the risk of catastrophe was increased by an order of magnitude, the average rate over its whole life would be doubled which may not be in the public interest. A more suitable criterion is perhaps one which would allow an average increase in risk of, say one third on top of the basic design risk when spread over the whole life of the aircraft an amount which would probably be acceptable within the concept (See Figure 1). It would then be possible to regard the 'through life' risk to an aircraft - e.g., a mean airworthiness target of not more than one airworthiness catastrophe per 10 millions (10^7) hours, as made up of two parts, the first being 3/4 of the total and catering for the basic design risk and the other being 1/4 of the total, forming an allowance to be used during the individual aircraft's whole life for unforeseen campaign situations such as described above.

3.6 Investigation has shown that a total of ten such occasions might arise during the life of an individual aircraft.

3.7 Using these criteria, there could then be during each of these emergency periods (assumed to be ten in number) a risk allowance contributed by the campaign alone of:

1×10^{-7} for 2.5% of the aircraft's life; or
5×10^{-7} for 0.5% of the aircraft's life; or
1×10^{-6} for 0.25% of the aircraft's life; or
1×10^{-5} for 0.025% of the aircraft's life, etc.

Without exceeding the agreed 'allowance' set -aside for this purpose.

3.8 Thus a 'reaction table' can be created as indicated in Table 1 (the last two columns assuming a typical aircraft design life of 60,000 hours and an annual utilisation of 3000 hours per annum) showing the flying or calendar time within which a defect should be corrected if the suggested targets are to be met.

Table 1

Estimated catastrophe rate to aircraft due to the defect under consideration (per a/c hour)	Average reaction time for aircraft at risk (hours)	On a calendar basis
4×10^{-8}	3750	15 months
5×10^{-8}	3000	12 months
1×10^{-7}	1500	6 months
2×10^{-7}	750	3 months
5×10^{-7}	300	6 weeks
1×10^{-6}	150	3 weeks
1×10^{-5}	15	Return to base

3.9 These principles may be applied to a single aircraft or a number of aircraft of a fleet but in calculating risk, all the risk should be attributed to those aircraft which may carry it, and should not be diluted by including other aircraft in the fleet which are known to be free of risk. (It is permissible to spread the risk over the whole fleet when a source is known to exist without knowing where). Where a fleet of aircraft is involved Column 2 may be interpreted as the mean time to rectification and not the time to the last one.

3.10 There is one further constraint. However little effect a situation may have on the 'whole life' risk of an aircraft, the risk should not be allowed to reach too high a level for any given flight. Thus while a very high risk could be tolerated for a very short period without unacceptable degradation of the overall airworthiness target, the few flights involved would be exposed to a quite unacceptable level of risk. It is therefore proposed that the Table 1 should have a cut-off at the 2×10^{-6} level so that no flight carries a risk greater than 20 times the target. At this level the defect is beginning to contribute to a greater likelihood of catastrophe than that from all other causes, including non-airworthiness causes, put together. If the situation is worse than this, grounding appears to be the only alternative with possibly specially authorised high-risk ferry flights to allow the aircraft to return to base empty. Figures 2 and 3 show a visualisation chart equivalent to Table 1, giving average rectification time (either in flight hours or months) based on probability of defect that must be corrected.

3.11 It will be seen that the above suggestions imply a probability of catastrophe from the campaign alone of 1.5/10,000 per aircraft during each separate campaign period (i.e., p = 0.015 per 100 aircraft fleet).

3.12 In addition, in order to take into account large fleet size effect, the expected probability of the catastrophic event during the rectification period on the affected fleet shall not exceed 0.1. See Figure 4.

3.13 It should also be noted that in assessing campaign risks against 'design risk', an element of conservatism is introduced, since the passenger knows

only 'total risk' (i.e. airworthiness plus operations risks) and the fatal accident rate for all reasons is an order of magnitude greater than that for airworthiness reasons only (i.e., 10^{-6} as against 10^{-7}). The summated campaign risk allowance proposed by this guideline is therefore quite a small proportion of the total risk to which a passenger is subject. When operating for short periods at the limit of risk proposed (2×10^{-6} per hour) the defect is however contributing 100% more risk than all other causes added together.

3.14 A similar approach is proposed to cover the case of defects associated to hazardous failure conditions for which the safety objectives defined by the applicable airworthiness requirements are not met. According to FAR/CS 25.1309, the allowable probability for each hazardous failure condition is set at 10^{-7} per flight hour compared to 10^{-9} per flight hour for a catastrophic failure condition. Figure 5 is showing a visualisation chart giving average rectification time based on probability of defect that should be corrected. This is similar to figure 2 but with lower and upper boundaries adapted to cover the case of hazardous failure conditions (probabilities of 10^{-7} and $2x10^{-4}$ respectively).

3.15 In addition, in order to take into account large fleet size effect, the expected probability of the hazardous event during the rectification period on the affected fleet shall not exceed 0.5. See Figure 6.

4. GUIDELINES

4.1 The above would lead to the following guidelines for a rectification campaign to remedy a discovered defect associated to a catastrophic failure condition without grounding the aircraft:

(i) Establish all possible alleviating action such as inspections, crew drills, route restrictions, and other limitations.

(ii) Identify that part of the fleet, which is exposed to the residual risk, after compliance has been established with paragraph (i).

(iii) Using reasonably cautious assumptions, calculate the likely catastrophic rate for each aircraft carrying the risk in the affected fleet.

(iv) Compare the speed with which any suggested campaign will correct the deficiency with the time suggested in Figure 2. The figure should not be used beyond the $2x10^{-6}$ level, except for specially authorised flights.

(v) Also ensure that the expected probability of the catastrophic event during the rectification period on the affected fleet is in accordance with Figure 4.

4.2 Similarly, the following guidelines would be applicable for a rectification campaign to remedy a discovered defect associated to a hazardous failure condition without grounding the aircraft:

(i) Establish all possible alleviating action such as inspections, crew drills, route restrictions, and other limitations.

(ii) Identify that part of the fleet, which is exposed to the residual risk, after compliance has been established with paragraph (i).

(iii) Using reasonably cautious assumptions, calculate the likely hazardous rate for each aircraft carrying the risk in the affected fleet.

(iv) Compare the speed with which any suggested campaign will correct the deficiency with the time suggested in Figure 5.

(v) Also ensure that the expected probability of the hazardous event during the rectification period on the affected fleet is in accordance with Figure 6.

4.3 It must be stressed that the benefit of these guidelines will be to form a datum for what is considered to be the theoretically maximum reaction time. A considerable amount of judgement will still be necessary in establishing many of the input factors and the final decision may still need to be tempered by non-numerical considerations, but the method proposed will at least provide a rational 'departure point' for any exercise of such judgement.

4.4 It is not intended that the method should be used to avoid quicker reaction times where these can be accommodated without high expense or disruption of services.

Figure 1

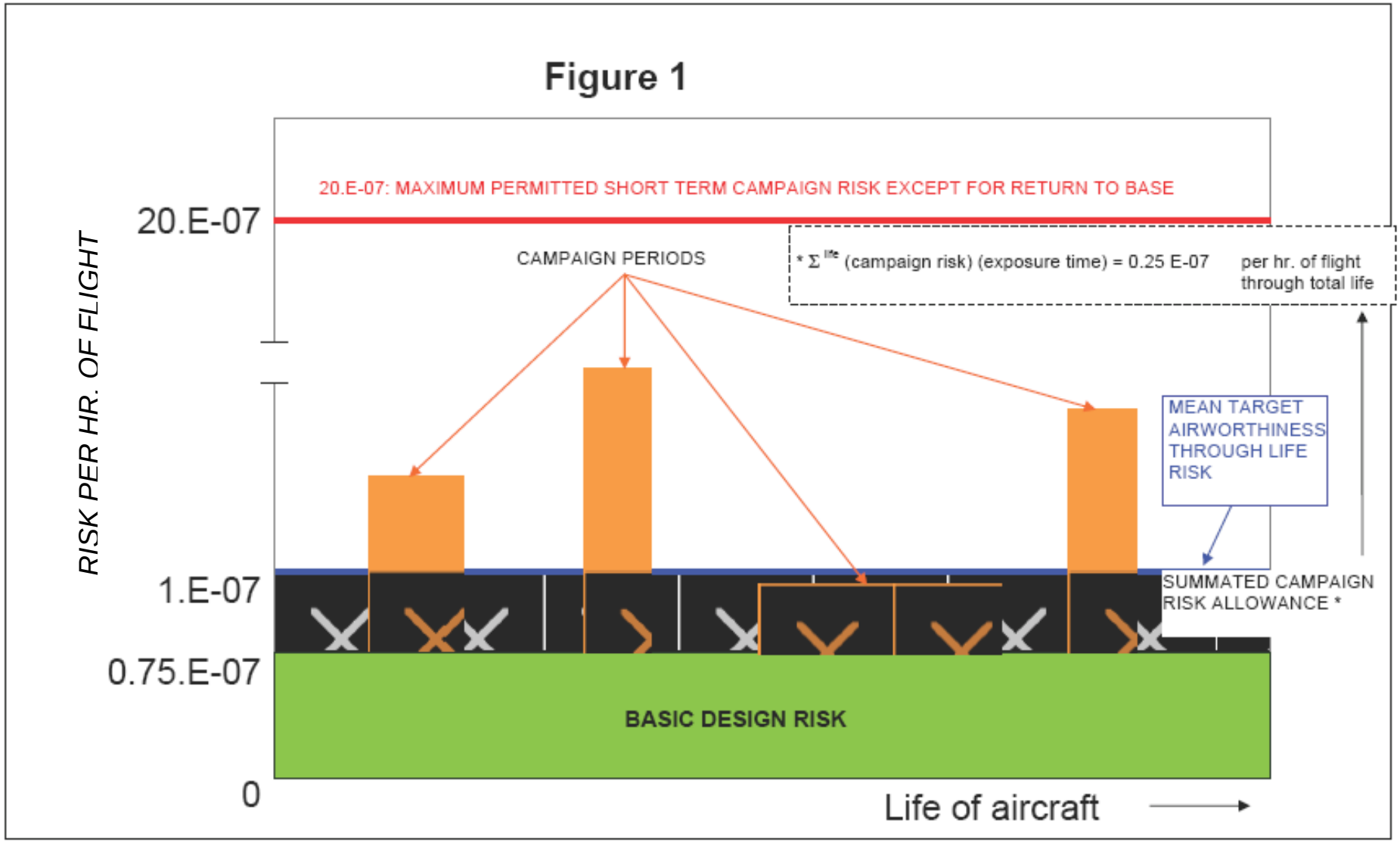

20.E-07: MAXIMUM PERMITTED SHORT TERM CAMPAIGN RISK EXCEPT FOR RETURN TO BASE
20.E-07
CAMPAIGN PERIODS
* Σ life (campaign risk) (exposure time) = 0.25 E-07 per hr. of flight through total life
MEAN TARGET AIRWORTHINESS THROUGH LIFE RISK
SUMMATED CAMPAIGN RISK ALLOWANCE *
1.E-07
0.75.E-07
BASIC DESIGN RISK
0
Life of aircraft
RISK PER HR. OF FLIGHT

Figure 2 - Visualisation Chart for CS-25 (Flight hours)

Assumptions: - aircraft life of 60,000 hours
- 10 'catastrophic events' campaigns

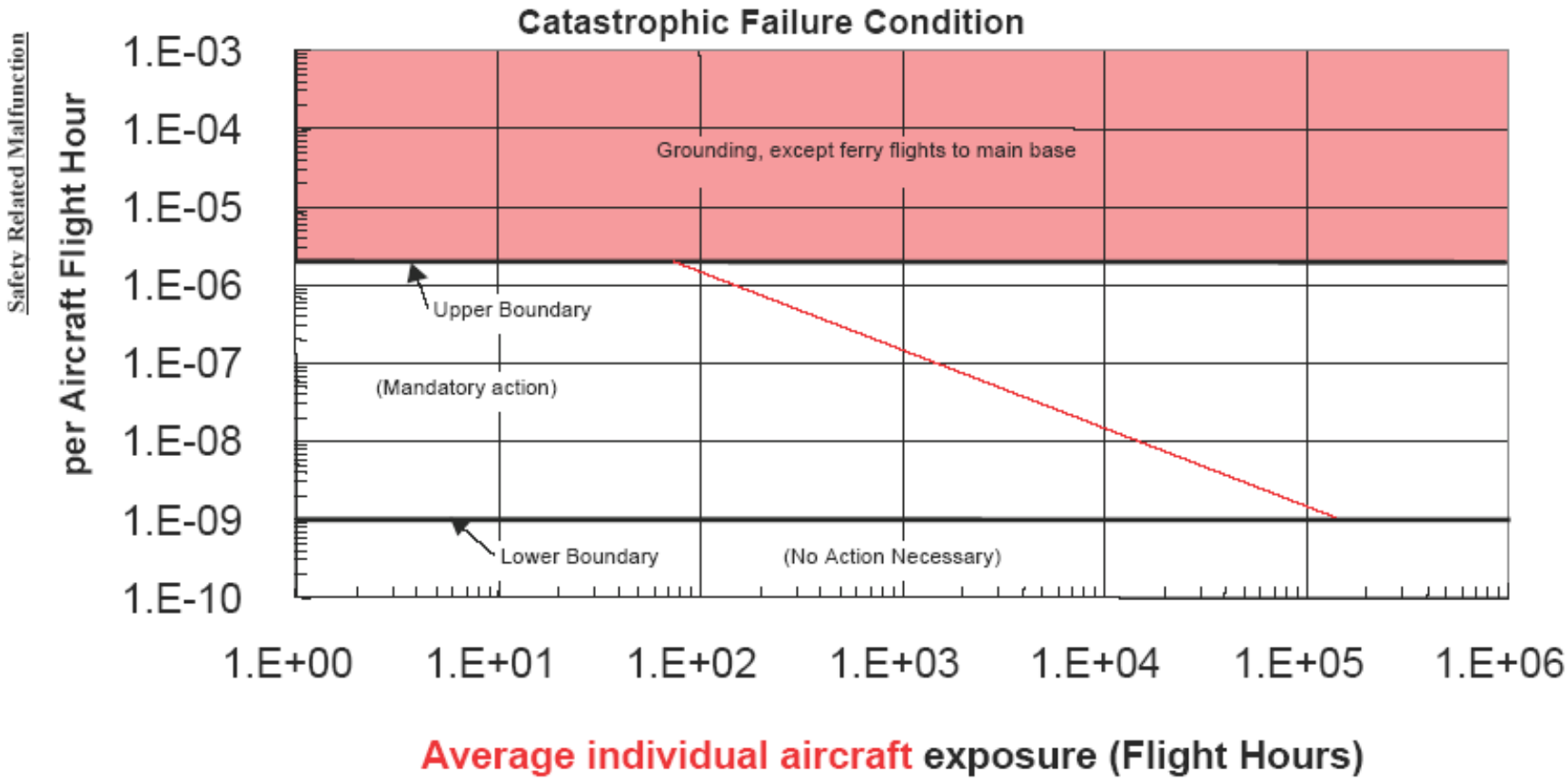
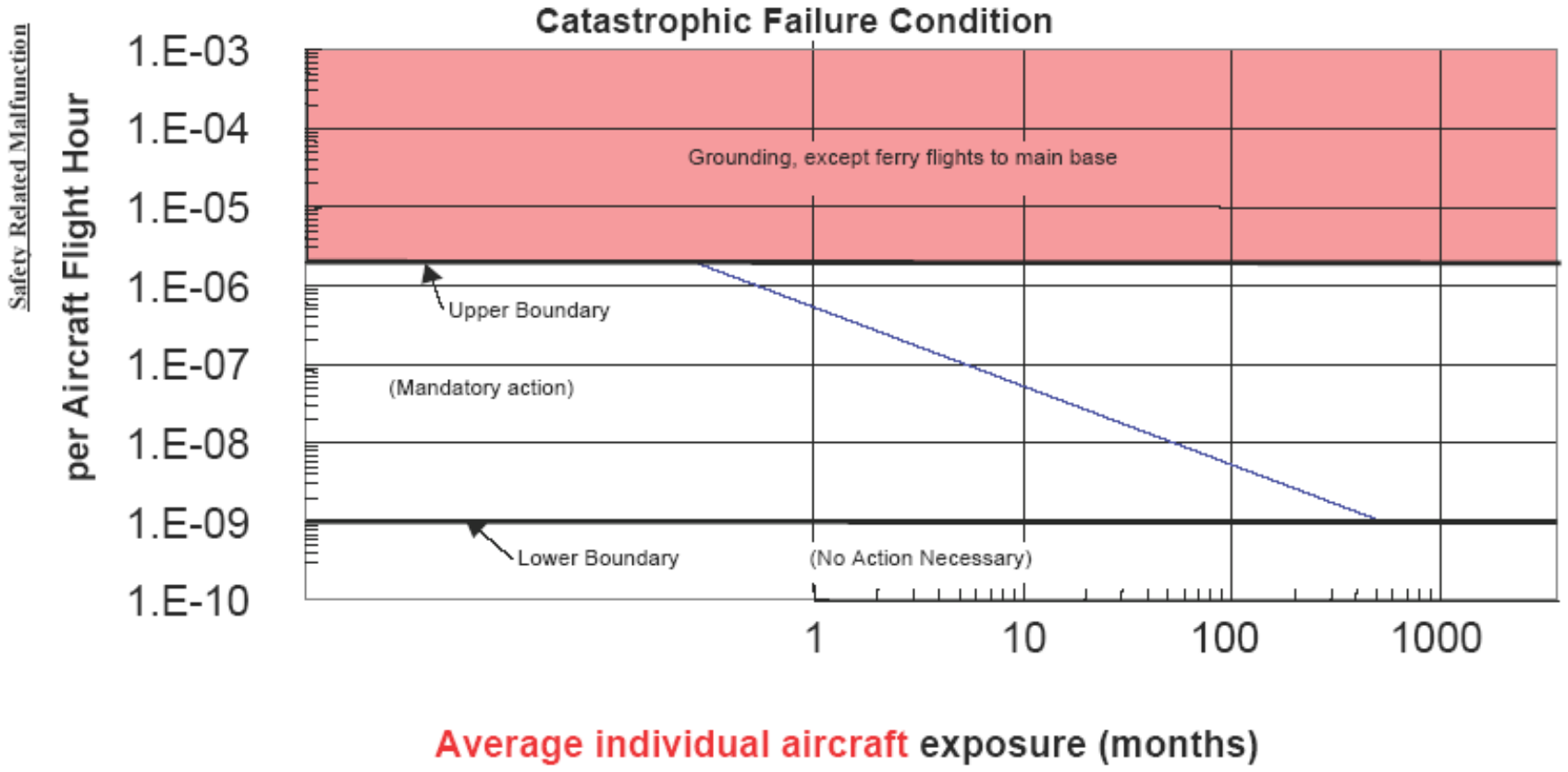


Figure 3 - Visualisation Chart for CS-25 (Calendar basis)

Assumptions: - aircraft life of 60,000 hours, 3000 hours per year
- 10 'catastrophic events' campaigns



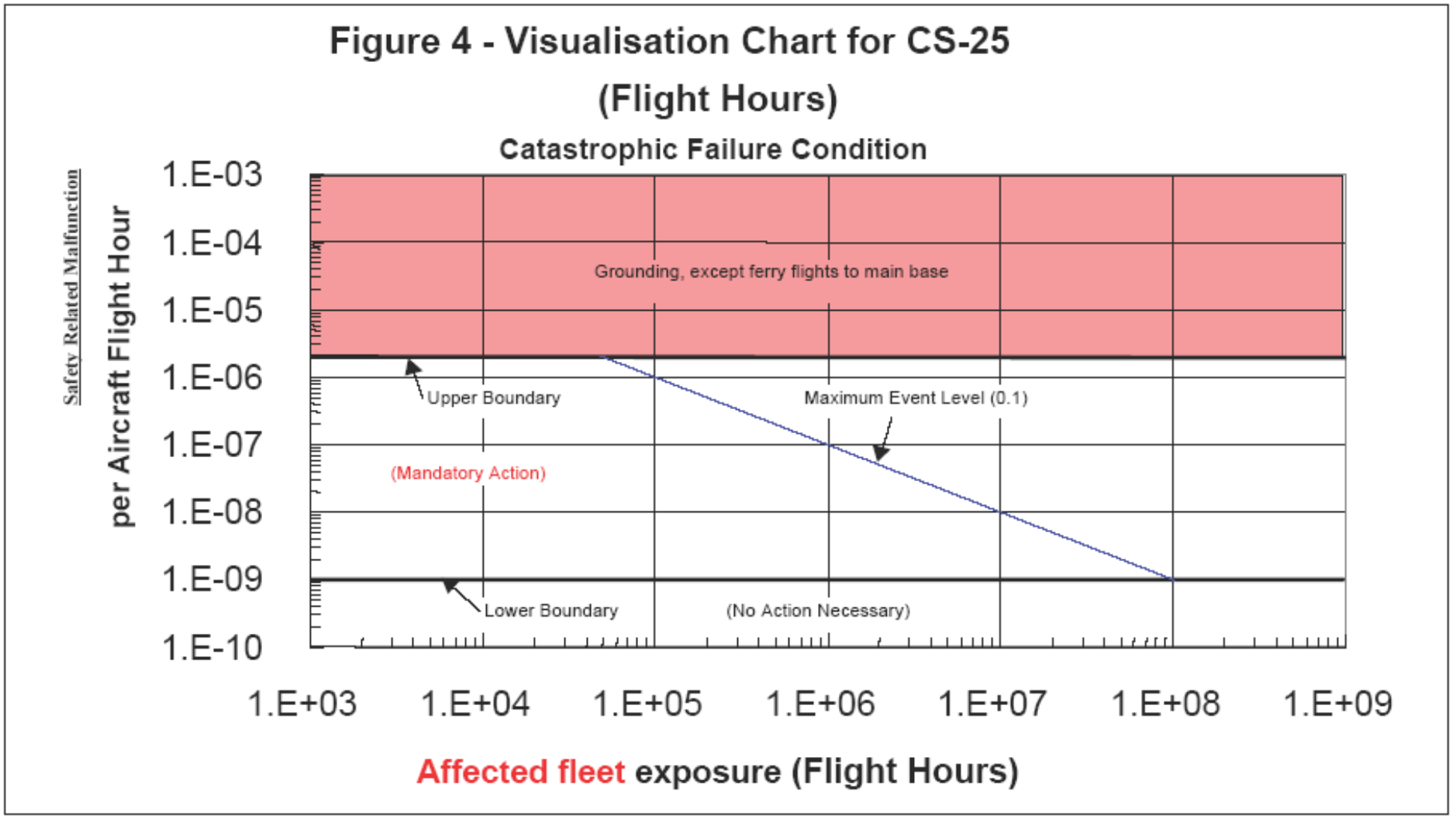


Figure 4 - Visualisation Chart for CS-25
(Flight Hours)
Catastrophic Failure Condition
Safety Related Malfunction per Aircraft Flight Hour
1.E-03
1.E-04
1.E-05
1.E-06
1.E-07
1.E-08
1.E-09
1.E-10
Grounding, except ferry flights to main base
Upper Boundary
Maximum Event Level (0.1)
(Mandatory Action)
Lower Boundary
(No Action Necessary)
1.E+03
1.E+04
1.E+05
1.E+06
1.E+07
1.E+08
1.E+09
Affected fleet exposure (Flight Hours)

Figure 5 - Visualisation Chart for CS-25 (Flight hours)

For Hazardous Failure Condition

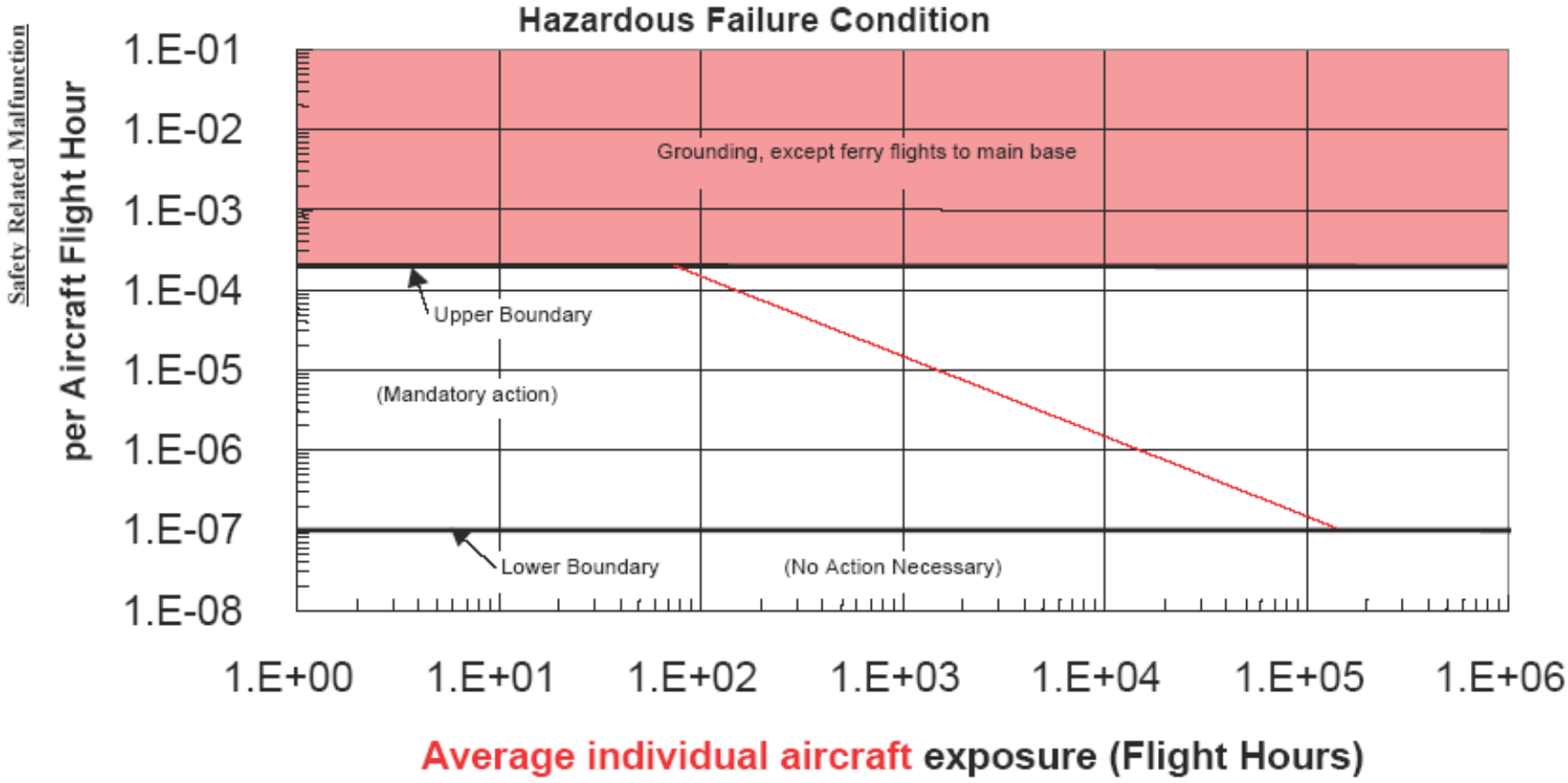
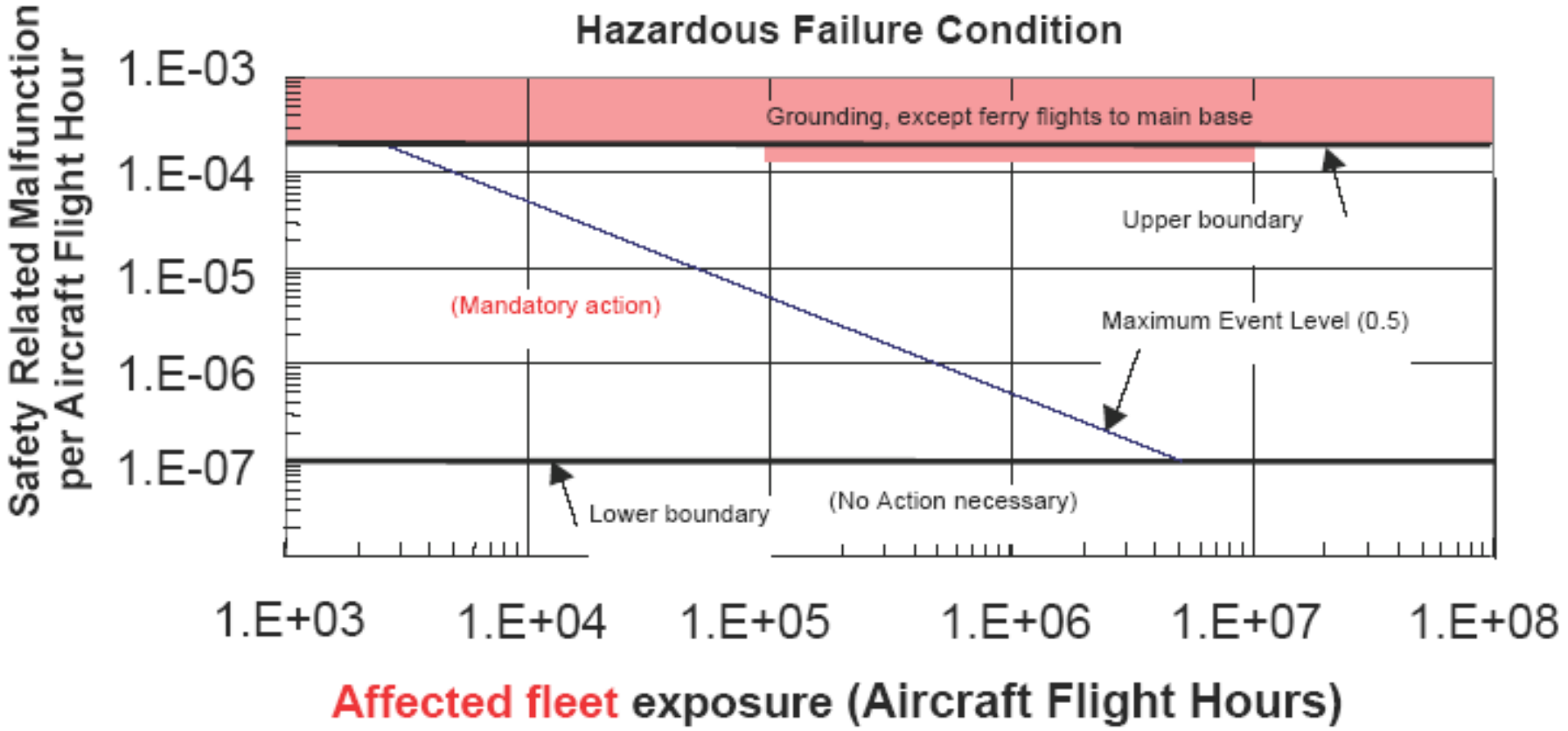


Figure 6 - Visualisation Chart for CS-25 (Flight Hours)



APPENDIX 9 : Determination Of An Unsafe Condition.

It is important to note that these guidelines are not exhaustive. However, this material is intended to provide guidelines and examples that will cover most cases, taking into account the applicable certification requirements.

1. INTRODUCTION.

Certification or approval of a product, part or appliance is a demonstration of compliance with requirements which are intended to ensure an acceptable level of safety. This demonstration however includes certain accepted assumptions and predicted behaviours, such as:

- fatigue behaviour is based on analysis supported by test,
- modelling techniques are used for Aircraft Flight Manual performances calculations,
- the systems safety analyses give predictions of what the systems failure modes, effects and probabilities may be,
- the system components reliability figures are predicted values derived from general experience, tests or analysis,
- the crew is expected to have the skill to apply the procedures correctly, and
- the aircraft is assumed to be maintained in accordance with the prescribed instructions for continued airworthiness (or maintenance programme), etc.

In service experience, additional testing, further analysis, etc., may show that certain initially accepted assumptions are not correct. Thus, certain conditions initially demonstrated as safe, are revealed by experience as unsafe. In this case, it is necessary to mandate corrective actions in order to restore a level of safety consistent with the applicable certification requirements.

2. GUIDELINES FOR ESTABLISHING IF A CONDITION IS UNSAFE.

The following paragraphs give general guidelines for analysing the reported events and determining if an unsafe condition exists, and are provided for each type of product, part or appliance subject to a specific airworthiness approval: type-certificates (TC) or Design Changes for aircraft, engines or propellers, or Technical Standard Orders (TSO).

This analysis may be qualitative or quantitative, i.e. formal and quantitative safety analyses may not be available for older or small aircraft. In such cases, the level of analysis should be consistent with that required by the

airworthiness requirements and may be based on engineering judgement supported by service experience data.

2.1 Analysis method for aircraft.

2.1.1 Accidents or incidents without any aircraft, engines, system, propeller or part or appliance malfunction or failure.

When an accident/incident does not involve any component malfunction or failure but when a crew human factor has been a contributing factor, this should be assessed from a man-machine interface standpoint to determine whether the design is adequate or not. Paragraph 2.5 gives further details on this aspect.

2.1.2 Events involving an aircraft, engines, system, propeller or part or appliance failure, malfunction or defect.

The general approach for analysis of in service events caused by malfunctions, failures or defects will be to analyse the actual failure effects, taking into account previously unforeseen failure modes or improper or unforeseen operating conditions revealed by service experience.

These events may have occurred in service, or have been identified during maintenance, or been identified as a result of subsequent tests, analyses, or quality control.

These may result from a design deficiency or a production deficiency (non conformity with the type design), or from improper maintenance. In this case, it should be determined if improper maintenance is limited to one aircraft, in which case an airworthiness directive may not be issued, or if it is likely to be a general problem due to improper design and/or maintenance procedures, as detailed in paragraph 2.5.

A) Flight.

An unsafe condition exists if:

- There is a significant shortfall of the actual performance compared to the approved performance (taking into account the accuracy of the performance calculation method), or

- The handling qualities, although having been found to comply with the applicable airworthiness requirements at the time of initial approval, are subsequently shown by service experience not to comply.

B) Structural or mechanical systems.

An unsafe condition exists if the deficiency may lead to a structural or mechanical failure which:

- Could exist in a Principal Structural Element that has not been qualified as damage tolerant. Principal Structural Elements are those which contribute significantly to carrying flight, ground, and pressurisation loads, and whose failure could result in a catastrophic failure of the aircraft.

- Could exist in a Principal Structural Element that has been qualified as damage tolerant, but for which the established inspections, or other procedures, have been shown to be, or may be, inadequate to prevent catastrophic failure.

- Could reduce the structural stiffness to such an extent that the required flutter, divergence or control reversal margins are no longer achieved.

- Could result in the loss of a structural piece that could damage vital parts of the aircraft, cause serious or fatal injuries to persons other than occupants.

- Could, under ultimate load conditions, result in the liberation of items of mass that may injure occupants of the aircraft.

- Could jeopardise proper operation of systems and may lead to hazardous or catastrophic consequences, if this effect has not been taken adequately into account in the initial certification safety assessment.

C) Systems.

The consequences of reported systems components malfunctions, failures or defects should be analysed.

For this analysis, the certification data may be used as supporting material, in particular systems safety analyses.

The general approach for analysis of in service events caused by systems malfunctions, failures or defects will be to analyse the actual failure effects.

As a result of this analysis, an unsafe condition will be assumed if it cannot be shown that the safety objectives for hazardous and catastrophic failure conditions are still achieved, taking into account the actual failure modes and rates of the components affected by the reported deficiency.

The failure probability of a system component may be affected by:

- A design deficiency (the design does not meet the specified reliability or performance).

- A production deficiency (non conformity with the certified type design) that affects either all components, or a certain batch of components.

- Improper installation (for instance, insufficient clearance of pipes to surrounding structure).

- Susceptibility to adverse environment (corrosion, moisture, temperature, vibrations etc.).

- Ageing effects (failure rate increase when the component ages).

- Improper maintenance.

When the failure of a component is not immediately detectable (hidden or latent failures), it is often difficult to have a reasonably accurate estimation of the component failure rate since the only data available are usually results of maintenance or flight crew checks. This failure probability should therefore be conservatively assessed.

As it is difficult to justify that safety objectives for the following systems are still met, a deficiency affecting these types of systems may often lead to a mandatory corrective action:

- back up emergency systems, or

- fire detection and protection systems (including shut off means).

Deficiencies affecting systems used during an emergency evacuation (emergency exits, evacuation assist means, emergency lighting system ...) and to locate the site of a crash (Emergency Locator Transmitter) will also often lead to mandatory corrective action.

D) Others.

In addition to the above, the following conditions are considered unsafe:

- There is a deficiency in certain components which are involved in fire protection or which are intended to minimise / retard the effects of fire / smoke in a survivable crash, preventing them to perform their intended function (for instance, deficiency in cargo liners or cabin material leading to non-compliance with the applicable flammability requirements).

- There is a deficiency in the lightning or High Intensity Radiated Fields protection of a system which may lead to hazardous or catastrophic failure conditions.

- There is a deficiency which could lead to a total loss of power or thrust due to common mode failure.

If there is a deficiency in systems used to assist in the enquiry following an accident or serious incident (e.g., Cockpit Voice Recorder, Flight Data Recorder), preventing them to perform their intended function, the DCA may take mandatory action.

2.2 Engines.

The consequences and probabilities of engine failures have to be assessed at the aircraft level in accordance with paragraph 2.1, and also at the engine level for those failures considered as Hazardous in the design code such as CS E-510 or FAR 33.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.3 Propellers.

The consequences and probabilities of propeller failures have to be assessed at the aircraft level in accordance with paragraph 2.1, and also at the propeller level for those failures considered as hazardous in the design code such as CS P-150.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.4 Parts and appliances.

The consequences and probabilities of equipment failures have to be assessed at the aircraft level in accordance with paragraph 2.1.

2.5 Human factors aspects in establishing and correcting unsafe conditions.

This paragraph provides guidance on the way to treat an unsafe condition resulting from a maintenance or crew error observed in service.

It is recognised that human factors techniques are under development. However, the following is a preliminary guidance on the subject.

Systematic review should be used to assess whether the crew or maintenance error raises issues that require regulatory action (whether in

design or other areas), or should be noted as an isolated event without intervention. This may need the establishment of a multidisciplinary team (designers, crews, human factors experts, maintenance experts, operators etc.)

The assessment should include at least the following:

- Characteristics of the design intended to prevent or discourage incorrect assembly or operation;

- Characteristics of the design that allow or facilitate incorrect operation,

- Unique characteristics of a design feature differing from established design practices;

- The presence of indications or feedback that alerts the operator to an erroneous condition;

- The existence of similar previous events, and whether or not they resulted (on those occasions) in unsafe conditions;

- Complexity of the system, associated procedures and training (has the crew a good understanding of the system and its logic after a standard crew qualification programme?);

- Clarity/accuracy/availability/currency and practical applicability of manuals and procedures;

- Any issues arising from interactions between personnel, such as shift changeover, dual inspections, team operations, supervision (or lack of it), or fatigue.

Apart from a design change, the corrective actions, if found necessary, may consist of modifications of the manuals, inspections, training programmes, and/or information to the operators about particular design features. The DCA may decide to make mandatory such corrective action if necessary.

APPENDIX 10 : Model Contents Of A DOM.

Preface

- Title page
- Content
- List of effective pages
- Revision highlights
- Corporate Commitment
- Introduction to the DOM
- Abbreviations & Definitions
- Referenced documents
- Cross reference list with AN 96 Requirements v.v.

Chapter 1 The Design Organisation

- Organisational Structure, description and charts
    - Chief Executive
    - Head of the Design Organisation
    - Head of the Design Assurance Department
    - Head of the Office of Airworthiness
    - Staff of the Office of Airworthiness
    - Compliance Verification Engineers
    - Other responsible managers/staff in DA and Engineering
    - Operational responsibilities
    - Functional responsibilities
    - Human resource management
    - Qualifications of nominated staff
    - Training
    - Vendors; outsourcing

Chapter 2 Terms of Approval

- DOA certificate
- Scope of Work
- Privileges
- Changes in the Scope of Work
- Surrender or revocation of the DOA

Chapter 3 The Design Assurance System

- Introduction
    - Definition of the DAS
    - Purpose of the DAS
    - Integration into the organisation
    - Changes to the DAS
    - Functional relationship with Third Parties
    - Audit Functions
    - Audit Procedures
    - Audit Programme

Chapter 4 Type Certification Procedures

- Introduction
    - Definition of the Type Design
    - Determination of the Type Certificate Basis
    - Certification Review Item (CRI) Procedure
    - Action Item (AI) Procedure
    - Certification Programme definition
        - Proposed Means of Compliance determination
        - Involvement of DCA
    - CVE approval procedure
    - Coordination with production
    - Coordination with DCA
    - Test preparation and witnessing
    - Report preparation and approval, including CVE statement
    - Data submittal to DCA
    - Preparation of the Compliance Checklist
    - Final Statement of Compliance Procedure
    - Issuance of approved data; manuals etc.

Chapter 5 Changes to the Type Design

- Introduction
    - Definition of the Change to the Type Certificate
    - Classification procedure minor/major
    - Approval Procedure for Minor Changes
        - Minor changes requiring certification substantiation
        - Minor changes not requiring certification substantiation
    - Approval procedure for Major Changes
        - Determination of the TC basis
        - Proposed means of compliance determination
        - Involvement of DCA
        - Involvement of TC/STC Holder
    - Report preparation and approval, including CVE statement
    - Data submittal to DCA
    - Preparation of the Compliance Checklist
    - Final Statement of Compliance Procedure
    - Amendment procedure of approved data; manuals etc.
    - Issuance of approved data; manuals etc.

Chapter 6 Repairs

- Introduction
    - Definition of the Repair, e.g. damage assessment
    - Classification procedure
    - Approval Procedure for Minor Repairs
        - Minor repairs requiring certification substantiation
        - Minor Repairs not requiring certification substantiation
    - Approval procedure for Major Repairs
        - Determination of the TC basis
        - Proposed means of compliance determination
        - Involvement of DCA (not applicable for Repairs designed by TC/SCT Holder)
        - Involvement of TC/STC Holder
    - Report preparation and approval, including CVE statement
    - Data submittal to DCA
    - Final Statement of Compliance Procedure
    - Amendment procedure of approved data; manuals etc.
    - Issuance of approved data; manuals etc.

Chapter 7 Continued Airworthiness

- Introduction
    - Service Difficulty Reporting and processing
    - Incident/accident investigation
    - Service Bulletin preparation
    - Coordination with DCA

Chapter 8 Third parties (Partners, subcontractors, vendors.)

- Introduction
    - Scope of work
    - Interface procedure
        - With usage of Third Party DOA
        - Third Party without DOA
    - Direct Delivery Authorisation
    - Continued Airworthiness procedures
    - Support procedure for Service Difficulties; Incidents; Accidents
    - Amendment procedure of approved data; manuals etc.
    - Issuance of approved data; manuals etc.
    - Audit Programme

Appendix 1 Personnel Data (confidential)

- Introduction
    - Curriculum Vitae of responsible staff
    - Training needs and training performed

APPENDIX 11 : Standardised Evaluation Criteria For DOA.

This appendix provides standardised evaluation criteria used in documenting the evaluation of the systems elements listed in **Table 1** for delegated facilities.

TABLE 1. SYSTEM ELEMENTS

Section	System Elements
1	Organisation and Responsibility
2	Project Management
3	Design Data Approval
4	Design Change Approval
5	Testing
6	Conformity Inspection
7	Airworthiness Certification
8	DCA Notification
9	Continued Airworthiness
10	Audit

SECTION 1. ORGANISATION AND RESPONSIBILITY.

The evaluation of the facility's organisation and responsibilities relative to the facility's delegation.

1D1. Does the DOA have and use a DOM appropriate to the approval that it holds, including description of responsibilities and authorities ?

1D2. Are procedures for the delegated functions set forth in a current DOM ?

Procedures for processing the technical data required for approval and issuance of design documents.

(1) Determination of certification basis.
(2) Classification of project significance and complexity.
(3) Method for developing certification plan.
(4) The identification (names, signatures, and responsibilities) of officials and of each staff member.
(5) A "Log of Revisions" page that identifies each revised item, page, and date of revision, and contains the signature of the person approving the change for the DCA.
(6) Approval of design data (drawings and reports) within the DOA organisation.
(7) Requests for conformity inspection, including test articles and test setups.
(8) Approval of certification documents, e.g., CofC, ASOC, AFMS.
(9) Conduct of inspections, including conformity and compliance inspections.

(10) Issuance of special airworthiness (experimental) certificates and reissuance of standard airworthiness certificates.
(11) Procedures for developing and determining the adequacy of technical data for major repairs.
(12) Procedures in establishing the applicability and limitations of approved repairs.
(13) Service Difficulties.
(14) Other functions within the scope of the delegation.

1D3. Is the DOM reviewed periodically by the DOA for adequacy and currency, and updated as necessary ?

1D4. Is the DOA, operating within its approved delegated authority ?

1D5. Does the DOA limit repair, rebuilding, or altering only to those products for which a production approval has been obtained ?

1D6. Does the DOA assure that it continues to meet the criteria for holding its approval ?

1D7. Does the DOA have a Coordinator as a focal point for communication with the DCA as it relates to the interpretation of regulations, policies, procedures, and maintenance of certification data and certification checklist ?

1D8. Does the Coordinator have sufficient authority to administer the pertinent requirement effectively ?

a. The Coordinator is in an organisational position with sufficient authority to administer the pertinent requirement effectively.
b. The Coordinator is actively involved in engineering processes and airworthiness activities defined by the DOA in order to administer the pertinent requirement effectively.

1D9. Are the organisations responsible for performing delegated engineering and flight test functions described and their levels of authority defined ?

The procedure manual includes as a minimum:
(1) A table of organisation that describes the functional relationship of upper management to the various organisational components.
(2) The purpose and objectives of the engineering and flight test organisation.
(3) The identification of the functions of staff members within the facility.
(4) The role of staff members in the facility and their responsibilities as representatives of the DCA, ensuring that no conflicting restraints are placed on the performance of their duties.

1D10. Are the organisations responsible for performing conformity inspection and airworthiness functions described and their levels of authority defined ?

The procedure manual includes as a minimum:

(1) A table of organisation that describes the functional relationship of upper management to the various organisational components.
(2) The purpose and objectives of the conformity inspection and airworthiness organisation.
(3) The identification of the functions of staff members within the facility.
(4) The role of staff members in the facility and their responsibilities as representatives of the DCA, ensuring that no conflicting restraints are placed on the performance of their duties.

1D11. Are approved procedures, regulations, and policies made available to responsible DOA staff members ?

a. The procedures manual provides for distribution of regulations, policy, and procedures.
b. The procedures manual provides that each appropriate employee has easy access to pertinent regulations, policy, and procedures.

1D12. Is there a staff of engineering, flight test, and inspection personnel, as appropriate, that can determine compliance to airworthiness requirements ?

1D13. Does the DOA maintain a current list of products or articles that have been repaired or modified under the delegated authorisation ?

1D14. Does the DOA keep current a list of all the certificates for which it holds approval ?

1D15. Is there a requirement for the DOA's personnel to have knowledge, skills, and abilities appropriate to their assignments and responsibilities ?

Procedures define the method for establishing and maintaining personnel qualifications appropriate to the delegated functions being performed.

1D16. Do the organisations and personnel identified in the DOA periodically receive training and updates for the functions and procedures that they have been delegated ?

There is objective evidence (on-going training requirements) that staff members are knowledgeable of the approved functions and procedures, including periodic changes, which have been delegated to them and to the facility.

1D17. Are tags, forms, and other certification documents described in the procedures manual and are the items properly controlled ?

Procedures include, as a minimum:
(1) A sample of each tag, form, and other document with instructions for use as applicable.
(2) A formal change control procedure.

1D18. Does the DOA retain records in accordance with the appropriate regulations ?

There is objective evidence that:
(1) A record retention schedule that complies with applicable regulations has been established.
(2) Technical data files, repair, rebuild, and alteration records, original application data, inspection records, and service difficulty records, as applicable, are maintained in accordance with record retention requirements.

1D19. In the case of aircraft, does the DOA have a flight safety program ?

Procedures provide for a flight safety program that includes, as a minimum:
(1) Monitoring of crew duty hours.
(2) Periodic review of accidents and incidents.
(3) Mandatory safety meetings.

SECTION 2. PROJECT MANAGEMENT.

Project management includes those functions related to the overall management and approval of a project within the delegated facility's approved procedures manual or handbook.

2D1. Has a certification basis or airworthiness requirement been established and used for the modified or repaired type certificated product ?

Procedures include, as a minimum:
(1) Method used to determine certification basis (regulatory requirements).
(2) Method for evaluating the regulatory requirement against the modification or repair.
(3) Method of documenting certification basis (regulatory) applicability.

2D2. When determining the certification basis, has the DOA made a determination on the use of the latest airworthiness standards ?

Procedures include, as a minimum:
(1) Method of documenting certification basis (regulatory) applicability, including the position relative to complying with the later standards.
(2) Method used in evaluating the basic regulatory requirements together with the applicable service experience.

2D3. Does the DOA make a determination as to whether a project is significant or non-significant prior to submitting the letter of intent to the DCA ?

Procedures include, as a minimum:
(1) Method used to determine and document the project criticality assessment.
(2) Method to incorporate the assessment findings into the letter of intent or other project notification form.

2D4. Has a certification basis been established and coordinated with the DCA for new type certification projects ?

Procedures include, as a minimum:
(1) Method used to determine certification basis (regulatory requirements).
(2) Method for evaluating the regulatory requirement against the proposed type certificated product.
(3) Method of documenting certification basis (regulatory) applicability.
(4) Method to notify the DCA of the proposed certification basis.

2D5. Are letters of intent or similar documents reviewed by the staff prior to submittal to the DCA ?

Procedures include a method to coordinate the letter of intent internally with engineering, flight test, and inspection staff members prior to submitting the letter to the DCA.

2D6. Does the DOA submit a Letter of Intent or similar document for project initiation to the DCA ?

Procedures include, as a minimum:
(1) Method to identify the information required in the Letter of Intent.
(2) A listing of staff member(s) authorised to approve and submit the Letter of Intent to the DCA within a prescribed time.

2D7. Is the DCA response to the letter of intent obtained prior to the issuance of the certificate ?

Procedures include a method to disposition the DCA response or requirements to the Letter of Intent.

2D8. Does the DOA obtain DCA's concurrence for the application of all equivalent safety provisions applied for ?

2D9. Are AD's identified for the product being modified/repaired and evaluated for their effect on the change in the type design ?

Procedures include, as a minimum:
(1) Identification of applicable AD's.
(2) Evaluation of the effect the AD has on the modified/repaired product.

NOTE: If an AD is identified as applicable, and as a result of the proposed modification or repair the requirements of the AD can no longer be accomplished, the delegated facility MUST obtain an alternate means of compliance to the AD from the DCA, PRIOR to the delegated facility's issuance of a design approval.

2D10. Does the DOA coordinate milestones and unique project requirements with the appropriate disciplines within the facility, and with the DCA ?

Procedures provide for communicating milestones and unique project requirements with the appropriate DOA personnel and with the DCA.

2D11. Are there means for the identification and resolution of significant technical, regulatory, and administrative issues that occur during the certification process within the facility, and with the DCA ?

Procedures include, as a minimum, a method to:
(1) Identify issue(s).
(2) Identify staff member participation.
(3) Request the DCA for an issue paper(s), if required.
(4) Incorporate the findings of the issue paper into the type design.

2D12. Do staff members communicate with each other for project coordination and, when applicable, with the DCA ?

Procedures promote, as a minimum, communication between:
(1) Staff members and management.
(2) Staff members for project coordination.
(3) Delegated facility staff members and the DCA.

2D13. Is there coordination between staff members on projects that require approvals in more than one technical area ?

Procedures include, as a minimum, a method to:
(1) Coordinate multi-discipline review and approval, e.g. airframe, systems, propulsion, flight test, and inspection.
(2) Authorise staff member(s) to review each data package for possible overlaps.

2D14. Are required certification tests identified, documented, and approved ?

There is objective evidence that staff members authorised to witness and approve test results have been identified. Procedures may provide for:
(1) Method to identify all tests to assure compliance with the applicable airworthiness requirements.
(2) Method to define and conduct tests, e.g., ground tests.
(3) Method to document and approve results, e.g., test report.

2D15. Does the DOA process and approve an authorisation, which authorises the official conformity, airworthiness inspections, and flight tests necessary to fulfill certain requirements for TC, and modification certification ?

Procedures include, as a minimum, a method to:
(1) Document the required official certification inspections and tests.
(2) Approve the required document, including, as applicable, the coordination with other staff members.
(3) Make and approve changes to this document.
(4) Control and file this document.
(5) Include DCA participation, as required.

2D16. Are compliance inspections being conducted by authorised staff members ?

Procedures provide for:
(1) Method to identify compliance inspection requirements.
(2) Method to document and disposition the findings of the compliance inspection.
(3) Identification of staff members authorised to conduct compliance inspections.

2D17. Are conformity inspections accomplished and documented prior to conducting certification tests ?

Procedures provide for a method to:
(1) Assure that conformity inspections are accomplished prior to certification tests.
(2) Define and conduct conformity inspections, e.g., ground tests.
(3) Document and approve results.

2D18. Are nonconforming products/parts dispositioned by engineering prior to tests or final approval ?

2D19. Does the DOA assure that DCA-requested participation and/or the determination of specific findings are completed ?

Procedures include, as a minimum, a method to assure that:
(1) DCA-requested participation and/or specific findings are included in the testing and inspection schedule.
(2) DCA-requested participation and/or specific findings are completed and documented.

2D20. When applicable, is the AFM/AFMS (Aircraft Flight Manual or Aircraft Flight Manual Supplement) properly formatted, documented, coordinated, approved, and controlled ?

Procedures include, as a minimum, a method to:
(1) Determine whether an AFM or AFMS is necessary.
(2) Assure that the AFM or AFMS is properly formatted.
(3) Assure that the document has been coordinated with all engineering disciplines.
(4) Assure that the AFM or AFMS is approved and referenced properly on the approval certificate prior to the issuance of the type certificate or supplemental type certificate.
(5) Process revisions to the AFM or AFMS.

2D21. Does the DOA process and approve a document, which documents those official conformity, airworthiness inspections, and flight tests necessary to fulfill the requirements for TC, and modification certification ?

Procedures include, as a minimum, a method to:
(1) Document the results of the official certification inspections and tests.
(2) Approve the required document, including, as applicable, coordination with other staff members.
(3) Make and approve changes to this document.
(4) Control and file this document.
(5) Identify timely completion of the document.
(6) Include DCA participation, as required.

2D22. Are projects that require amendment identified, documented, and approved ?

2D23. Upon the completion of a project, does the DOA document the project certification activities in a report such as a certification summary report ?

Procedures include, as a minimum, a method to:
(1) Identify the documentation to be used for summarising project activities.
(2) Complete the required documentation and forms.
(3) Approve these documents, and identify those staff members authorised to do so.
(4) Make and approve changes to this document.
(5) Control and file these documents.

2D24. Does the coordinator assure that the type design data, technical data, and/or repair data are approved, documented, and controlled ?

Procedures include, as a minimum:
(1) Methods for documenting data approvals.
(2) A description of the data approval process, including personnel authorised to approve the data.
(3) A means of controlling the issuance and distribution of data approvals.

SECTION 3. DESIGN DATA APPROVAL.

The planning and integration of the DOA's procedures for the approval of the design/repair data (including software) as delegated to the DOA.

3D1. Is the type design data, technical data, and/or repair data documented and controlled ?

Procedures include, as a minimum:
(1) Methods for documenting and retaining data approvals.
(2) A means of controlling the issuance and distribution of approval documents.
(3) A means of documenting and controlling test plans, reports, and data.
(4) A means of documenting and controlling required documents, e.g., instructions for continued airworthiness, flight manuals, installation/operation instructions.

3D2. Are documents and forms, identified and listed in the procedures manual or handbook, used to document the approval of data and to make findings of compliance ?

Procedures provide for documenting approved data and findings of compliance on specified forms.

3D3. During the approval process, is there a determination on and classification of the type of data being approved ?

Procedures include, as a minimum:
(1) Determination and classification of data by engineering disciplines, such as requiring DCA/designee approval.
(2) Determination and classification of repair as major or minor.

3D4. Is there a drawing control system ?

Procedures provide for:
(1) Drawings that are adequate, complete, and legible.
(2) Identification of drawings.
(3) Indication of drawing approval, including DCA approval.

(4) Maintenance and security of drawings.
(5) Use of current drawings and removal of obsolete drawings.
(6) A list of drawings and specifications necessary to define configuration of the DCA-approved design.
(7) Control of preliminary/experimental drawings.
(8) Existence of adequate backup methods for software used for drawing control.

3D5. Is the type design data, technical data, and/or repair data approved ?

The procedures include, as a minimum:
(1) Description of the data approval process, including personnel authorised to approve the data.
(2) Methods to obtain complete design data and approval documents in accordance with certification plan.
(3) Methods to approve master document (data) and/or certification compliance checklist.
(4) Methods to approve test plans, data, and reports.
(5) Methods to approve required documents, e.g., instructions for continued airworthiness, flight manuals, installation instructions.

3D6. Is there a Software Configuration Management Plan (SCMP) or procedure to control airborne software configuration ?

Procedures provide for:
(1) Installation of the correct version of the software in the certification test article or in the delivered product in accordance with the DCA-approved design in the certification program.
(2) Method by which controlled software containing the DCA-approved design data is transitioned into production. The media containing the software installed in the product is directly traceable to the Software Configuration Management (SCM) library.

3D7. Has a criticality assessment and the software verification been accomplished in accordance with RTCA/DO–178 or other accepted/approved documents (e.g., RTCA/DO–236, etc.) ?

Procedures provide for a properly documented software criticality assessment and verification process.

3D8. Is there a Configuration Index Document (CID) listing all software documents under configuration control and defining the hardware and software part numbers ?

Procedures provide for traceability of hardware and software part numbers to the drawing control system.

3D9. Are there practices and procedures for reporting, tracking, and resolving software problems ?

Procedures provide for:
(1) Methods for corrective action, for problems found, include provisions for airborne software and hardware/software combinations. Procedures may parallel or be part of hardware corrective action procedures.
(2) Method to dispose and delete obsolete or non-current software.

3D10. Are there methods and facilities to protect computer programs from unauthorised access, inadvertent damage, or degradation ?

Procedures provide for:
(1) Configuration control of the airborne software within the product design files.
(2) Limited access to software files.
(3) Separate archives for masters and duplicates.
(4) That masters and duplicates are not revived by the same machine simultaneously.

3D11. Are there procedures to ensure that the software development environment (i.e., compilers, loaders, linkers, editors, emulators, etc.) is identified, documented and archived for each version of the delivered airborne software version ?

Procedures provide for methods to identify, document, and archive the software development environment for each version of delivered airborne software.

3D12. Is airborne software programmed media handled and stored properly (e.g., environmental controls and magnetic interference precautions) ?

SECTION 4. DESIGN CHANGE APPROVAL.

The planning and integration of the DOA's procedures for the approval of changes to the DOA design data. This includes software used in type-certificated aircraft or related products (airborne software).

4D1. Are the changes to the type design data, technical data, and/or repair data documented and controlled ?

Procedures include, as a minimum:
(1) Methods for documenting and retaining data approvals.
(2) A means of controlling the issuance and distribution of approval documents.
(3) A means of documenting and controlling test plans, reports, and data.

(4) A means of documenting and controlling required documents, e.g., instructions for continued airworthiness, flight manuals, installation/operation instructions.

4D2. Does the DOA determine if a design change or repair is major or minor ?

There is objective evidence that changes to the DOA design change, or a repair, have been properly classified as major or minor.

4D3. Are minor design changes approved under a method acceptable to the DCA ?

4D4. Are major changes to type design, technical data, and/or repair data approved ?

4D5. Are documents and forms, identified and listed in the DOM, used to document the approval of design changes and findings of compliance ?

4D6. Are corrective actions identified in AD incorporated into the DCA approved design, when applicable ?

There is objective evidence that design changes necessary to correct unsafe conditions identified in AD's have been incorporated into the DCA-approved design.

4D7. Does the DOA specify the repairable damage limits when applicable ?

SECTION 5. TESTING.

The function which provides for the testing, including both component and final product tests, required to establish that the approved design or changes thereof are in compliance with the applicable requirement.

5D1. Are all certification tests identified, documented, and approved ?

Procedures provide for a method to:
(1) Identify all certification tests, and the disposition of the conformity inspections associated with the test plans.
(2) Define and approve tests, including pass/fail criteria.

5D2. Are staff members responsible for the development of test plans, witnessing of tests, and the documentation of test results identified ?

Procedures provide for an organisational chart or table that identifies the staff, and their responsibility and authority for developing and approving test plans; witnessing tests; and documenting and approving test results.

5D3. Does equipment used for test has the degree of accuracy necessary to determine conformity of the characteristic being measured/tested ?

Procedures provide for:

(1) The degree of accuracy and current calibration of all measurement devices and test equipment.
(2) Measurement devices and test equipment capable of the accuracy necessary and adequate for the intended purpose, including measurement devices and test equipment substituted for those specified.
(3) A list of measurement devices and test equipment used to determine conformity of the characteristics being tested.

5D4. Is there appropriate safety equipment available during certification testing ?

Procedures include the method for the training of personnel, and the control and availability of appropriate safety equipment.

5D5. Does the DOA's authorised staff members assure that conformity inspections are completed prior to conducting certification tests ?

Procedures provide for a method to:

(1) Verify that certification conformity inspections have been accomplished; for example, parts, installation, and/or test setup.
(2) Review conformity inspection records.
(3) Disposition nonconformity inspection records.

5D6. Does the DOA's staff members, including inspection personnel, participate in the review of test instructions or procedures ?

Procedures provide for a method:

(1) For the delegated facility staff members, including inspection personnel, to review test instructions or procedures prior to release.
(2) To evaluate and verify conformity to approved design. This includes the identification of inspection points that ensure conformity to approved design.
(3) For inspection equipment to be available or procured that will adequately verify conformity to approved design, and that can be controlled for accuracy, when required.

5D7. Are test results documented and approved ?

Procedures provide for documentation to include as a minimum:

(1) Test results.
(2) Approval of test results.

5D8. Are certification test discrepancies documented and dispositioned ?

Procedures provide for a method to:
(1) Document discrepancies.
(2) Disposition discrepancies, e.g., re-evaluate test procedures, rework and re-conform test setup, redesign.

5D9. Does the DOA allow for the use of personnel other than those identified in the DOM to assist in witnessing the required certification tests ?

Procedures include:
(1) The method of approving personnel to conduct and witness required certification tests.
(2) The requirements and controls, including training, for authorised persons to document and approve applicable data.

SECTION 6. CONFORMITY INSPECTION.

The function which establishes control of the prototype/test article conformity to approved drawings.

6D1. Are Statements of Conformity properly submitted ?

There is objective evidence that:
(1) The method for verifying the statement of conformity, for the product manufactured, altered, or repaired, has been submitted to the appropriate delegated facility staff member.
(2) The statement of conformity has been signed by an authorised person who holds a responsible position in the manufacturing organisation or repair station.

6D2. Are conformity inspections documented ?

Procedures include, as a minimum, a method to:
(1) Obtain the statement of conformity from the applicant.
(2) Conduct conformity inspections.
(3) Complete the conformity inspection records.
(4) Document the detail parts, assemblies, and installation conformities recorded on the conformity inspection record, including design data revision level and release date of design data.
(5) Document and coordinate disposition of nonconformities or deviations with the engineering organisation.
(6) Verify and/or conform that special processes called out in design data have been accomplished in accordance with the process requirements.

6D3. Does equipment used for inspection has the degree of accuracy necessary to determine conformity of the characteristic being inspected ?

Procedures provide for:
(1) The degree of accuracy and a current calibration of all measurement devices and test equipment.
(2) Measurement devices and test equipment capable of the accuracy necessary and adequate for the intended purpose, including measurement devices and test equipment substituted for those specified.
(3) A list of measurement devices and test equipment used to determine conformity of characteristics being inspected.

6D4. Are "at-risk" conformity inspection records generated and tracked for in-process conformity inspections and do these records reflect the final approved design ?

Procedures provide for a method to assure that in-process conformity records:
(1) Are generated and maintained.
(2) Reflect the final approved design.

6D5. Do the DOA inspection staff members conduct conformity inspections at the supplier/vendor when conformity cannot be determined upon receipt ?

Procedures provide for:
(1) Only authorised staff members to conduct conformity inspections.
(2) Method to conduct conformity inspections at suppliers/vendors.

6D6. Are methods for identification, control, and disposition of nonconforming products/parts provided ?

Procedures provide for:
(1) Methods used for identification, control, and disposition of nonconforming products/parts.
(2) Method to secure nonconforming material, with access limited to authorised personnel.
(3) Disposition of nonconforming items, including standard repairs and MRB actions, only through the delegated facility engineering review and approval process.

6D7. Is software identified/marked externally/internally in accordance with the engineering drawing requirements ?

Work instructions detail the identification/marking requirements.

6D8. Are special processes coordinated with engineering and inspection personnel ?

Procedures provide for the engineering and inspection organisations to review design and technical data changes prior to release to ensure that:

(1) The product can be properly evaluated and verified to be in conformity to approved design.

(2) Inspection equipment is available or can be procured that will adequately verify conformity to approved design, and that can be controlled for accuracy, when required.

6D9. Does the DOA inspection personnel verify that the approved data are adequate for a multiple approval and the installation is airworthy ?

Procedures provide for a method to:

(1) Verify that the approved data are adequate for a multiple approval and to provide feedback to the Coordinator.

(2) Determine that the installation is airworthy and to provide feedback to the Coordinator.

SECTION 7. AIRWORTHINESS CERTIFICATION.

The function which provides for the issuance of appropriate airworthiness certificates.

7D1. Have applications for airworthiness certification been properly completed as identified in approved procedures, and submitted to the DCA, as applicable ?

Procedures define the responsibilities and method for airworthiness certificate application.

7D2. Have limitations and conditions been obtained from the DCA prior to issuing experimental airworthiness certificates ?

There is objective evidence that the necessary limitations and conditions have been obtained from the DCA prior to issuing experimental airworthiness certificates.

7D3. Have applicable airworthiness certificates been obtained for the purposes for which the aircraft is flown ?

There is objective evidence that the proper airworthiness certificates have been obtained for the purposes for which the aircraft is flown.

7D4. Are Airworthiness Directives (AD) incorporated ?

There is objective evidence that applicable AD’s have been complied with prior to operating the product.

7D5. If an export airworthiness approval has been issued, have the necessary documents and instructions been forwarded to the aviation authority of the importing country, or to other locations as specified in the special requirements of importing countries ?

There is objective evidence that all the documents and information necessary for proper operation of the product being exported have been forwarded to the cognizant aviation authority. For unassembled aircraft, this includes manufacturing assembly instructions and a DCA-approved flight test check off form.

7D6. Have export airworthiness approvals been obtained for all products exported ?

Procedures provide for:

(1) Methods for applying for export airworthiness approvals, and the responsibilities of personnel authorised to submit applications.
(2) A list of the products for which export airworthiness approvals are obtained.
(3) All exported products to meet special requirements of the importing country. Procedures provide for properly annotating any deviation on the exporting documentation, and including a letter of acceptance from the importing country for such deviations.
(4) Retention of copies of DCA Export Certificate of Airworthiness, and/or DCA Airworthiness Approval Tags, as applicable.

7D7. Are flight manuals, supplements, and current weight and balance data furnished with each aircraft before issuance of standard or restricted airworthiness certificate ?

Procedures provide for the furnishing of aircraft flight manuals, supplements, and current weight and balance data with each aircraft.

7D8. Have airworthiness approval tags been issued by authorised personnel ?

Procedures provide for identification of personnel authorised to issue airworthiness approval tags.

SECTION 8. DCA NOTIFICATION.

The function which notifies the DCA of specific conditions as required by the approved procedures and by the requirement. This includes procedures for positive feedback, recording, reporting, and investigation of significant or reported failures, malfunctions, or defects. This function would also provide for determining cause and effecting appropriate corrective actions on such failures, malfunctions, or defects.

8D1. Does the DOA submit required information to the DCA ?

There is objective evidence that:

(1) an application for amendment to the production certificate has been submitted to the DCA for new models and type certificates.

(2) the following type certificate data has been submitted to the DCA for new products or amended type certificates:

(a) Type certificate application.

(b) Statement of applicable airworthiness requirements.

(c) Statement certifying compliance of type design to applicable requirements.

(d) Statement certifying that required technical data and type inspection report have been placed in the technical data file.

(e) Proposed type certificate data sheet.

(f) Aircraft Flight Manual (if required), operating limitations summary, or other information necessary for safe operation of the product.

8D2. Does the DOA notify the DCA within 48 hours of any change that could affect its ability to maintain its authorisation eligibility ?

There is objective evidence that the DCA was notified within 48 hours of any change (including a change of personnel) that could affect the ability of the DOA to maintain its authorisation eligibility.

8D3. Does the DOA investigate unairworthy conditions or unsafe features or characteristics reported by the DCA ?

There is objective evidence that the DOA has:

(1) Investigated reports of unairworthy conditions or unsafe features or characteristics reported by the DCA.

(2) Reported investigation results and the action, if any, taken or proposed to the DCA.

8D4. Does the DOA notify the DCA when a Type Certificate, or Licensing Agreement is transferred ?

SECTION 9. CONTINUED AIRWORTHINESS.

The function which assures the continued airworthiness of the product.

9D1. Does the DOA develop Instructions for Continued Airworthiness ?

9D2. Does the DOA make available Instructions for Continued Airworthiness, including changes, to appropriate persons ?

9D3. Are design changes considered in Instructions for Continued Airworthiness, when appropriate ?

Procedures provide for a method to:
(1) Consider the effect on the Instructions for Continued Airworthiness as a result of design changes.
(2) Revise Instructions for Continued Airworthiness, as required.

9D4. Does the DOA, in developing repair data, specify new inspection limits, when applicable ?

Procedures include development of inspection limits when applicable.

9D5. Are there provisions for receiving feedback on service problems from users/installers of the product/part thereof ?

Procedures provide for:
(1) Identification of a specific function to receive reports of service difficulties.
(2) Determination of appropriate manufacturing or design responsibilities for the reported problem.
(3) A system of tracking for accountability.

9D6. Are service problems investigated, and prompt corrective actions taken, by the DOA ?

Procedures provide for:
(1) A method of investigating, identifying, locating and reporting suspected unsafe products.
(2) Prompt corrective action, which includes, as a minimum:
    (a) Root cause determination and correction of deficient design or manufacturing.
    (b) A means of reporting, purging, tracking, and accountability of known unsafe products.

9D7. Are failures, malfunctions, and defects reported to the DCA ?

When procedures for reporting failures, malfunctions, and defects to the DCA have been established, they should provide for, as a minimum:

(1) Definitions of reportable conditions.
(2) Evaluation of conditions to determine their reportability.
(3) Documentation and reporting method(s).
(4) Submittal of each report by the most expeditious method available within 24 hours of occurrence, with provisions for weekends and holidays.

9D8. When corrective action is required by AD's, is information on the design changes made available to all owners and operators of the product ?

9D9. Is a record or file of reported service difficulties generated and maintained ?

When procedures for preparing a record or file of service difficulties have been established, they should provide for, as a minimum:

(1) Dates of receipt, what was reported, and action taken.
(2) Record legibility, completeness, and accuracy.
(3) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

9D10. Is there a means for keeping users of the product/part thereof informed of service information ?

Procedures provide for informing product users of service-related information for suspected or known unsafe conditions, e.g., service bulletins.

9D11. Does the DOA evaluate the effect on continued airworthiness or service issues for the product based on results from follow-on life cycle testing ?

Procedures provide for the evaluation of test results from follow-on life cycle testing for their effect on the continued airworthiness of the product.

9D12. Are service bulletins and maintenance manuals approved by authorised personnel ?

Procedures define specific organisational and individual responsibilities for approving service bulletins and maintenance manuals.

9D13. Are service bulletins, maintenance manuals, and changes thereto, forwarded to the DCA ?

Procedures provide for the submittal of service bulletin and maintenance manual issuances, and changes thereto, to the DCA.

9D14. Does the DOA assure that only approved technical data, including changes, are used for repair, rebuilding, and alterations ?

Procedures provide, as a minimum:
(1) Method to approve the technical data.
(2) Indication of appropriate revision level of the technical data on inspection documents and work instructions.

SECTION 10. AUDIT.

The function of a scheduled and systematic evaluation by the delegated facility to ascertain its own compliance to its DCA-approved DOM, as well as applicable requirement.

NOTE: The establishment and operation of an internal audit program (sometimes referred to as a self-audit program) or external audit program (sometimes referred to as a surveillance audit program) is not a mandatory requirement placed upon DOA, but is considered to be a "good" practice. If the DOA has a documented and operational internal and/or external audit program, it should be reviewed during the evaluation for adequacy and observance with the established procedures.

10D1. Does the DOA have an internal auditing program to verify compliance with its approved procedures, established policies, and approved data ?

Procedures provide for:
(1) Auditor qualifications and training.
(2) Formal audit checklists that systematically evaluate all major activities controlled by the delegated function.
(3) Audit planning to include an audit schedule that is available and followed.
(4) Special audits when major deficiencies within the DOA’s system are detected, or when there are significant organisational changes.
(5) Conducting and reporting of the results of the internal audits.
(6) Methods for identifying nonconformances, and obtaining required corrective action to include the identification of personnel responsible for the corrective action.
(7) Follow-up for corrective action effectiveness.

10D2. Does the DOA partner with the organisation that produces parts and assemblies, and perform installations, to share audit information ?

Procedures provide for:

(1) Description of the interface/relationship between the delegated function and:
  (a) certificated PAH and its approved quality system.
  (b) certificated repair station and its corresponding Inspection and Procedures Manual; *or*, the PAH and its corresponding approved quality system.
(2) Recommendation of special audits when major deficiencies in procurement, fabrication, and/or installation are detected during conformity inspections, or when there are significant changes to the repair station's, operator's, or PAH's organisation.
(3) Methods for identifying nonconformances, and obtaining required corrective action to include the identification of personnel responsible for the corrective action.
(4) Follow-up for corrective action effectiveness.

10D3. Does the DOA periodically review implemented modifications or repairs for compliance to the developed data ?

Procedures provide for a periodic review of implemented modifications or repairs for compliance to the developed data.

10D4. Is there feedback to higher-level management concerning the results of the internal audits ?

Procedures provide for:

(1) Periodic management review of the audit program to include internal audit results, nonconformances, corrective actions, and corrective action effectiveness.
(2) Review of internal audit results by personnel having responsibility for the area that was audited.
(3) Revision to DOM to prevent reoccurrence of actual or potential nonconformances.