

AMC & GM
ACCEPTABLE MEANS OF COMPLIANCE AND
GUIDANCE MATERIAL TO SIM-TO-LT-035
(FIN EMAR 21)

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INTRODUCTION

This instruction adheres to the applicable sections of EUROPEAN MILITARY AIRWORTHINESS REQUIREMENT EMAR 21 AMC & GM Edition no. 2.0, 4 Oct 2022 as published and approved by the Military Airworthiness Authorities (MAWA) Forum under the umbrella of the European Defence Agency (EDA).

GENERAL

SECTION A TECHNICAL REQUIREMENTS

SUBPART A - GENERAL PROVISIONS

AMC to 21.A.2 Undertaking by another organisation than the applicant for, or holder of, a certificate

In order to undertake the actions and obligations of the holder of, or applicant for, the certificate, the organisation should have an agreement in place with an approved Design Organisation who has access to the data related to the type design

AMC 21.A.3A(a) Collection, investigation and analysis of data related to Flammability Reduction Means (FRM) reliability

Holders of a type certificate, restricted type certificate, supplemental type certificate or any other relevant approval deemed to have been issued under SIM-To-Lt-035 and which have included an FRM in their design should assess on an on-going basis the effects of aeroplane component failures on FRM reliability. This should be part of the system for collection, investigation and analysis of data required by SIM-To-Lt-035 21.A.3A(a). The applicant/holder should do the following:

- a) Demonstrate effective means to ensure collection of FRM reliability data. The means should provide data affecting FRM reliability, such as component failures.
- b) Unless alternative reporting procedures are approved by the Authority, provide a report to the Authority every six months for the first five years after service introduction. After that period, continued reporting every six months may be replaced with other reliability tracking methods found acceptable to the Authority or eliminated if it is established that the reliability of the FRM meets, and will continue to meet, the exposure specifications as defined by the applicable airworthiness requirements.
- c) Develop service instructions or revise the applicable aeroplane manual, according to a schedule approved by the Authority, to correct any failures of the FRM that occur in service that could increase any fuel tank's Fleet Average Flammability Exposure to more than that specified by the applicable airworthiness requirements.

AMC No 2 to 21.A.3A(a) Collection, investigation and analysis of data related to ETOPS significant occurrences

- 1) Holders of a type-certificate, restricted type-certificate, supplemental type-certificate or any other relevant approval deemed to have been issued under SIM-To-Lt-035 and which

includes extended range operation with two-engined aeroplane (ETOPS) capability should implement a specific tracking, reporting and resolution system for ETOPS significant occurrences, suitable to ensure the initial and continued fleet compliance with the applicable ETOPS reliability objectives. This system should be part of the system for collection, investigation and analysis of data required by SIM-To-Lt-035 21.A.3A(a).

Appropriate coordination should exist between engine TC holder, propeller TC holder and APU MTSO authorization holder with the aircraft TC holder to ensure compliance with the ETOPS reliability objectives.

- 2) For tracking, reporting and resolution of ETOPS significant occurrences refer to the latest edition of EASA AMC 20-6 (part of AMC-20 document), together with military specific considerations that can be found in the EMAD 20 document.

GM 21.A.3A(a) System for Collection, Investigation and Analysis of Data

In the context of this 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.

GM 21.A.3A(b) Occurrence reporting

For occurrence reporting, additional guidance material can be found in EASA AMC 20-8, (part of EASA AMC 20 document) together with the military specific considerations that can be found in EMAD 20-8 (part of EMAD 20).

In particular:

- a) The products and part and appliances design rules prescribe that occurrences defined as a failure, malfunction, defect or other occurrence which has resulted in or may result in an unsafe condition must be reported to the Authority;
- b) According to the product and part and appliances production rules occurrences defined as a deviation which could lead to an unsafe condition must be reported to the Authority.

AMC 21.A.3A(b)(2) Reporting to the Authority

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 Authority 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 should 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.

AMC 21.A.3B(b) 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 Authority considers there is an unsafe condition. There may be other cases where overriding safety considerations may lead the Authority 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.

GM 21.A.3B(b) 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 continuing 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.

See AMC 21.A.3B(b) for definition of "unsafe condition" used in SIM-To-Lt-035 21.A.3B(b).

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: Military Type Certificates (MTC) or Military Supplemental Type Certificates (MSTC) for aircraft, engines or propellers, or Military Technical Standard Orders (MTSO).

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 are to 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 has to 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 has to 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.

2.1.2.1. 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.

2.1.2.2. 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.

Typical examples of such elements are listed, as guidance, in EASA Certification Specification for Large Aircraft (CS – 25) AMC 25.571(a) "damage tolerance and fatigue evaluation of structure", and in the equivalent material for rotorcraft.

- 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.

2.1.2.3. Systems

The consequences of reported systems components malfunction, failures or defects are to 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 is 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.

2.1.2.4. 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 Authority 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 applicable airworthiness requirements. Further guidance at the engine level for those failures considered as hazardous can be found in CS-E-510 under EASA Certification Specification – Engines (CS-E).

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 applicable airworthiness requirements. Further guidance at the propeller level for those failures considered as hazardous can be found in CS-P-150 under EASA Certification Specification – Propellers (CS-P).

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 is to be used to assess whether the crew or maintenance error raises issues that require regulatory action (whether in design or other areas), or is to 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 is to 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 Authority may decide to make mandatory such corrective action if necessary.

GM 21.A.3B(d)(4) Compliance time charts for military aircraft

If it is not possible to find mitigations and/or limitations that re-establish compliance with all the applicable safety requirements, an increased risk for an individual failure could be acceptable for a fixed period of time if it is demonstrated that during this period the cumulative probability of catastrophic event per flight hour is still compliant with the type certification basis.

Exceptions are possible in accordance with National regulations.

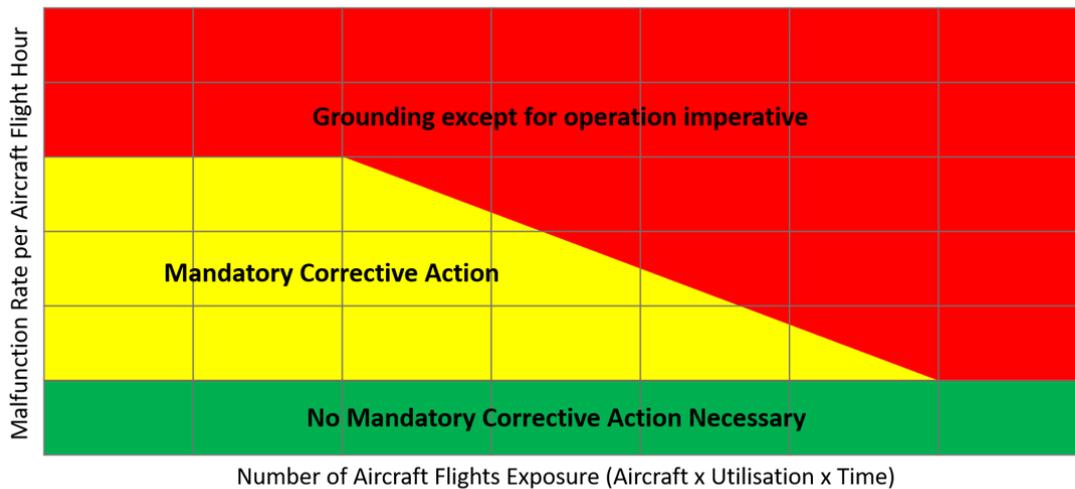
The residual risk during the time allowed to fix the defect is to be identified and minimized. Risk assessment techniques could be used to establish the deadline period to fix defects as agreed by the National Authority.

The civil regulations EASA Part 21 (21.A3b) allow a time period that is directly related to the level risk i.e. higher the risk the shorter the time period. These regulations have hard limits for the maximum instantaneous risk, the maximum risk for an individual aircraft and maximum cumulative risk for the fleet. The basis of these regulations considers typical civil operation, of 10 major safety campaigns during an aircraft life, a hull life of 60,000 hours and that 75% of the risk is attributed to the design. Using the above assumptions, they calculate an acceptable time period for restoration of risk levels to certification levels.

For military aircraft, the above assumptions are not necessarily valid and the acceptable levels of risk likely to be different, however the principles of the civil system can be equally applied to the military regulations. The graphical representation below, on a logarithmic scale, is adapted from civil regulations AMC to EASA

Part 21.A3b, without the numerical limits, and can be used to enable the Authority (where national regulations allow) to determine appropriate numerical limits, considering the role of the aircraft. There will be different limits for Catastrophic and Hazardous failures.

Risk and Reaction Times



AMC 21.A.4 Transferring of information on eligibility and approval status from the design organisations to production organisations

Where there is a need to provide (normally outside the design organisation) a visible statement of approved design data or airworthiness, operational suitability or environmental protection data associated with the approved design data, the following minimum information should be provided. The need for a visible statement may be in relation to Company holding a military production organisation approval (MPOA) in relation to SIM-To-Lt-035 21.A.163 (c).

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

Information to be provided:

Company Name: the name of the responsible design organisation (MTC, MSTC, approval of repair or minor change design, MTSO authorisation holder) issuing the information.

Date: the date at which the information is released.

Eligibility: indicate the specific products or articles, in case of MTSO 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 continuing airworthiness could be stated. Marking requirements of SIM-To-Lt-035 Subpart Q should be taken into account.

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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 MTSO authorisation or MPA marking, or previous national 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 (AMC No 1 to 21.A.133(b) and (c))
- b) Information regarding eligibility for installation (replacement parts, repair, modification, etc.)
- c) Direct Delivery Authorisation (AMC No 1 to 21.A.133(b) and (c))

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 MSTC, 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 the EMAR Form 1 (SVY901).

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

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

SUBPART B - TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b)
Flight Test Operations Manual (FTOM)

1. General

- a) Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

- b) Format

The FTOM may:

- be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (ADOA)¹ documents, or
- be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

- c) Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

- a) Exposition (not applicable in the case of ADOA)¹:

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

- b) Risk and safety management:

¹ Also referred to as APDOA by EASA

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c) Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d) Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e) Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f) Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

i. documents associated with a Flight Test Programme:

– Flight Order for a given flight, which should include:

- a list of the tests to be performed and associated conditions;
- safety considerations relevant to the flight;
- category of the flight (e.g. Category 1);
- composition of the crew;
- names of persons other than crew members;
- aircraft configuration items relevant to the test to be highlighted to the crew;
- loading of the aircraft;

- reference to approved flight conditions; and
 - restrictions relevant to the flight to be highlight-ed to the crew.
- Flight crew report.
- ii. documentation and information to be carried on the aircraft during flight test;
 - iii. record-keeping: the FTOM should describe the policy relative to record-keeping.
- g) Permit to fly:
- The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.
- h) Currency and training:
- The FTOM should describe how training for flight test is organised.
- Currency of the flight test crew may be ensured either through recent experience or refresher training.
- The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.
- A system should be established to record the currency of the flight test crew's training.

AMC 21.A.14(b) Alternative Procedures to demonstrate design capability

Alternative procedures are an acceptable means to demonstrate design capability in the cases described in SIM-To-Lt-035 21.A.14, SIM-To-Lt-035 21.A.112B, or SIM-To-Lt-035 21.A.432B. In the context of specific projects, the implementation of procedures required for a design organisation approval in accordance with SIM-To-Lt-035 Subpart J will ensure that the applicant performs the relevant activities as expected by the Authority. The establishment of these alternative procedures may be seen as a starting phase for a SIM-To-Lt-035 Subpart J military design organisation approval, allowing at a later stage, at the discretion of the applicant, to move towards a full SIM-To-Lt-035 Subpart J military design organisation approval by the addition of the missing elements.

1. Scope

- 1.1. As alternative to SIM-To-Lt-035 Subpart J, a manual of procedures should set out specific design practices, resources and sequence of activities relevant for the specific projects, taking account of SIM-To-Lt-035 requirements.
- 1.2. These procedures should be concise and limited to the information needed for quality and proper control of activities by the applicant/holder, and by the Authority.

2. Management of the (supplemental) type-certification process

- 2.1. Certification programme: See AMC 21.A.15(b) for type certification and AMC 21.A.93(b) for supplemental type certification.
- 2.2. Compliance demonstration: see GM 21.A.20
- 2.3. Reporting: see GM 21.A.20(b)
- 2.4. Compliance documentation: see AMC 21.A.20(c).
- 2.5. Declaration of compliance: see GM 21.A.20(d)

3. Management of changes to type certificates, repair designs and production deviations

- 3.1. Management of changes to a type certificate or supplemental type certificate (hereinafter referred to as 'changes'), repair designs and production deviations from the approved design data

The applicant should provide procedures acceptable to the Authority for classification and approval of changes (see paragraphs 3.2 and 3.3), and repair designs and production deviations from the approved design data (see paragraph 3.4).

3.2. Classification

3.2.1. Content

The procedure should address the following points:

- the identification of the product configuration(s) to which the change is to be made,
- the identification of the areas of the product that are changed or affected by the change,
- the identification of any reinvestigations that are necessary (see SIM-To-Lt-035 21.A.93(b)(2)), including the identification of the applicable airworthiness codes / airworthiness requirements established under EMACC, or environmental protection requirements, and means of compliance,
- changes initiated by subcontractors;
- documents to justify the classification;
- authorised signatories. The criteria used for classification should be in compliance with SIM-To-Lt-035 21.A.91 and corresponding interpretations.

3.2.2. Identification of changes

The procedure should indicate how the following are identified:

- major changes;

- those minor changes where additional work is necessary to demonstrate compliance with the airworthiness requirements;
- other minor changes that require no further demonstration of compliance.

3.2.3. Considerations of effects of the change

The procedure should show how the effects on airworthiness, operational suitability or environmental protection are analysed, from the very beginning, by reference to the applicable airworthiness codes and requirements.

If no specific airworthiness codes or requirements are applicable to the change, the above review should be carried out at the level of the part or system where the change is integrated and where specific airworthiness codes or requirements are applicable.

3.2.4. Control of changes initiated by subcontractors

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

3.2.5. Documents to justify the classification

All decisions of classification of changes should be documented and approved by the Authority. It may be in the format of meeting notes or a register.

3.2.6. Authorised signatories

The procedure should identify the persons authorised to sign the proposed classification before release to the Authority for approval.

3.3. Approval of changes

3.3.1. Content

The procedure should address the following points:

- compliance documentation;
- approval process;
- authorised signatories.

3.3.2. Compliance documentation

For major changes and those minor changes where additional work to demonstrate compliance with the applicable type-certification basis, operational suitability data certification basis, and environmental protection requirements (hereinafter referred to as the 'certification basis') is necessary, compliance documentation should be established in accordance with AMC 21.A.20(c).

3.3.3. Approval process

- A. For the approval of major changes, a certification programme as defined in AMC 21.A.93(b) must be established.
- B. For major changes and those minor changes where additional work to show compliance with the applicable certification basis is necessary, the procedure should define a document to support the approval process.

This document should include at least:

- identification and brief description of the change and its classification;
 - references to the applicable certification basis;
 - references to the compliance documents;
 - effects, if any, on limitations and on the approved design data;
 - the name of the authorised signatory.
- C. For the other minor changes, the procedure should define a means:
 - to identify the change;
 - to present the change to the Authority for approval.

3.3.4. Authorised signatories

The procedure should identify the persons authorised to sign the change before release to the Authority for approval.

3.4. Repair designs and production deviations from the approved design data

A procedure following the principles of paragraphs 3.2 and 3.3 should be established for the classification and approval of repair designs and unintentional deviations from the approved design data occurring in production (concessions or non-conformance's). For repair designs, the procedure should be established in accordance with SIM-To-Lt-035 Section A Subpart M and associated acceptable means of compliance (AMC) or guidance material (GM).

- 4. Issue of data and information (including instructions) to owners, operating organisations and others required to use the data and information.

4.1. General

Data and information include the operational suitability data.

4.2. Data related to changes

The data and information (including instructions) issued by the holder of a (military) design approval (a TC, STC, approval of a change, approval of a repair design) are intended to provide the owners of a product with all necessary data to embody a change or repair on the product, or to inspect it.

The data and information (including instructions) may be issued in a format of a Service Bulletin as defined in S1000D Chapters, or in structural repair manuals, maintenance manuals, engine and propeller manuals, etc.

The preparation of this data involves design, production and inspection. The three aspects should be properly addressed and a procedure should exist.

4.3. Procedure

The procedure should address the following points:

- preparation;
- verification of technical consistency with corresponding approved change(s), repair design(s) or approved data, including effectivity, description, effects on airworthiness or operational suitability, especially when limitations are changed;
- verification of the feasibility in practical applications;
- approval for the release of the data and information.

The procedure should include the information or instructions prepared by subcontractors or vendors, and declared applicable to its products by the holder of the (military) TC, STC, approval of changes to type design or approval of repair design.

4.4. Statement

The data and information (including instructions) should contain a statement showing Authority approval.

5. Obligations addressed in SIM-To-Lt-035 21.A.44 (TC holder), SIM-To-Lt-035 21.A.118A (STC holder) or SIM-To-Lt-035 21.A.451 (major repair design approval holder.)

The applicant for alternative procedures to demonstrate their design capabilities should establish the necessary procedures to show to the Authority how it will fulfil the obligations required under SIM-To-Lt-035 21.A.44, SIM-To-Lt-035 21.A.118A or SIM-To-Lt-035 21.A.451, as appropriate.

6. Control of design subcontractors

The applicant for alternative procedures to demonstrate their design capabilities should establish the necessary procedures to show to the Authority how it will control design subcontractors and ensure the acceptability of the parts or appliances that are designed, or the design tasks that are performed.

GM 21.A.14(b) Alternative procedures

Design organisations approved under SIM-To-Lt-035 Section A Subpart J (“Subpart J MDOA”) is to be the normal approach for military type certification, military supplemental type certification, approval of major changes to type design or approval of major repair design, except when agreed otherwise by the Authority in accordance with SIM-To-Lt-035 21.A.14, SIM-To-Lt-035 21.A.112B and SIM-To-Lt-035 21.A.432B.

The acceptance of alternative procedures, as defined in AMC 21.A.14(b), is to be limited where the Authority finds it more appropriate for the conduct of military type certification, military supplemental type certification, approval of changes to type design, approval of repair design.

Products with simple or limited scope of design

As the complexity of a product grows, so does the size of a design organisation, along with an increasing degree of specialisation of various parts of the organisation to meet the growing demands of different disciplines. This creates complex communication relationships and workflows.

‘Simple or limited scope of design’ should therefore be understood as the opposite of ‘complex’, see also 21.A.15(b)(6) Level of involvement (LoI).

AMC 21.A.14(d) Alternative Demonstration of Capability

In specific cases, governmental organisations might be required to act as the holder of military type-certificates or restricted type-certificates. Often, these entities do not meet the qualification requirement of 21.A.14(a) by own means. In such cases, 21.A.2 is usually considered being sufficient to discharge actions and obligations to another person or organisation. However, some legal constellations still require the accountability to remain with the government owned entity, in which case the qualification requirement of 21.A.14(a) can only be met jointly. In such cases, the agreement required by 21.A.2 should also provide sufficient detail on the processes and procedures governing the co-operation, including allocation of tasks, rights, obligations, and privileges among the entities involved.

To undertake actions and obligations on behalf of the holder of a military certificate, the contracted organisation shall

- ensure the necessary access to the data related to the type design
- establish sufficient cooperation with the Authority to ensure oversight

In the case that alternative procedures (refer to SIM-To-Lt-035 21.A.14(b)) for establishing a Design Assurance System are used, such procedures shall be acceptable to the Authority in fulfilling the obligations required under SIM-To-Lt-035 21.A.44.

AMC 21.A.15(a), 21.A.93(a), 21.A.113(a), 21.A.432C(a) Form and manner

The applicant should file an application using the forms or tools specified by the Authority. In doubt, the applicant should consult with the Authority to get informed about the relevant forms, tools, and procedure.

The application should be completed in accordance with the instructions given in the forms or tools or as received from the authority and sent to the addressee nominated by the Authority by fax, email, or regular mail.

AMC 21.A.15(b) Content of the certification programme

The certification programme is a document that allows the applicant and the Authority to manage and control the evolving product type design or Operational Suitability Data, as well as the process of compliance demonstration by the applicant and its verification by the Authority when required.

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

The level of detail in the certification programme depends on the complexity of the product and its intended use.

In particular, the following information should typically be expected:

General

- Identification of the relevant personnel who make decisions affecting airworthiness, operational suitability and environmental protection, and who will interface with the Authority, unless otherwise identified to the Authority (e.g. within the approved design organization procedures).
- A project schedule including major milestones.
- Subcontracting arrangements for design, operational suitability, environmental protection and/or production as well as design organisation approval (DOA) responsibility sharing.

SIM To-Lt-035 21.A.15(b)(1) 'a detailed description of the type design, including all the configurations to be certified'

An overview of the:

- architecture, functions, systems;
- dimensions, design weights, payloads, design speeds;
- engines and power/thrust rating;
- materials and technologies;
- maximum passenger seating capacity, minimum flight and cabin/mission crew;

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- cabin configuration aspects;
- options (e.g. weight variants, power/thrust rating variants, optional avionics equipment items, auxiliary power unit (APU) choices, brake options, tire options, floats, skids);
- mission (role) configuration options (other than cabin configuration), including aircraft level provisions for external stores, pods, tanks, or other similar equipment options,
- noise/emissions level; and
- other items, if considered to be more appropriate, that address the specific aeronautical product.

SIM-To-Lt-035 21.A.15(b)(2) 'proposed operating characteristics and limitations'

- Operating speed limitations.
- Service ceiling, maximum airfield elevation.
- Cabin pressure.
- Limit load factors.
- Number of passengers, minimum crew, payload, range.
- Weight and centre-of-gravity (CG) envelope and fuel loading.
- Performance.
- Environmental envelope.
- Runway surface conditions.
- Other items, if considered to be more appropriate, that address the specific aeronautical product.

SIM-To-Lt-035 21.A.15(b)(3) 'the intended use of the product and the kind of operations for which certification is requested'

- Category A or B (relevant for EASA CS-27 and EASA CS-29), ditching, take-off and landing on water, emergency floatation equipment.
- Extended overwater operation, high-altitude operation (above 41 000 ft).
- High-airfield operation, steep approach, short take-off and landing, extended-range twin-engine operations (ETOPS), all-weather operations (AWO), visual flight rules (VFR)/instrument flight rules (IFR), reduced vertical separation minimum (RVSM), required navigation performance (RNP) type, increased bank angles, single-pilot operation, flight into known icing conditions.
- Flight in ice crystal icing.
- Engine operations in ice-forming conditions, helicopter hoist operations, operation on unpaved runway, operation on narrow runway.
- Take-off and landing in tailwind.

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- Volcanic-ash operation (limitation or operation as per EASA CS 25.1593 and EASA CS-E 1050).
- Design service goal (DSG)/limit of validity targets.
- Fatigue missions (general description of assumptions for flight durations, main phases, and parameters, as appropriate).
- Military kind of operations (e.g. Air to Air refuelling, Low Level Flight, Ship-Based-Operations and Landing, carriage or release of weapons and stores)
- Other items, if considered to be more appropriate, that address the specific aeronautical product.

SIM-To-Lt-035 21.A.15(b)(4) 'a proposal for the initial type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements.'

The proposed certification basis should include applicable airworthiness codes or standards, proposed special conditions, proposed equivalent safety findings, as well as a proposed 'elect to comply' and proposed deviations, as applicable. When the certification basis is established using EMACC, the justification for the de-selection of criteria (tailoring of EMACC) as well as justification for the mapping of specific requirements to each selected criteria shall be documented.

SIM-To-Lt-035 21.A.15(b)(5) 'a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as "compliance demonstration items" (CDIs), including references to their proposed means of compliance and related compliance documents'

See AMC 21.A.15(b)(5) for the determination of the compliance demonstration items (CDIs).

SIM-To-Lt-035 21.A.15(b)(6) on information relevant for the determination of the level of involvement (LoI)

The applicant should provide sufficient detailed information about the novelty, complexity, and criticality aspects of each proposed CDI.

It is recommended to provide this information at the level of each certification panel or discipline affected by a proposed CDI. Further interpretative material on the necessary level of details is provided in AMC 21.A.15(b)(6).

The applicant should provide detailed information about the proposed means of compliance with the applicable requirements identified under 21.A.15(b)(4). The information provided should be sufficient for the Authority to determine its (initial) LoI. This should include the following, as far as this information is available at the time of submission to Authority:

- a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC 21.A.15(b) below for the relevant codes), and the related compliance document(s);
- identification of industry standards (Society of Automotive Engineers (SAE), American Society for Testing and Materials (ASTM), European Organisation for Civil Aviation Equipment (EUROCAE), Aerospace and Defence Industries Association of Europe (ASD), etc.), methodology documents, handbooks, technical procedures, technical documents and specifications specified in the type certificate data sheet, certification memoranda, policy statements, guidance material, etc., that should be followed in the demonstration of compliance;

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- when the compliance demonstration involves testing, a description of the ground and flight test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and
- when the compliance demonstration involves analyses/calculations, a description/identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose; furthermore, the validation and verification of such tools and methods should be addressed.

For every aspect mentioned above, the applicant should clearly identify whether the demonstration of compliance involves any method (analysis or test) which is novel or unusual for the applicant. This should include any deviations from the published AMC to the relevant airworthiness codes.

Appendix to AMC 21.A.15(b) Means of compliance codes

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: Calculation/ Analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analysis
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related products(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	Note: Equipment qualification is a process that may include all previous means of compliance at equipment level.

AMC 21.A.15(b)(5) Breakdown of the certification programme into compliance demonstration items (CDIs)

1. What is a CDI?

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

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

The chosen breakdown into CDIs may affect the resulting risk classes (please refer to AMC 21.A.15(b)(6)), but should not have any effect on the compliance demonstration itself or on the Authority's LoI.

2. The grouping of compliance demonstration activities and data

The compliance demonstration activities and data grouped in a CDI may demonstrate compliance with a requirement, a group of requirements, or even a part of a requirement. In this context, 'requirement' means any element of the type-certification basis or operational suitability data (OSD) certification basis.

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

CDIs may be tailored to the scope and size of the project. On simple projects, a CDI may address all the compliance demonstration activities within a given technical area (e.g. avionics, flight, structures, hydro-mechanical systems, OSD-cabin crew data (CCD), armament etc.) or of the whole project.

A CDI should not be too large, by combining completely unrelated compliance demonstration activities or data, so that it becomes meaningless, but neither should it be so small that it might not be considered in isolation from some other related compliance demonstration activities or data.

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

Another way to meaningfully group the data is to do it at the level of the technically related compliance demonstration activities and data. This may facilitate the assessment of those activities and data against the novelty, complexity, and criticality criteria (see AMC 21.A.15(b)(6)). The resultant CDI may encompass various means of compliance.

3. Description of CDIs

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

- the scope of the CDI; and
- the information on the novelty, complexity, and criticality of the item being certified.

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

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

Additionally, it is recommended to identify the certification panel(s) or discipline(s) affected by each CDI, as this will support the determination of the novelty, complexity, and criticality, and finally identify the performance of the design organisation approval (DOA) holder.

AMC 21.A.15(b)(6) Level of involvement (LoI) in a certification project for a type certificate (TC), a major change to a TC, a supplemental type certificate (STC), a major repair design or military technical standard order (MTSO) authorisation for an auxiliary power unit (APU)

1. Definitions

Risk: the combination of the likelihood and the potential impact of a non-compliance with part of the certification basis.

Likelihood: a prediction of how likely an occurrence of non-compliance with part of the certification basis is, based on a combination of the novelty and complexity of the proposed design and its related compliance demonstration activities, as well as on the performance of the design organisation.

Criticality: a measure of the potential impact of a non-compliance with part of the certification basis on product safety or on the environment.

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

Certification panels: The Authority's certification team may be structured in sub-groups (like EASA panels) covering dedicated areas of expertise and being composed of one or more experts who are responsible for a particular technical area.

Discipline: a discipline is a technical subarea of a certification panel.

Level of involvement (LoI): the compliance demonstration activities and data that the Authority retains for verification during the certification process, as well as the depth of the verification.

2. Background

The applicant has to submit a certification programme for their compliance demonstrations in accordance with SIM-To-Lt-035 21.A.15(b). The applicant has to break down the certification programme into

meaningful groups of compliance demonstration activities and data, hereinafter referred as 'CDIs', and provide their proposal for the Authority's Lol.

The applicant should also indicate the certification panel(s) that is (are) affected by each CDI.

This AMC explains:

- a) how to propose the Authority's Lol for each CDI as per SIM-To-Lt-035 21.A.15(b)(6), 21.A.93(b)(3)(iii), 21.A.432C(b)(6) as well as 21.A.113(b); and
- b) how the Authority will determine its Lol on the basis of the criteria established in SIM-To-Lt-035 21.B.100.

The Authority will review the proposal and determine its Lol. Both parties, in mutual trust, should ensure that the certification project is not delayed through the Lol proposal and determination.

Additionally, in accordance with SIM-To-Lt-035 21.A.20, the applicant has the obligation to update the certification programme, as necessary, during the certification process, and report to the Authority any difficulty or event encountered during the compliance demonstration process which may require a change to the Lol that was previously notified to the applicant.

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

In accordance with SIM-To-Lt-035 21.A.33, 21.A.447 and 21.A.615, irrespective of the Lol, the Authority has the right to review any data and information related to compliance demonstration.

Note: This AMC should not be considered to be interpretative material for the classification of changes or repairs.

3. Principles and generic criteria for the Lol determination

The Authority determines its Lol based on the applicant's proposal in view of the risk (the combination of the likelihood of an unidentified non-compliance and its potential impact). This is performed after proper familiarisation with the certification project in three steps:

- Step 1: identification of the likelihood of an unidentified non-compliance,
- Step 2: identification of the risk class, and
- Step 3: determination of the Authority's Lol.

This AMC contains criteria, common to all certification panels, for the determination of:

- any novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
- the complexity of the design and/or compliance demonstration;
- the performance and experience of the design organisation of the applicant in the domain concerned;

- the criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and
- the data and activities to be retained by the Authority.

Note: EASA provides additional information on the criteria for the determination of the Lol in product certification, e.g. as contained in EASA Certification Memorandum (CM) 21.A/21.B-001, which may be used for reference but should not be considered to be AMC.

3.1. Lol determination at CDI level

The determination of the Authority's Lol is performed at the level of the CDI (please refer to AMC 21.A.15(b)(5)).

The applicant should demonstrate that all affected elements of the type-certification basis of the OSD certification basis, and of the environmental protection requirements, the corresponding means and methods of compliance, as well as the corresponding certification activities and data, are fully covered by the proposed CDIs. If the provided data does not clearly show that this is the case, the applicant should clearly state to the Authority that all the above-mentioned elements are fully covered.

Note: There could be different ways to 'clearly show' that all the elements of the certification basis are included in at least one CDI. For instance, this could be achieved by means of a 'CDI reference' column added in the table that lists all the elements of the certification basis.

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

3.2.1. Principle

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

- novelty,
- complexity, and
- the performance of the design organisation.

3.2.2. Novelty

For the purpose of risk class determination, the following simplification has been made: a CDI may be either novel or non-novel.

Whether or not a CDI is novel is based on the extent to which the respective elements of the certification project, as well as the related requirement or means of compliance, are new/novel to either the industry as a whole, or to the applicant, including their subcontractors, or from a certification panel perspective.

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

When an applicant utilises a type of technology for the first time, or when that applicant is relatively unfamiliar with the technology, this technology is considered to be 'novel', even if other applicants may be already familiar with it. This also means that a type of technology may no longer be novel for one applicant, while it may still be novel for other applicants.

The following list includes some examples:

- new materials or combinations of materials;
- a new application of materials or combinations of materials;
- new manufacturing processes;
- a new or unusual aircraft configuration and/or system architecture;
- a novel reconfiguration of systems;
- a new interface or interaction with other parts or systems;
- the unusual location of a part or a system, or an unusual construction;
- a new or unusual use;
- new functions;
- new kinds of operations;
- the potential for new failure modes;
- the introduction of a new threat (e.g. new threats regarding fire, fuel, hydrogen, energy storage devices, etc.) or a new prevention/detection/mitigation method;
- new maintenance techniques;
- novel operating conditions or limitations;
- a new human-machine interface (HMI); or
- new flight¹ or cabin crew tasks.

Another consideration is the extent to which the requirements, means of compliance or guidance have changed or need to be adapted due to particular novel features of the design. The following list includes some examples:

- recently issued or amended airworthiness codes with which the applicant has little or no experience;
- new or adapted special conditions;
- new or adapted equivalent safety findings;

¹ Flight crew may also consist of additional crew members, such as load master or jump master, hoist operator etc., as applicable.

- new or adapted deviations;
- new or adapted guidance or interpretative material;
- new or adapted means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices), e.g. the replacing of tests by simulation, numerical models or analytical methods;
- the use of new or adapted industry standards or in-house methods, as well as the Authority's familiarity with these standards and methods;
- a change in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs; or
- novelty in the interpretation of the results of the compliance demonstration, e.g. due to in-service occurrences (compliance demonstration results are interpreted differently from the past).

Additional new guidance/interpretative material, e.g. in the form of new EASA certification memoranda (EASA CM), may be considered for the determination of novelty if its incorrect application/use may lead to an unidentified non-compliance. In the context of novelty, the time between the last similar project and the current project of the applicant should also be considered.

Regardless of the extent of an organisation's previous experience in similar projects, a CDI may be classified as novel if there are specific discontinuities in the process for transferring information and know-how within the organisation.

3.2.3. Complexity

For the purpose of risk class determination, the following simplification has been made: a CDI may be either complex or non-complex. For each CDI, the determination of whether it is complex or not may vary based on factors such as the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), interpretation of the results of the compliance demonstration, interfaces with other technical disciplines/CDIs, and the requirements. The compliance demonstration may be considered to be 'complex' for a complex (or highly integrated) system, which typically requires more effort from the applicant. The following list includes some examples:

- Compliance demonstration in which challenging assessments are required, e.g.:
 - for requirements of a subjective nature, i.e. they require a qualitative assessment, and do not have an explicit description of the means of compliance with that requirement, or the means of compliance are not a common and accepted practice; this is typically the case where the requirement uses terms such as 'subjective', 'qualitative', 'assessment' or 'suitable'/'unsuitable'

- in contrast, engineering judgement for a very simple compliance demonstration should not be classified as ‘complex’;
 - a test for which extensive interpretation of the results may be anticipated;
 - an analysis that is sensitive to assumptions and could potentially result in a small margin of safety;
 - the classification of structures, depending on the conservatism of the method;
 - an advanced analysis of dynamic behaviour;
 - a multidisciplinary compliance demonstration in which several panels are involved and interface areas need to be managed (e.g. sustained engine imbalance, extended-range twin-engine operation performance standards (ETOPS), 2X.1309 assessment, flight in known icing conditions, full authority digital engine control (FADEC)-controlled engines, etc.);
 - when the representativeness of a test specimen is questionable, e.g. due to its complexity;
- the introduction of complex work-sharing scheme with system or equipment suppliers.

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

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

3.2.4. Performance of the design organisation

The assessment of the level of performance of the design organisation takes into account the applicant’s experience with the applicable certification processes, including their performance on previous projects and their degree of familiarity with the applicable certification requirements.

For approved design organisations, the Authority uses relevant data to consider the design organisation’s expected performance at an organisational, panel or discipline level, depending on the availability of data¹.

¹ The ultimate objective is to define the organisation’s performance at the discipline level.

This data stems from design organisation audits, the applicant's measured level of performance on previous projects, and their performance during the familiarisation phase. The Authority shares the data with the respective design organisation in an appropriate manner.

For each CDI proposed by the applicant, the DOA holder's performance associated with the affected disciplines or panels is to be considered.

If one CDI affects more panels or disciplines than the others, a conservative approach should be followed in selecting the lower performance level. As an alternative, that CDI may be assessed separately for each affected certification panel or discipline.

If, for a well-established organisation, there is no shared performance data available at the panel level, it may be acceptable to propose the overall DOA holder's performance. If the organisation or its scope are fundamentally new, the 'unknown' level of performance should be conservatively proposed by the applicant.

The determination of the performance of the design organisation may also take into consideration information that is more specific or more recent than the information on the DOA holder's dashboard, e.g. experience gained during technical familiarisation with the current certification project, the performance of compliance verification engineers and of the affected technical areas, as well as the performance of the design organisation in overseeing subcontractors and suppliers.

The performance of some applicants' organisations is not known if:

- the Authority has agreed in accordance with SIM-To-Lt-035 21.A.14(b) that the applicants may use procedures that set out specific design practices, as an alternative means to demonstrate their capability (excluding military technical standard order (MTSO) applicants for other than APU.

In these cases, the assumed level of performance is 'unknown'.

Exceptionally, the Authority may consider a higher level of performance for a specific CDI if that is proposed and properly justified by the applicant.

The following list includes some examples:

- a CDI with which the Authority is fully familiar and satisfied (from previous similar projects) regarding the demonstration of compliance proposed by the applicant;
- if the applicant fully delegates the demonstration of compliance to a supplier that holds a DOA, the performance level of the supplier may be proposed.

3.2.5. Likelihood of an unidentified non-compliance

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

The likelihood of an unidentified non-compliance should not be confused with the likelihood of occurrence of an unsafe condition as per AMC 21.A.3B(b). In fact, that AMC provides the

Authority’s confidence level that the design organisation addresses all the details of the certification basis for the CDI concerned, and that a non-compliance will not occur.

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

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

3.3. Criticality

The second step that is necessary to determine the risk class is the assessment of the potential impact of a non-compliance on part of the certification basis regarding the airworthiness or the environmental protection of the product. For the purpose of risk class determination, the following simplification has been made: the impact of a non-compliance can be either critical or non-critical.

Some of the guidance below has been derived from GM 21.A.91, not due to a major/minor change classification, but because the same considerations may be applied to determine the effect of a non-compliance on the airworthiness or environmental protection at the CDI level. It is therefore normal that some of the CDIs of a major change that consists of several CDIs may be critical, and others may be non-critical.

The potential impact of a non-compliance within a CDI should be classified as critical if, for example:

- a function, component or system is introduced or affected where the failure of that function, component or system may contribute to a failure condition that is classified as hazardous or catastrophic at the aircraft level, for instance for ‘equipment, systems and installations’, e.g. where applicable as defined in EASA CS.2X.1309;
- a CDI has an appreciable effect on the human–machine interface (HMI) (displays, approved procedures, controls or alerts);
- airworthiness limitations or operating limitations are established or potentially affected;
- a CDI is affected by an existing airworthiness directive (AD), or affected by an occurrence (or occurrences) potentially subject to an AD, a known in-service issue or by a safety information bulletin (SIB); or
- a CDI affects parts that are classified as critical, e.g. as per EASA CS 27.602/29.602, CS-E 515, or that have a hazardous or catastrophic failure consequence (e.g. a principal structural element as per EASA CS 25.571).

If the classification of the potential impact of a non-compliance within a CDI as critical is based on the criterion that the CDI is affected by an AD, then the impact of a non-compliance within that CDI may be reclassified by the Authority as non-critical due to the involvement of the Authority in the continued-airworthiness process.

During the early stages of a project, the criticality in terms of the potential safety consequence of a failure may not always be known, but should be conservatively estimated and the Lol should be subsequently re-evaluated, if appropriate.

3.4. Method for the determination of risk classes

The risk is determined as a combination of the potential impact of an unidentified non-compliance with part of the certification basis (vertical axis) and of the likelihood of the unidentified non-compliance (horizontal axis) using the following matrix. As a consequence, four qualitative risk classes are established at the CDI level.

Step 2 — Risk classes				
Likelihood (see Section 3.2.5)	Very low	Low	Medium	High
Criticality (see Section 3.3)				
Non-critical	Class 1	Class 1	Class 2	Class 3
Critical	Class 1	Class 2	Class 3	Class 4

The various inputs and the resulting risk class determination are of a continuous nature, rather than consisting of discrete steps. The selected risk class provides the order of magnitude of the Authority’s involvement and is used as a qualitative indicator for the determination of the Authority’s involvement described in Section 3.5 below.

Under specific circumstances, the risk class that is determined on the basis of the above criteria may be reduced or increased on the basis of justified and recorded arguments. For a reused and well-proven item of compliance demonstration for which:

- the CDI is independent of the affected product type or model; and
- the design, operation, qualification, and installation of the product are basically the same; and
- the certification process is identical to one that was used in a modification already approved by the Authority,

the CDI may be accepted as being similar, resulting in reduced Lol, as the likelihood of an unidentified non-compliance is low. Furthermore, when an identical CDI is reused for the compliance demonstration in a new project, there is no involvement in the compliance demonstration verification, as the likelihood of an unidentified non-compliance is very low.

3.5. Determination of the Authority’s Lol

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

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

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

It is recommended that an Lol should be proposed for each of the technical areas (see certification panels and disciplines) involved. Depending on the risk classes determined in Section 3.4 above, the Authority's Lol in:

- a) compliance demonstration verification data; and
- b) compliance demonstration activities (witnessing of tests, audits, etc.),

may be as follows:

- risk Class 1: there is no Authority involvement in verifying the compliance data/activities performed by the applicant to demonstrate compliance at the CDI level;
- risk Class 2: the Authority's Lol is typically limited to the review of a small portion of the compliance data; there is either no participation in the compliance activities, or the Authority participates in a small number of compliance activities (witnessing of tests, audits, etc.);
- risk Class 3: in addition to the Lol defined for Class 2, the Authority's Lol typically comprises the review of a large amount of compliance data, as well as the participation in some compliance activities (witnessing of tests, audits, etc.); and
- risk Class 4: in addition to the Lol defined for Class 3, the Authority's Lol typically comprises the review of a large amount of compliance data, the detailed interpretation of test results, and the participation in a large number of compliance activities (witnessing of tests, audits, etc.).

By default, the following activities require the Authority's involvement in all cases:

- initial issues of, and changes to, a flight manual (for those parts that require approval by the Authority and that do not fall under the DOA holder's privilege);
- classification of failure cases that affect the handling qualities and performance, when:
 - performed through test (in flight or in a simulator); and

- initial issues of, and non-editorial changes to, airworthiness limitations.

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

4. Documentation of the Lol

The Lol proposal in the certification programme should include the applicant's proposal regarding the compliance demonstration verification activities and data that would be retained by the Authority, as well as the data on which the Lol proposal has been based. For this purpose, the applicant should appropriately document the analysis per CDI, considering the above criteria. In cases where the rationale for the assessment is obvious, it is considered to be sufficient for the applicant to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

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

5. Sampling during surveillance of the DOA holder

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

GM 21.A.15(c) Updates to the certification programme

SIM-To-Lt-035 21.A.15(b) recognises that the initial submission of the certification programme may not be fully complete, e.g. due to schedule constraints of the design, analysis and testing activities.

Furthermore, even if the initial submission of the certification programme is complete, it may be necessary to amend it throughout the duration of the project.

The certification programme should be updated and resubmitted to the Authority. In particular, updates to the following elements should be provided:

- any complementary information that was not included in the initial submission of the certification programme;
- any change in the intended use or kind of operations of the product itself, or of the aircraft on which the product is installed;
- a change in the key characteristics of the product such as but not limited to any declared limits that are intended to be recorded in the type certificate data sheet (TCDS);

- any change in the product design or its characteristics that may affect the criteria used to assess the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data (OSD) certification basis or the environmental protection requirements, including the potential impact of that non-compliance on product safety or environmental protection, as defined in SIM-To-Lt-035 21.A.15(b)(6);

Note: An update of the DOA dashboard after the first issuance of the certification programme only needs to be considered if there is a significant change in the performance.

- any change to the initial type-certification basis, OSD certification basis or environmental protection requirements, as applicable to the product, regardless whether the change is initiated by the Authority or by the applicant;
- any change in the breakdown of the certification programme into compliance demonstration items (CDIs) or in the content of those CDIs;
- any change in the proposed means of compliance, including its/their methodology;
- any change in the structure of compliance documents that may affect the determination of Authority's level of involvement (LoI);
- any relevant change to the design organisation approval (DOA) holder's personnel (and design organisation (DO) suppliers) who are involved in the project; and
- any changes to the schedule that impact on the LoI of the Authority.

Following each update to the certification programme as submitted by the applicant, the Authority may update the determination of its LoI.

GM 21.A.15(d) Operational Suitability Data (OSD)

Based on the OSD-Elements defined in SIM-To-Lt-031 21.1(k), any extension to an application for a TC or RTC should cover the following areas, also referred to as OSD-constituents, as applicable:

1. the minimum syllabus of pilot type rating training, including determination of type rating;
2. the definition of scope of the aircraft validation source data to support the objective qualification of simulator(s) associated to the pilot type rating training, or provisional data to support their interim qualification;
3. the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;
4. determination of type or variant for (cabin and mission) crew and type specific data for (cabin and mission) crew;
5. the master minimum equipment list; and
6. other type-related operational suitability elements.

General:

In the application-extension for approval of operational suitability data, the TC applicant may apply for the approval of different types of operations. If the aircraft is certificated for certain types of operations (e.g. ETOPS, RNP, LVO, LLF, AAR), the impact on the OSD constituents should be addressed.

The five defined OSD constituents are listed in (1) to (5) above. They may not be all applicable to all aircraft types. The content of each of the OSD constituents is defined in the applicable airworthiness codes or standards, such as EASA certification specifications and will be approved under a type certificate (TC), supplemental type certificate (STC) or change to those certificates.

Regarding the determination of type or variant (4):

The criteria for the determination whether an aircraft with a new type certificate (TC) is considered a new type or is a variant with reference to another aircraft type from the same TC holder for the purpose of the specific OSD constituent are provided in applicable airworthiness codes or standards for OSD, such as EASA certification specifications for maintenance certifying staff data, flight crew data and cabin crew data.

Regarding other type-related operational suitability elements (6)

In addition to the five defined OSD constituents, there may be other data which could qualify as OSD when it is relevant for the operational suitability of the aircraft type, is not included in the type design and is specific to that aircraft type.

The term 'element' as used in this GM carries its normal dictionary meaning, i.e. part, portion, component, etc.

In order for this 'element' to qualify as 'other type-related operational suitability element', the following conditions should apply:

- it concerns data (not the approval of equipment);
- the data is type specific;
- the data is not already part of the 'classic' part of the type certificate (TC) (such as Airworthiness Limitations Section (ALS), aircraft flight manual (AFM), etc.);
- the data is relevant for the safe operation of the aircraft type; and
- conditions/criteria for the approval of the data can be established.

If data can be included in one of the five defined OSD constituents, it does not qualify as an additional operational suitability element. For example, the pilot training necessary to introduce an electronic flight bag (EFB) can be included in the OSD constituent flight crew data (FCD), and is not considered an additional operational suitability element.

GM 21.A.15(e) and (f) Period of validity for the application for a type certificate (TC) or restricted type certificate (RTC)

SIM-To-Lt-035 21.A.15(e) establishes a maximum period of validity for an application for a TC or an RTC. During this period, the type-certification basis, operational suitability data (OSD) certification basis, and the environmental protection requirements (hereinafter referred to as the 'certification basis'), established and notified by the remain effective. However, the period of validity of the certification basis is limited so that the standards notified as part of the certification basis at the time of application do not become outdated.

For various reasons (e.g. development, business, commercial, etc.), the applicant may not be able to complete the certification within the established time limit. In this case, the applicant can apply for an extension of the initial application (see SIM-To-Lt-035 21.A.15(f)).

In this case, the applicant proposes a 'new target date' to the Authority for the issuance of the certificate. Respecting the time limits established under 21.A.15(e), the Authority may then use that date to notify airworthiness codes and standards that will become the reference for a revised certification basis.

GM 21.A.20 Compliance demonstration process

SIM-To-Lt-035 21.A.20 applies to the compliance demonstration process for a type certificate (TC) (or a restricted type certificate (RTC)) and, by cross references to SIM-To-Lt-035 Subpart D and E, to compliance demonstration processes for major changes to a TC (see SIM-To-Lt-035 21.A.97(b)(3)) and an supplemental type certificate (STC) (see SIM-To-Lt-035 21.A.115(b)(4)).

Applicants for a TC (or an RTC) should apply SIM-To-Lt-035 21.A.20 in full. Applicants for a major change to a TC (or an STC) are required (see SIM-To-Lt-035 21.A.97(b)(3) and 21.A.115(b)(4)) to apply SIM-To-Lt-035 21.A.20 as applicable to the change.

'As applicable to the change' means that:

- the certification programme to be followed is the one prepared for the major change or STC in accordance with SIM-To-Lt-035 21.A.93, as accepted by the Authority; and
- the certification basis (consisting of the type-certification basis, operational suitability data (OSD) certification basis, and the applicable environmental protection requirements) is the one established by the Authority in accordance with SIM-To-Lt-035 21.A.101 and notified to the applicant (for a major change to a TC or for an STC).

SIM-To-Lt-035 21.A.20 also applies to major changes to a TC or an STC approved by design organisation approval (DOA) holders under their privilege as per SIM-To-Lt-035 21.A.263(c)(8) or (9) (see also SIM-To-Lt-035 21.A.97(b)(3) and 21.A.115(b)(4)). As in this case there is no application and no involvement of the Authority, SIM-To-Lt-035 21.A.20 should be applied with the following adaptations:

- the certification programme to be followed, including the certification basis and the detailed means of compliance, should be almost identical to the one accepted by the Authority for a major change

or an STC when approved for the scope of the privilege as per SIM-To-Lt-035 21.A.263(c)(8) or (9); it may differ in some aspects (e.g. the detailed description of the changes), but it should be shown to remain in the frame of the corresponding justification document; and

- the means by which such compliance has been demonstrated (see SIM-To-Lt-035 21.A.20(a)) and the final declaration of compliance (see SIM-To-Lt-035 21.A.20(e)) should be kept on record and submitted to the Authority only if requested during its DOA continued surveillance process.

GM 21.A.20(b) Reporting on the compliance demonstration process

The applicant should report to the Authority any unexpected difficulty or event encountered during the compliance demonstration that invalidates or appreciably affects the assumptions previously made, for example:

- an increase in the severity of the consequences of a certain condition (e.g. failure mode) of the product;
- significantly reduced margin(s) for the 'pass-fail' criteria of the compliance demonstration;
- changes to the test sequences and conditions that are not in line with the certification specifications or guidance;
- an unusual interpretation of the results of the compliance demonstration; and
- any significant failure or finding resulting from the tests performed as per SIM-To-Lt-035 21.A.33 or 21.A.35.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact on the certification programme and, if necessary, amend it as per SIM-To-Lt-035 21.A.15(c).

AMC 21.A.20(c) Compliance documentation

1. Compliance documentation comprises of one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analysis etc. and provides a record of the means by which compliance with the applicable type certification basis, the operational suitability data certification basis and environmental protection requirements is demonstrated.
2. Each compliance document should normally contain:
 - the reference of the elements of airworthiness codes or standards prescribed in the certification basis, special conditions or environmental protection requirements addressed by the document;
 - substantiation data demonstrating compliance (except test or inspection programmes/plans);
 - a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

- the appropriate authorised signature.
3. Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with SIM-To-Lt-035 21.A.55.

GM 21.A.20(d) Final statement

All compliance demonstrations in accordance with the certification programme, including all the inspections and tests in accordance with SIM-To-Lt-035 21.A.33 and all flight tests in accordance with SIM-To-Lt-035 21.A.35, should be completed before issuance of the final statement of compliance required by SIM-To-Lt-035 21.A.20(d).

If so agreed by the Authority, some compliance documentation may be produced after issuance of the final statement of compliance required by SIM-To-Lt-035 21.A.20(d).

‘No feature or characteristics’ in SIM-To-Lt-035 21.A.20(d)(2) means the following: while every effort is made to address in the applicable certification basis all the risks to product safety or to the environment that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant has to declare that they have not identified any such features or characteristics.

SIM-To-Lt-035 21.A.20 also applies by reference to minor changes, in which case the risk to product safety or to environmental protection is quite low. Nevertheless, minor changes should not be approved if either the applicant/design organisation approval (DOA) holder approving minor changes under their privileges, or the Authority, is aware of a feature or characteristic that may make the product unsafe for the uses for which certification is requested.

GM 21.A.21(a)(3)(A) Clarification of the term ‘determined’

A type certificate ‘determined’ in accordance with SIM-To-Lt-035 means a type certificate, or equivalent document,

- issued by the Authority under acceptable ‘legacy’ safety system;
- issued by another State of Design under an acceptable safety system in which such products have been certificated based on acceptable airworthiness codes and standards;

allowing for the issuance of a certificate of airworthiness under that safety system.

‘Acceptable’ means that national regulations provide for the acceptance of products that have not been certified under SIM-To-Lt-035 and when the Authority has determined that the airworthiness codes and standards or service experience or the applicable safety system provide for a level of safety equivalent to that required by the SIM-To-Lt-035.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c) Approval of operational suitability data (OSD)

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by SIM-To-Lt-035 21.A.21(b), 21.A.95(c), 21.A.97(c) and 21.A.115(c) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is to be used by a training organisation for the purpose of obtaining a licence, rating, or attestation, or by an operating organisation required to use such data. This is normally done before the entry into service of the first aircraft by the operating organisation but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in SIM-To-Lt-035 21.A.97(c) and 21.A.115(c) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

AMC 21.A.33 Inspections and tests

Use of the term ‘applicant’: SIM-To-Lt-035 21.A.33 is applicable to type certification, major changes, major repairs and supplemental type certificates (STCs), and through reference in SIM-To-Lt-035 21.A.604 to (M)TSO for auxiliary power units (APUs). Despite using the word ‘applicant’, it is also applicable to major changes, major repairs and STCs approved under DOA privileges (see SIM-To-Lt-035 21.A.263(c)(5), (8) or (9)).

Proposed type design: this term defines the type design (or the portion of the type design) as it is determined at the time when the inspection or test is undertaken.

Statement of conformity: for each certification inspection or test, the statement of conformity issued in accordance with SIM-To-Lt-035 21.A.33(c) must address the conformity of the test specimen (see SIM-To-Lt-035 21.A.33(b)(1)) as well as of the test equipment and measuring equipment (see SIM-To-Lt-035 21.A.33(b)(2)).

Conformity of the test specimen: the statement of conformity required by SIM-To-Lt-035 21.A.33(c) is intended to ensure that the manufactured test specimen adequately represents the proposed type design. Possible types of non-conformity may be the following:

- Non-conformity between the design of the test specimen and the proposed type design at the time of the test. These are typically identified in the early stage of the test planning, and should be

addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

- Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

Type certification is typically an iterative process in which the design is under continuous evolution. If the type design evolves after the time of the inspection or test, then the final type design should be checked against the proposed type design (as it was at the time of the inspection or test), and the differences (if any) should be analysed to ensure that the inspection or test results are representative of the final configuration. However, such changes made to the type design may lead to the invalidation of the inspection or test results and a need to repeat the inspection or test. It is recommended that the design organisation should have a thorough configuration management process to track the evolving type design.

Conformity of test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

- definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and
- definition of the measuring equipment:
- type/model of sensors, together with their technical characteristics;
- position and orientation of exciters and sensors; and
- electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through certification test plans and supporting documentation, according to the design assurance system, if applicable. The test plan should also include the following elements:

- the test cases, methods, and procedures for test execution;
- the pass–fail criteria; and
- pre-, during- and post-test inspections.

The statement of conformity of SIM-To-Lt-035 21.A.33(c) should confirm that the test and measuring equipment conform to its purpose, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This can be done either in the statement of conformity or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term ‘adequate’: the test specimen, as well as the test and measuring equipment, are considered to be ‘adequate’ as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up does not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or masking any potential failure mode or behaviour).

Changes that affect the validity of the statement of conformity (see SIM-To-Lt-035 21.A.33(e)(2)): if changes need to be introduced to the test specimen or to the test and measurement equipment after the statement of conformity is issued (and before the test is undertaken), the statement of conformity must be updated. The updated statement of conformity must be made available to the Authority before the test if the Authority has informed the applicant that it will witness or carry out the tests.

Development versus certification tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for certification (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of SIM-To-Lt-035 21.A.33.

Any planned test event should be classified in advance as either a development test or a certification test. Tests that support the compliance demonstration should be classified as certification tests.

Nevertheless, if agreed by the Authority, it is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a certification test as long as it meets the requirements of SIM-To-Lt-035 21.A.33. For this reason, it is important to keep the configuration of such tests under the control of the design organisation.

In addition to this, the level of involvement (LoI) notified by the Authority, should be taken into account: if the Authority has determined that it will witness or conduct a certain test, this test may need to be repeated so that the Authority can witness or conduct the test.

If the test specimen used for a certification test has already undergone a series of previous tests that may affect or ultimately invalidate its acceptance as required by SIM-To-Lt-035 21.A.33(b), this aspect should be considered when issuing the statement of conformity required by SIM-To-Lt-035 21.A.33(c), and specific analyses or inspections may be required to support such a statement.

Because of the above aspects, applicants are advised to inform the Authority if they intend to conduct a campaign of development tests that may eventually be used as certification tests.

Availability of compliance data (see SIM-To-Lt-035 21.A.33(d)(1)): data and information requested from the applicant for review should be made available in a reliable and efficient way that is agreed between the applicant and the Authority.

SIM-To-Lt-035 21.A.33(d)(1) refers to any data or information related to compliance data; the scope of that requirement is therefore not limited to inspections and tests. In particular, SIM-To-Lt-035 21.A.33(d)(1) is not limited to data and information related to compliance demonstration items (CDIs) in which the Authority is involved.

GM 21.A.33(d) Inspections and Tests

The applicant should inform the Authority sufficiently in advance about the execution of inspections and tests that are used for compliance demonstration purposes unless the Authority has explicitly excluded these inspections and tests from its involvement.

Additionally, the applicant may propose to the Authority to perform or witness flight or other tests of particular aspects of the product during its development and before the type design is fully defined. However, before the Authority performs or witnesses any flight or other test, the applicant should ensure by appropriate means that the design is mature enough so that no features of the product preclude the safe conduct of the evaluation requested.

The Authority may require any such tests to be repeated once the type design is fully defined to ensure that subsequent changes have not adversely affected the conclusions from any earlier evaluation.

A statement of conformity as per SIM-To-Lt-035 21.A.33(c) is also required for the above tests.

GM 21.A.35 Flight Tests

Detailed material on flight testing is included in the applicable airworthiness codes and associated guidance material.

GM 21.A.35(b)(2) Objective and Content of Function and Reliability Testing

1. OBJECTIVE

The objective of this testing is to expose the aircraft to the variety of uses, including training, that are likely to occur when in routine service to provide an assurance that it performs its intended functions to the standard required for certification and should continue to do so in service.

2. CONTENT OF FUNCTION AND RELIABILITY TESTING

The testing should cover both routine operations and some simulation of abnormal conditions. The details of the programme should be agreed with the Authority prior to commencement of testing.

It may be possible to combine this testing with any required to demonstrate compliance with the applicable type-certification basis or certification basis for operational suitability data. This will be agreed on a case-by-case basis with the Authority.

Where possible, testing conditions should be defined with the co-operation of an operating organisation.

A substantial proportion of the flying should be on a single aircraft. The flying should be carried out to a continuous schedule on an aircraft that is very close to the final type design, operated as though it were in service and should include a range of representative ambient operating conditions and airfields.

GM 21.A.35(f)(1) Flying Time for Function and Reliability Testing

All flying carried out with engines and associated systems not significantly different from the final type certificate standard may count towards the 300 hours airframe flight time required by SIM-To-Lt-035 21.A.35(f)(1). At least 150 of the 300 flying hours is to be conducted on a dedicated production configured aircraft. The requirement for 300 hours relevant flight time whenever a new turbine engine is incorporated applies regardless of whether the airframe/engine combination is subject to a new type certificate or is to be certificated as a change or supplement to an existing type certificate.

GM 21.A.35(f)(2) Flying Time for Function and Reliability Testing

All flying carried out on an aircraft not significantly different from the final type design may count towards the 150 hours airframe flight time required by SIM-To-Lt-035 21.A.35(f)(2).

AMC 21.A.44(a) Continue to meet the qualification requirements for eligibility

To ensure that the holder of a type certificate or restricted type certificate remains capable to undertake the required actions and obligations, SIM-To-Lt-035 21.A.44 (a) also requires the holder to continue to meet the requirements of SIM-To-Lt-035 21.A.14.

To comply with this requirement, the holder of a type-certificate or restricted type-certificate shall inform the Authority without undue delay of any circumstances that significantly affect the ability of the holder to effectively discharge its obligations.

If the actions and obligations of the holder of a type-certificate or restricted type-certificate are undertaken on its behalf by another person or organisation in accordance with SIM-To-Lt-035 21.A.2, these circumstances shall include any changes to the relevant arrangements with the other organisation or findings regarding its safety performance.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

- a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.

- b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

SUBPART D - CHANGES TO MILITARY TYPE-CERTIFICATES AND MILITARY RESTRICTED TYPE-CERTIFICATES

GM 21.A.90A Scope

The term 'changes to the type certificate' is consistently used in SIM-To-Lt-035 Subpart D and E, as well as in the related AMC and GM. This term does not refer to changing the document that reflects the type certificate (TC) but to the elements of the TC as defined in SIM-To-Lt-035 21.A.41. It means that the processes for the approval of changes, as described in the said two Subparts, do not only apply to changes to the type design, but may also apply to changes to:

- the operating limitations;
- the type certificate data sheet (TCDS) for airworthiness and emissions;
- the applicable type-certification basis and environmental protection requirements with which the applicant has to demonstrate compliance;
- any other conditions or limitations prescribed for the product by the Authority;
- the applicable operational suitability data (OSD) certification basis;
- the OSD; and
- the TCDS for noise.

NOTE: OSD is only applicable to aircraft TCs and not to engine or propeller TCs. Therefore, changes to OSD are only relevant for changes to aircraft TCs.

GM 21.A.91 Classification of changes to a type certificate (TC)

1. Purpose of classification

Classification of changes to a type certificate (TC) into MAJOR or MINOR is to determine the approval route to be followed in SIM-To-Lt-035 Subpart D, i.e., either SIM-To-Lt-035 21.A.95 or SIM-To-Lt-035 21.A.97, or alternatively whether application and approval has to be made in accordance with SIM-To-Lt-035 Subpart E.

2. Introduction

2.1. SIM-To-Lt-035 21.A.91 proposes criteria for the classification of changes to a TC as minor and major.

- a) This GM is intended to provide guidance on the phrase 'appreciable effect' affecting the airworthiness of the product or affecting any of the other characteristics mentioned in SIM-To-Lt-035 21.A.91, where 'airworthiness' is interpreted in the context of a product in conformity with type design and in condition for safe operation. It provides complementary guidelines to assess a change to the TC in order to fulfil the requirements of SIM-To-Lt-035 21.A.91 and 21.A.117 where classification is the first step of a procedure.

Note: For classification of Repairs see GM 21.A.435(a).

- b) Although this GM provides guidance on the classification of major changes, as opposed to minor changes as defined in SIM-To-Lt-035 21.A.91, the GM and SIM-To-Lt-035 21.A.91 are deemed entirely compatible.

- 2.2. For an MTSO authorisation, SIM-To-Lt-035 21.A.611 gives specific additional requirements for design changes to MTSO articles.

For APU, this GM should be used.

3. Assessment of a change for classification

3.1. Changes to the TC

SIM-To-Lt-035 21.A.91 addresses all changes to any of the aspects of a TC. This includes changes to a type design, as defined in SIM-To-Lt-035 21.A.31, as well as to the other constituents of a TC, as defined in SIM-To-Lt-035 21.A.41.

3.2. Reserved

3.3. Classification Process (see attached diagram in Appendix A)

SIM-To-Lt-035 21.A.91 requires all changes to be classified as either major or minor, using the criteria of SIM-To-Lt-035 21.A.91 and the complementary guidance of paragraph 3.4.

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

When the strict application of the paragraph 3.4 criteria results in a major classification, the applicant may request re-classification, if justified, and the Authority could take the responsibility in re-classifying the change.

A simple design change planned to be mandated by an airworthiness directive may be re-classified minor due to the involvement of the Authority in the continued airworthiness process when it is agreed between the Authority and the DOA holder.

Reasons for a classification decision are to be recorded.

3.4. Complementary guidance for classification of changes.

A change to the TC is judged to have an 'appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, exhaust emission, operational suitability or other characteristics affecting the airworthiness, environmental protection or operational

suitability of the product' and, therefore, should be classified as major, in particular but not only, when one or more of the following conditions are met:

- a) where the change requires an adjustment of the type certification basis or the OSD certification basis (special conditions or equivalent safety findings) other than elect to comply with later airworthiness codes or requirements;
- b) where the applicant proposes a new interpretation of the airworthiness requirements used for the type certification basis that has not been published as AMC material or otherwise agreed with the Authority;
- c) where the demonstration of compliance uses methods that have not been previously accepted as appropriate for the nature of the change;
- d) where the extent of new substantiation data necessary to comply with the applicable airworthiness requirements and the degree to which the original substantiation data has to be re-assessed and re-evaluated is considerable;
- e) where the change alters the airworthiness limitations or the operating limitations;
- f) where the change is made mandatory by an airworthiness directive or the change is the terminating action of an airworthiness directive (ref. SIM-To-Lt-035 21.A.3B), see Note 1;
- g) where the design change introduces or affects functions where the failure effect is classified catastrophic or hazardous.

Note 1: A change previously classified as minor and approved prior to the airworthiness directive issuance decision needs no re-classification. However, the Authority retains the right to review the change and re-classify/re-approve if found necessary.

Note 2: The conditions listed in (a) to (g) above are an explanation of the criteria noted in SIM-To-Lt-035 21.A.91.

3.5. Complementary guidance on the classification of changes to OSD

This paragraph provides firstly general guidance on minor OSD change classification, and secondly additional guidance specific to each OSD constituent.

Changes to OSD are considered minor when they:

- incorporate optional information (representing improvements/enhancements);
- provide clarifications, interpretations, definitions or advisory text; or
- do not change the intent of the OSD document, e.g. changes to:
 - titles, numbering, formatting, applicability;
 - order, sequence, pagination; or
 - sketches, figures, units of measurement, and correction of editorial mistakes such as:

- spelling; or
- reference numbers.

Given the structure and individual intent of the separate OSD constituents, the interpretation of ‘appreciable’ is also affected by the specific nature of the applicable airworthiness codes or standards (e.g. EASA certification specifications (CS)) for that constituent. Therefore, specific guidance on each of the OSD constituents should be consulted. The guidance listed in (a) to (e) below assumes that EASA CS-MMEL, CS-FCD, CS-CCD, CS-SIMD and CS-MCSD are used. It should be adopted for other OSD specific airworthiness codes or standards.

a) Master minimum equipment list (MMEL)

- 1) A change to the MMEL is judged to have an ‘appreciable effect on the operational suitability of the aircraft’ and, therefore, should be classified as major, in particular but not only when one or more of the following conditions are met:
 - i. where the change requires an adjustment of the OSD certification basis;
 - ii. where the applicant proposes changes to the means of compliance with the requirements used for the OSD certification basis (i.e. MMEL safety methodology);
 - iii. where the extent of substantiation data and the degree to which the substantiation data has to be assessed and evaluated is considerable, in particular but not only when:
 - A. the substantiation data involving the review of failure conditions that are classified as hazardous or catastrophic has to be evaluated;
 - B. the assessment of the failure effects (including next worst failure/event effects) on crew workload and the applicable crew procedures has to be evaluated; or
 - C. the capability of the aircraft to perform types of operation (e.g. extended-range twin operations (ETOPS), instrument flight rules (IFR)) under MMEL is extended.
- 2) A change to the MMEL is judged not to have an ‘appreciable effect on the operational suitability of the aircraft’ and, therefore, should be classified as minor, in particular but not only when one or more of the following conditions are met:

Modifications to an existing item when:

- i. the change only corresponds to the applicability of an item for configuration management purposes;
- ii. the change corresponds to the removal of an item;
- iii. the change corresponds to the increase in the number of items required for dispatch; and

- iv. the change corresponds to a reduction in the rectification interval of an item.

Addition of a new item when:

- v. it is considered as non-safety-related (refer to CS-MMEL, GM2 MMEL.110); or
- vi. it is indicated as eligible for minor change classification in 1 to GM1 CS-MMEL-145.

b) Flight crew data (FCD)

1) FCD change related to change to the type design

When classifying the FCD change as minor or major, the method of CS-FCD, Subpart D could be used, using the following steps.

- i. An analysis should be performed to assess the change impact on the FCD through the allocation of difference levels realised with operator difference requirement (ODR) tables as per CS FCD.400. In this case, the base aircraft is the aircraft without the type design change, whereas the candidate aircraft is the aircraft which includes the type design change.
 - A. If a no more than level B difference is assigned for training, checking and currency for the candidate aircraft, the related FCD change should be classified as minor.
 - B. If a difference level C, D or E for training, checking and currency is assigned to the candidate aircraft, the related FCD change should be classified as major.
- ii. Notwithstanding the above, the change to FCD should be classified as major when a T1 or T2 test is found necessary by the applicant to confirm that the aircraft with the type design change is not a new type for pilot type rating.

2) Stand-alone changes to FCD are not related to any type design changes. They may be triggered for example by in-service experience or by the introduction of data at the request of the applicant after type certification.

- i. Introduction of credits in training, checking or currency should be classified as major. Example: addition of further-differences training, common take-off and landing credits, etc.
- ii. Stand-alone changes to FCD that correspond to a change of the intent of a data should be classified as major. Example: addition of a training area of special emphasis (TASE) or prerequisite, expansion of a TASE.

c) Cabin crew data (CCD)

1) OSD change related to change to the type design

When classifying the OSD CCD change as minor or major, the method from CS-CCD, Subpart B should be used.

- i. An analysis should be performed to assess the change impact on the OSD CCD through the identification of the difference and its impact on operation in the aircraft difference table (ADT) as per CS CCD.200. In this case, the base aircraft is the aircraft without the type design change, whereas the candidate aircraft is the aircraft which includes the type design change.
 - A. If the difference has no impact on the operation of an element of the ADT for the candidate aircraft, the related OSD CCD change should be classified as minor.
 - B. If the difference has an impact on the operation of an element of the ADT for the candidate aircraft, the related OSD CCD change should be classified as major.
 - ii. Notwithstanding the above, the change to OSD CCD should be classified as major when an ADT analysis is found necessary by the applicant to confirm that the aircraft with the type design change is not a new type for cabin crew.
- 2) Stand-alone changes to OSD CCD are not related to any type design changes. They may be triggered for example by in-service experience or by the introduction of data at the request of the applicant after type certification.
- i. Stand-alone changes to cabin aspects of special emphasis (CASE) should be classified as major. Example: addition of further CASE, expansion of CASE.
 - ii. When classifying stand-alone changes to type-specific data for cabin crew the method from CS-CCD, Subpart B should be used. An analysis should be performed to assess the change impact on the type-specific data through the identification of the difference and its impact on operation in the ADT as per CS CCD.200.
 - A. If the change does not concern a determination element of CS CCD.205, the stand-alone change should be classified as minor.
 - B. If the change has no impact on the operation of an element of the ADT, the stand-alone change should be classified as minor.
 - C. If the change has an impact on the operation of an element of the ADT, the stand-alone change should be classified as major.
- d) Simulator data (SIMD)

The OSD constituent 'simulator data' does not include the data package that is necessary to build the simulator. It includes only the definition of the scope of validation source data to

support the objective qualification of a simulator. So, when this guidance discusses changes to 'simulator data', this concerns only changes to the 'definition of scope of validation source data' and not changes to the data package.

- 1) A change to the SIMD should be classified as major, in particular but not only when one or more of the following conditions are met:
 - i. when a change to the SIMD introduces validation source data from an engineering platform where the process to derive such data has not been audited by the Authority in the initial SIMD approval; or
 - ii. when the process to derive validation source data from an engineering platform is changed.
- 2) A change to the SIMD could be classified as minor, in particular but not only when one or more of the following conditions are met:
 - i. changes to engineering validation data independent of the aircraft due to improvements or corrections in simulation modelling (e.g. aerodynamics, propulsion);
 - ii. configuration changes to the aircraft where the process to derive validation source data from an engineering platform is unchanged;
 - iii. changes to validation source data by using better, more applicable flight test data; or
 - iv. editorial changes to the validation data roadmap (VDR).

e) Maintenance certifying staff data (MCSD)

[Reserved]

3.6. Complementary guidance for the classification of changes to aircraft flight manuals (AFMs)

The following changes to the AFM are deemed to be minor:

- a) revisions to the AFM associated with changes to the type design that are classified as minor in accordance with SIM-To-Lt-035 21.A.91;
- b) revisions to the AFM that are not associated with changes to the type design (also identified as stand-alone revisions) which fall into one of the following categories:
 - 1) changes to limitations or procedures that remain within already certified limits (e.g. weight, structural data, noise, etc.);
 - 2) consolidation of two or more previously approved and compatible AFMs into one, or the compilation of different parts taken from previously approved and compatible AFMs that are directly applicable to the individual aircraft (customisation); and
 - 3) the introduction into a given AFM of compatible and previously approved AFM amendments, revisions, appendices or supplements; and

c) administrative revisions to the AFM, defined as follows:

1) for the AFMs issued by the TC holder:

- i. editorial revisions or corrections to the AFM;
- ii. changes to parts of the AFM that do not require approval by the Authority;
- iii. conversions of previously Authority-approved combinations of units of measurement added to the AFM in a previously approved manner;
- iv. the addition of aircraft serial numbers to an existing AFM where the aircraft configuration, as related to the AFM, is identical to the configuration of aircraft already covered by that AFM;
- v. the removal of references to aircraft serial numbers no longer applicable to that AFM; and
- vi. the translation of an Authority-approved AFM into the language of the State of design or State of registration;

2) for AFM supplements issued by STC holders:

- i. editorial revisions or corrections to the AFM supplement;
- ii. changes to parts of the AFM supplement that are not required to be approved by the Authority;
- iii. conversions of previously Authority-approved combinations of units of measurement added to the AFM supplement in a previously approved manner;
- iv. the addition of aircraft serial numbers to an existing AFM supplement where the aircraft configuration, as related to the AFM supplement, is identical to that of the aircraft already in that AFM supplement; 'identical' means here that all the aircraft have to belong to the same type and model/variant;
- v. the addition of a new STC to an existing AFM supplement, when this supplement is fully applicable to the new STC;
- vi. the removal of references to aircraft serial numbers that are no longer applicable to that AFM supplement;
- vii. the translation of an Authority-approved AFM supplement into the language of the State of design or the State of registration.

3.7. Complementary guidance for classification of changes to environmental protection characteristics
See Section 8 of Appendix A to GM 21.A.91.

Appendix A to GM 21.A.91 Examples of Major Changes per discipline

The information below is intended to provide a few major change examples per discipline, resulting from application of SIM-To-Lt-035 21.A.91 and paragraph 3.3 conditions. It is not intended to present a comprehensive list of all major changes. Examples are categorised per discipline and are applicable to all products (aircraft, engines and propellers). However, a particular change may involve more than one discipline, e.g., a change to engine controls may be covered in engines and systems (software).

Those involved with classification are to always be aware of the interaction between disciplines and the consequences this will have when assessing the effects of a change (i.e., operations and structures, systems and structures, systems and systems, etc.; see example in paragraph 2 (ii)).

Specific rules may exist which override the guidance of these examples.

SIM-To-Lt-035 contains only a negative definition for a change classification as a minor change. However, in the following list of examples it was preferred to give examples of major changes.

Where in this list of examples the words 'has effect' or 'affect(s)' are used, they have always to be understood as being the opposite of 'no appreciable effect' as in the definition of minor change in SIM-To-Lt-035 21.A.91. Strictly speaking the words 'has appreciable effect' and 'appreciably affect(s)' would have been used, but this has not been done to improve readability.

1. Structure

- i. changes such as a cargo door cut-out, fuselage plugs, change of dihedral, addition of floats;
- ii. changes to materials, processes or methods of manufacture of primary structural elements, such as spars, frames and critical parts;
- iii. changes that adversely affect fatigue or damage tolerance or life limit characteristics;
- iv. changes that adversely affect aero-elastic characteristics;
- v. changes that affect primary structural element loads and their path.

2. Cabin Safety

- i. changes which introduce a new cabin layout of sufficient change to require a re-assessment of emergency evacuation capability or which adversely affect other aspects of passenger or crew safety.

Items to consider include, but are not limited to:

- changes to or introduction of dynamically tested seats;
- change to the pitch between seat rows;
- change of distance between seat and adjacent obstacle like a divider;
- changes to cabin lay outs that affect evacuation path or access to exits;
- installation of new galleys, toilets, wardrobes, etc.;

- installation of new type of electrically powered galley insert.

- ii. changes to the pressurisation control system which adversely affect previously approved limitations.

3. Flight

- i. changes which adversely affect the approved performance, such as high altitude operation, brake changes that affect braking performance, deck landing, operation with night vision devices, air to air refuelling, low level flight.
- ii. changes which adversely affect the flight envelope.
- iii. changes which adversely affect the handling qualities of the product including changes to the flight controls function (gains adjustments, functional modification to software) or changes to the flight protection or warning system.

4. Systems

For systems assessed under the applicable airworthiness requirements, e.g. EASA CS 25.1309, the classification process is based on the functional aspects of the change and its potential effects on safety.

- i. Where failure effect is 'Catastrophic' or 'Hazardous', the change is to be classified as major.
- ii. Where failure effect is 'major', the change is to be classified as major if:
 - aspects of the compliance demonstration use means that have not been previously accepted for the nature of the change to the system; or
 - the change affects the pilot/system interface (displays, controls, approved procedures); or
 - the change introduces new types of functions/systems such as GPS primary, TCAS, Predictive wind-shear, HUD.

The assessment of the criteria for software changes to systems also needs to be performed.

When software is involved, account is to be taken also of the following guidelines:

Where a change is made to software produced in accordance with the guidelines of EUROCAE ED-12C/RTCA DO-178C "Software Considerations in Airborne Systems and Equipment Certification" (refer EASA AMC 20-115 and EMAD 20), the change is to be classified as major if either of the following apply, and the failure effect is Catastrophic, Hazardous or Major:

- i. the executable code for software, determined to be Level A or Level B in accordance with the guidelines, is changed unless that change involves only a variation of a parameter value within a range already verified for the previous certification standard; or
- ii. the software is upgraded to or downgraded from Level A, Level B or Level C; or

- iii. the executable code, determined to be level C, is deeply changed, e.g., after a software reengineering process accompanying a change of processor.

For software developed to guidelines other than EUROCAE ED-12C/ RTCA DO-178C, the applicant is to assess changes in accordance with the foregoing principles.

For other codes the principles noted above may be used. However, due consideration is to be given to specific requirements/interpretations.

In the context of a product information security risk assessment (PISRA), a change that may introduce the potential for unauthorised electronic access to product systems should be considered to be 'major' if there is a need to mitigate the risks for an identified unsafe condition. The following examples do not provide a complete list of conditions to classify a modification as major, but rather they present the general interactions between security domains. Examples of modifications that should be classified as 'major' are when any of the following changes occur:

- A new digital communication means, logical or physical, is established between a more closed, controlled information security domain, and a more open, less controlled security domain.

- For example, in the context of large aircraft, a communication means is established between the aircraft control domain (ACD) and the airline information services domain (AISD), or between the AISD and the passenger information and entertainment services domain (PIESD) (see ARINC 811).

As an exception, new simplex digital communication means (e.g. ARINC 429) from a controlled domain to a more open domain is not considered as major modification, if it has been verified that the simplex control cannot be reversed by any known intentional unauthorised electronic interaction (IUEI).

- A new service is introduced between a system of a more closed, controlled information security domain and a system of a more open, less controlled security domain, which allows the exploitation of a vulnerability of the service that has been introduced, creating a new attack path.

For example:

- opening and listening on a User Datagram Protocol (UDP) port in an end system of an already certified topology;
 - activating a protocol in a point-to-point communication channel.

- The modification of a service between a system of a more closed, controlled security domain and a system of a more open, less controlled security domain.
- The modification of a security control between a system of a more closed, controlled information security domain and a system of a more open, less controlled security domain.

5. Propellers

Changes to:

- diameter;
- airfoil;
- planform;
- material;
- blade retention system, etc.

6. Engines

Changes:

- i. that adversely affect operating speeds, temperatures, and other limitations;
- ii. that affect or introduce parts (as identified by the applicable airworthiness requirements) where the failure effect has been shown to be hazardous;
- iii. that affect or introduce engine critical parts (as identified by the applicable airworthiness requirements) or their life limits;
- iv. to a structural part which requires a re-substantiation of the fatigue and static load determination used during certification;
- v. to any part of the engine which adversely affects the existing containment capability of the structure;
- vi. that adversely affect the fuel, oil and air systems, which alter the method of operation, or require reinvestigation against the type-certification basis;
- vii. that introduce new materials or processes, particularly on critical components.

7. Rotors and drive systems

Changes that:

- i. adversely affect fatigue evaluation unless the service life or inspection interval are unchanged. This includes changes to materials, processes or methods of manufacture of parts, such as:
 - rotor blades;

- rotor hubs including dampers and controls;
 - gears;
 - drive shafts;
 - couplings.
- ii. affect systems the failure of which may have hazardous or catastrophic effects. The design assessment will include:
- cooling system;
 - lubrication system;
 - rotor controls.
- iii. adversely affect the results of the rotor drive system endurance test, such as the rotor drive system required in EASA CS 27/29.917.
- iv. adversely affect the results of the shafting critical speed analysis such as required by EASA CS 27/29.931.

8. Environment (where applicable)

A change that introduces an increase in noise or emissions. Where a change is made to an aircraft or aircraft engine for which compliance with ICAO Standards and Recommended Practices for environmental protection (ICAO Annex 16) is required or stated, the effect of the change on the product's environmental characteristics should be taken into account. Examples of changes that might have an appreciable effect on the product's environmental characteristics, and might therefore be classified as major changes, can be found in Appendix A to EASA GM 21.A.91. The examples are not exhaustive and will not, in every case, result in an appreciable change to the product's environmental characteristics, and therefore, will not per se and in every case result in a 'major change' classification.

9. Power plant Installation

Changes which include:

- i. control system changes which affect the engine/propeller/airframe interface;
- ii. new instrumentation displaying operating limits;
- iii. modifications to the fuel system and tanks (number, size and configuration);
- iv. change of engine/propeller type.

10. Operational capabilities

Changes to operational capabilities that have an appreciable impact on third party safety, such as

- i. in-flight refuelling capabilities;
- ii. external stores and tanks, including jettison devices;
- iii. armament, including high power laser;

- iv. equipment that has an appreciable affect on Electromagnetic Environmental Effects (E3) integrity (e.g. new radar)
- v. aerial delivery systems;

A classification process would be:

AMC&GM
ACCEPTABLE MEANS OF COMPLIANCE AND GUIDANCE MATERIAL TO
SIM-To-Lt-035 (FIN EMAR 21)

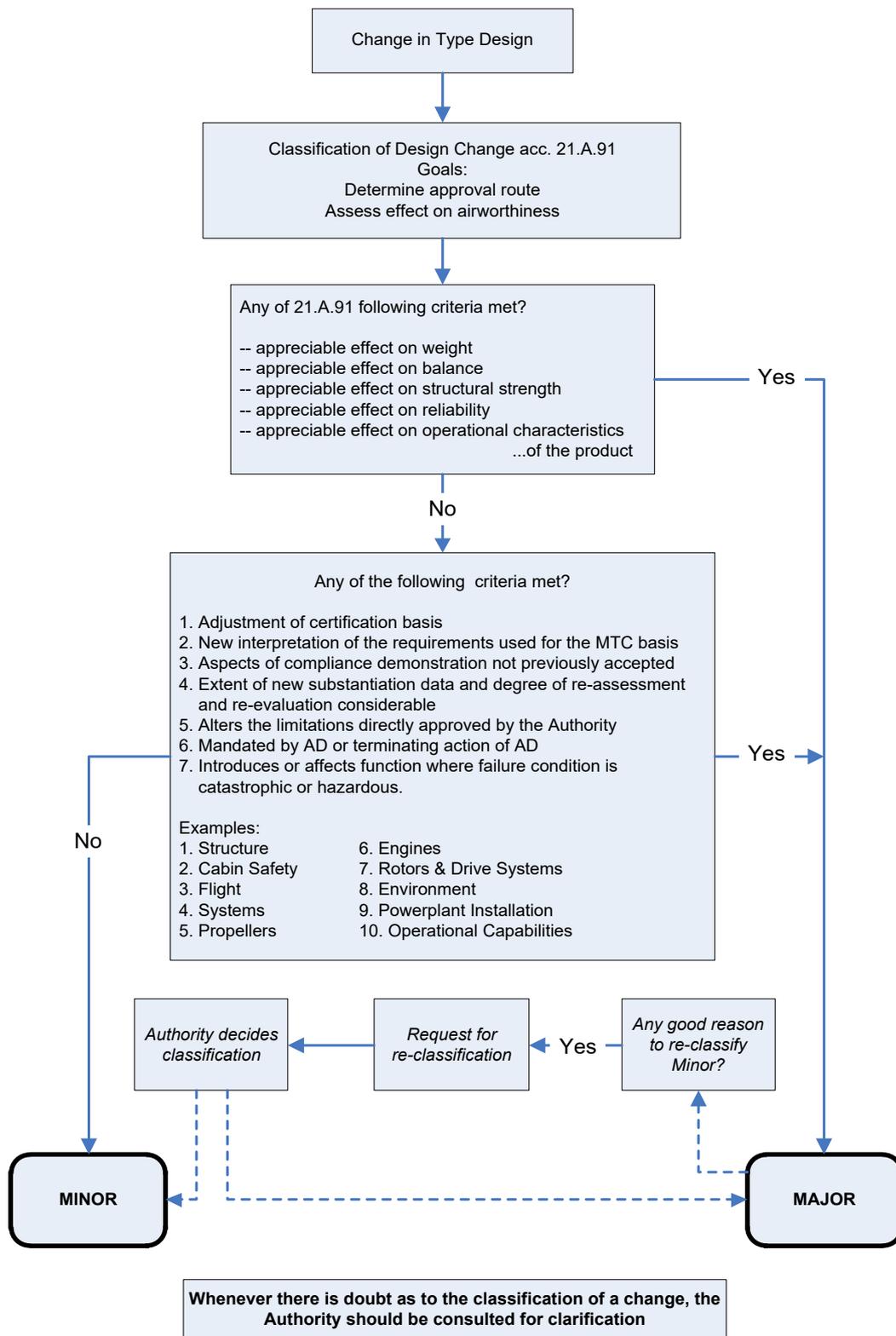


Figure 1 Classification Process

GM 21.A.92 (a) Eligibility to apply for approval of a major change to a type-certificate

The expression “Only the type-certificate holder may apply for approval of a major change to a type-certificate under this Subpart” includes any person or organisation acting on behalf of the type-certificate holder in accordance with SIM-To-Lt-035 21.A.2, subject to the arrangements with the Holder.

AMC 21.A.15(a), 21.A.93(a), 21.A.113(a), 21.A.432C(a) Form and manner

The applicant should file an application using the forms or tools specified by the Authority. In doubt, the applicant should consult with the Authority to get informed about the relevant forms, tools, and procedure.

The application should be completed in accordance with the instructions given in the forms or tools or as received from the authority and sent to the addressee nominated by the Authority by fax, email, or regular mail.

AMC 21.A.93(b) Certification programme for a change to a TC or an STC

The description of the change should include an explanation of the purpose of the change, the pre-modification and post-modification configuration(s) of the product, schematics/pictures, and any other detailed features and boundaries of the physical change (this may be supplemented by drawings or outlines of the design, if this helps to understand the design change), as well as the identification of the changes in areas of the product that are functionally affected by the change, and the identification of any changes to the approved manuals. Guidance on areas that are changed and affected by the change is found in GM 21.A.101, Section 3.9.1.

Identification of reinvestigations referred to in SIM-To-Lt-035 21.A.93(b)(2), necessary to demonstrate compliance, does not mean the demonstration of compliance itself, but the list of affected items of the applicable certification basis for which a new demonstration is necessary, together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

Before submitting the application for a change, the analysis and classification activities of SIM-To-Lt-035 21.A.91 and 21.A.101 should be performed using the corresponding GM. For repair designs, the analysis of SIM-To-Lt-035 21.A.91 should be performed using GM 21.A.435(a).

For a major change, AMC 21.A.15(b) should be used as applicable to the change.

GM No 1 to 21.A.93(b)(1)(iii) Interaction of changes to the type design and changes to operational suitability data (OSD)

In general, it has to be assumed that changes to the type design can have an effect on the OSD.

Due to the alleviating nature of the OSD constituent master minimum equipment list (MMEL), the impact of design changes on the MMEL can be treated differently from the impact on other OSD constituents. Therefore, a separate GM No 2 to 21.A.93(b)(1)(iii) is available to explain the interaction between design changes and the MMEL. The following guidance is, therefore, only applicable to the other OSD constituents.

In assessing the interactions between the changes to the type design and to the OSD, the following can be taken into consideration (see Figure 1):

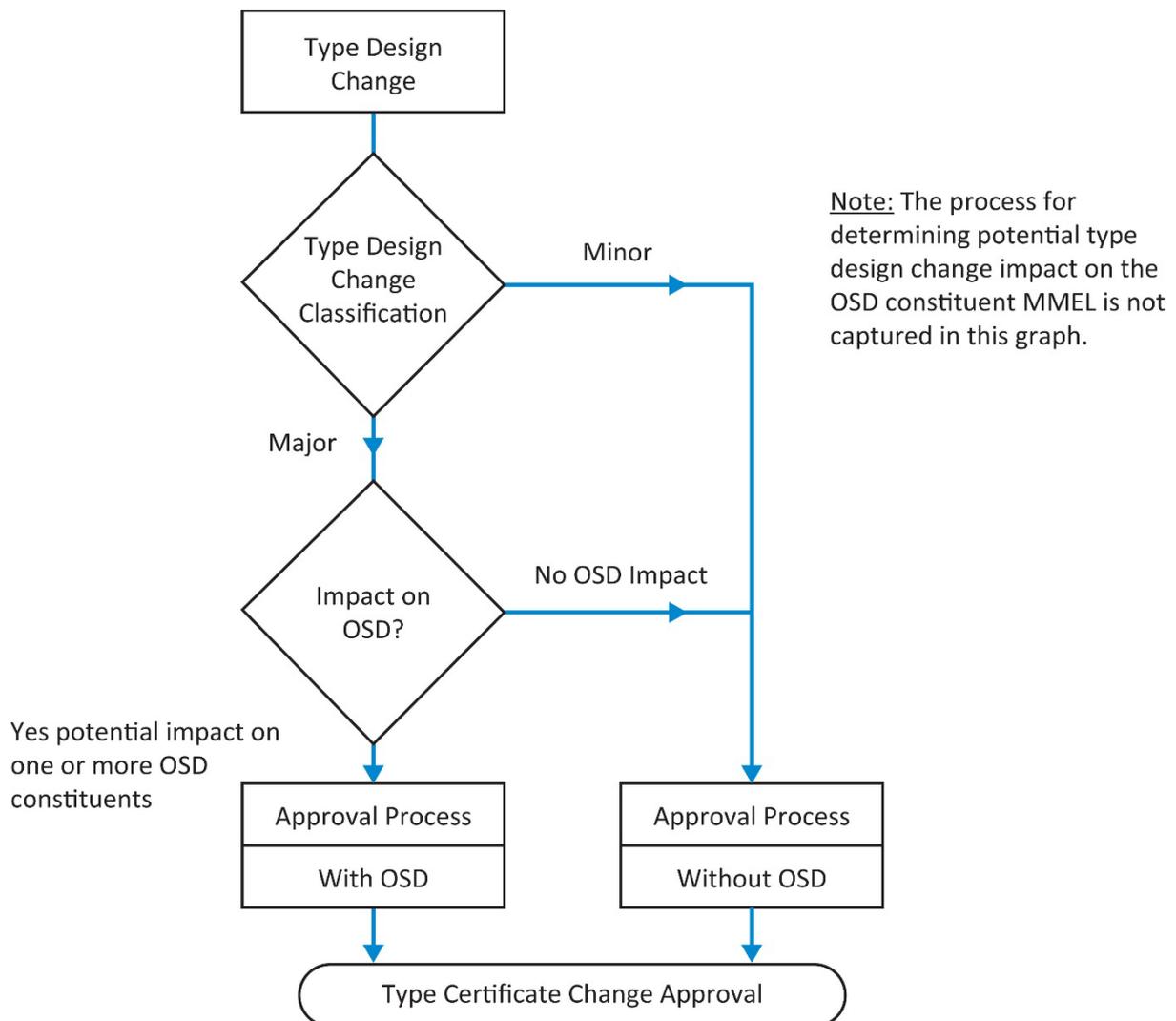


Figure 1

- a) Changes to the type certificate (TC) that only include a minor change to the type design ('stand-alone' type design changes) do not have an effect on the OSD. No dedicated assessment of the effects of the minor type design change on the OSD is needed in this case.
- b) TC changes that only include a major type design change do not need to be assessed for their effect on the OSD in case the experience of the applicant has demonstrated that similar changes do not have an effect on the OSD. Examples of major type design changes and their expected effect on OSD constituents can be found in EASA GM, e.g. GM No 1 to 21.A.93(b)(1)(iii).
- c) Design changes to aircraft for which OSD is not required cannot trigger the need to establish OSD.
- d) (removed).
- e) When the design change makes an OSD constituent applicable (see GM No 1 to 21.A.15(d) – Clarification of the applicability of operational suitability data (OSD) constituents) where it was not applicable before, that OSD constituent should be added to the application for the approval of the change to the TC.

GM No 2 to 21.A.93(b)(1)(iii) Interaction of changes to the type design and changes to the master minimum equipment list (MMEL)

In general, it has to be assumed that changes to the type certificate (TC) that affect the type design can have an effect on the MMEL.

Due to its alleviating nature, the MMEL is developed to improve aircraft use, thereby providing a higher availability of military aircraft for operations.

Therefore, not introducing MMEL relief for new equipment, system or function has no effect on the safety of the operation. The introduction of MMEL relief for new equipment can, therefore, be treated as a stand-alone MMEL change, separately from the design change, and can be processed at a later date than the date of entry into service of the aircraft including the design change.

Not modifying an MMEL item whose validity is altered by a type design modification may, however, have an effect on the safety of the operation. The applicant for a change to the TC that changes the type design should, therefore, identify whether this change needs to be supplemented by a change to the MMEL. However, the update of an MMEL relief for an already addressed equipment, system or function can be treated at a later date than the date of entry into service of the aircraft including the design change, provided that the change to the MMEL is of an alleviating nature. When the change to the MMEL is not of an alleviating nature, it has to be approved according to SIM-To-Lt-035 21.A.97(b)(2) and (c).

It may be assumed that a change to the type design requires a change to the MMEL if any of the following conditions are fulfilled:

- a) the change affects an existing MMEL item in a more restrictive manner: there is a change to equipment, system or function linked to an MMEL item, or a change to the operational limitations and procedures linked to an MMEL item;
- b) the change invalidates the assumptions used to justify an existing MMEL item, and requires a more restrictive MMEL item; and
- c) the change invalidates any dispatch conditions of the MMEL.

The following diagram summarises the interaction between type design changes and changes to MMEL (see Figure 1).

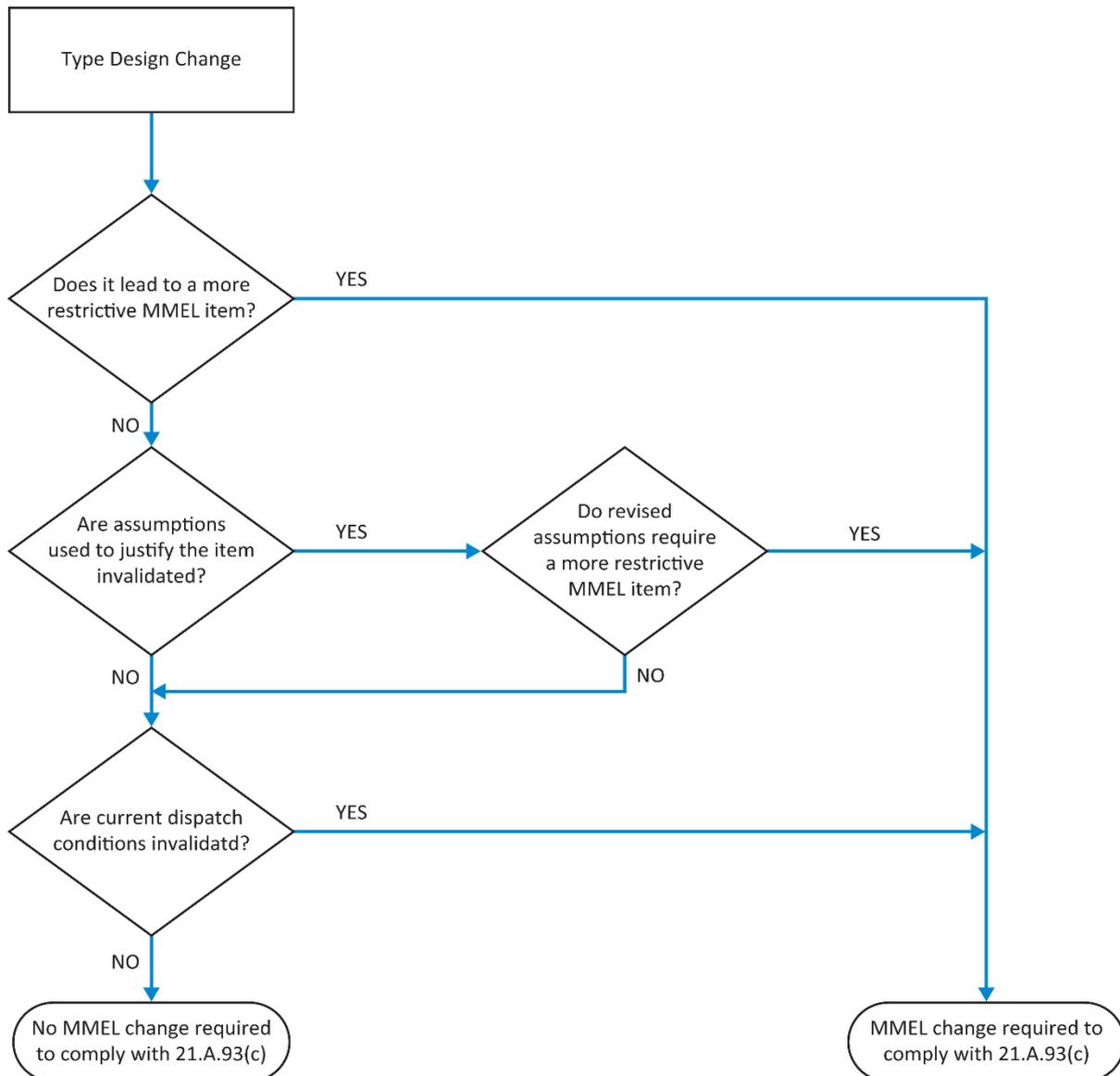


Figure 1

GM 21.A.93(c) Period of validity for the application

For guidance on the determination of the period of validity for the application, refer to GM 21.A.15(e) and (f).

AMC 21.A.95 Requirements for the approval of a minor change

- a) Applicability of SIM-To-Lt-035 21.A.95 SIM-To-Lt-035 21.A.95 has to be complied with by applicants for the approval of a minor change to a type certificate (TC), and by design organisation approval (DOA) holders that approve minor changes under their own privileges.

SIM-To-Lt-035 21.A.95(e), however, only applies to projects for which an application is submitted to the Authority. For DOA holders that approve minor changes under their privileges, the substantiating data and the statement of compliance required by SIM-To-Lt-035 21.A.95(e) should be produced but do not need to be submitted to the Authority. They should be, however, kept on record and submitted to the Authority on request during the DOA continued surveillance process.

- b) The approval process

The approval process comprises the following steps:

Note: Steps 1, 2 and 5 should be followed only by applicants for minor changes approved by the Authority. DOA holders that approve minor changes under their privileges should refer to AMC No 1 to 21.A.263(c)(2) or AMC No 2 to 21.A.263(c)(2), as applicable to their approval process.

- 1) Application

When the minor change is approved by the Authority, an application should be submitted to the Authority as described in SIM-To-Lt-035 21.A.93(a) and (b) and in AMC 21.A.93(a).

- 2) Certification programme

The certification programme should consist of the information defined in SIM-To-Lt-035 21.A.93(b)(1) and 21.A.93(b)(2). Please refer to AMC 21.A.93(b) for further information.

- 3) Certification basis

- 4) Demonstration of compliance

- 5) Statement of compliance

- c) Certification basis

The certification basis for a minor change consists of a subset of the elements of the product's certification basis 'incorporated by reference in the type certificate' (see also the additional

guidance below on the meaning of airworthiness codes that became applicable after those ‘incorporated by reference in the type certificate’), which have been identified in accordance with SIM-To-Lt-035 21.A.93(b)(2) due to a reinvestigation of compliance being necessary because compliance was affected by the minor change (see also additional guidance below on the meaning of ‘specific configurations’).

The certification basis ‘incorporated by reference in the type certificate’ is the certification basis for the product as recorded in the type certificate data sheet (TCDS) for the product type/model in the configuration(s) identified in accordance with SIM-To-Lt-035 21.A.93(b)(1)(i).

The certification basis contains the applicable codes, standards or other related requirements for airworthiness and (for aircraft only) operational suitability data, environmental protection requirements as specified by the Authority, including a reference to their amendment level, as complemented by special conditions, equivalent safety findings, deviations, an ‘elect to comply’, etc., as applicable. See also the additional guidance below on the meaning of ‘Minor changes affecting OSD constituents’.

By derogation from the above, airworthiness codes, standards or other related requirements that became applicable after those incorporated by reference in the TC may be used for the approval of a minor change (see the guidance below on airworthiness codes that became applicable after those ‘incorporated by reference in the type certificate’).

If other changes are required for the embodiment of the minor change, the certification basis corresponding to the product modified by these other changes should also be considered when determining the certification basis for the minor change.

d) Demonstration of compliance required by SIM-To-Lt-035 21.A.95(b)(1) and (2)

The applicant needs to demonstrate compliance with the certification basis established for the minor change for all areas that are either physically changed or functionally affected by the minor change.

- 1) Means of compliance: the applicant should define and record the means (calculation, test or analysis, etc.) by which compliance is demonstrated. Appendix A to AMC 21.A.15(b) may be used to describe how compliance is demonstrated.
- 2) Compliance documents: the compliance demonstration should be recorded in compliance documents. For minor changes, one comprehensive compliance document may be sufficient, provided that it contains evidence of all aspects of the compliance demonstration. AMC 21.A.20(c) can also be used, where applicable.
- 3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

e) Definition of the change to the type certificate

The change to the type certificate should be defined in accordance with GM 21.A.90A.

f) Embodiment/installation instructions

The instructions for the embodiment/installation of the change (e.g. service bulletin, modification bulletin, production work order, etc.) should be defined. This may include the installation procedure, the required material, etc.

g) Minor changes affecting OSD constituents (i.e. master minimum equipment list (MMEL))

Some minor changes to the type design may only have an effect on the MMEL (see GM No 1 to 21.A.93(b)(1)(iii)). In such cases, GM No 2 to 21.A.93(b)(1)(iii) is also applicable. This also means that a dedicated assessment of the effects of the minor type design change on the other OSD constituents is not needed.

h) Meaning of 'specific configurations' in point 21.A.95(f)

These 'specific configurations' are defined as the combination of the product type/model (on which the minor change will be installed) with (if applicable) the list of those already approved changes (minor, major, supplemental type certificate (STC)) that are required for the installation of the minor change.

i) Airworthiness codes that became applicable after those incorporated by reference in the type certificate

- 1) Minor changes are those changes that do not affect the airworthiness of the product and thus are, by definition, non-significant as per SIM-To-Lt-035 21.A.101. This means that the certification basis for the minor change may consist of the items of the certification basis incorporated by reference in the TCDS of the product type/model, and normally it should not be necessary for a minor change to use airworthiness codes, standards or other related requirements that became applicable after those that are incorporated by reference in the type certificate.
- 2) On the other hand, the applicant may elect to use later amendments of the affected airworthiness codes, standards or other related requirements for the compliance demonstration. This does not affect the classification of the change; however, the applicant should also comply with any other airworthiness codes, standards or other requirements that the Authority considers to be directly related.
- 3) If other changes are required for the installation of the minor change (as explained in 'specific configurations'), the certification basis for the minor change should also take into account the corresponding airworthiness codes, standards or other related requirements.

j) Meaning of 'no feature or characteristics' in SIM-To-Lt-035 21.A.95(b)(4)

See GM 21.A.20(d).

GM 21.A.95(b) Requirements for the approval of a minor change

The level of detail of the documents that are referred to in SIM-To-Lt-035 21.A.93(b) should be the same regardless of whether the change is approved by the Authority or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

AMC 21.A.97 Requirements for the approval of a major change

1. AMC/GM to SIM-To-Lt-035 21.A.20 should be used for a major change approved by the Authority.
2. For the application of SIM-To-Lt-035 21.A.97(c), see GM to SIM-To-Lt-035 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c).
3. In accordance with SIM-To-Lt-035 21.A.97(c), the compliance demonstration process always takes into account the specific configuration(s) in the type certificate (TC) to which the major change under approval is applied. These configurations may be defined by type models/variants or by design changes to the type design. The demonstration of compliance covers these applicable specific configurations. Consequently, the approval of the major change excludes any other configurations, in particular those that already exist but are not considered in the compliance demonstration process, as well as those that may be certified in future.
4. For major changes approved by the design organisation approval (DOA) holder on the basis of their privilege as per SIM-To-Lt-035 21.A.263(c)(8), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

GM 21.A.97(b) Requirements for the approval of a major change

The level of detail of the documents that are referred to in SIM-To-Lt-035 21.A.93(b) should be the same regardless of whether the change is approved by the Authority or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

GM 21.A.101 Establishing the certification basis of changed aeronautical products

This guidance material (GM) provides guidance for the application of the 'Changed Product Rule (CPR)', pursuant to SIM-To-Lt-035 21.A.101 and 21.A.19 for changes made to type-certified aeronautical products.

1. Chapter 1: Introduction

1.1. Purpose.

This GM provides guidance for establishing the certification basis for changed aeronautical products pursuant to SIM-To-Lt-035 21.A.101. The guidance is also intended to help applicants and approved design organisations to determine whether it will be necessary to apply for a new type certificate (TC) under SIM-To-Lt-035 21.A.19, Changes requiring a new type certificate. The guidance describes the process for establishing the certification basis for a change to a TC, for a supplemental type certificate (STC), or for a change to an STC, detailing the requirements (evaluations, classifications, and decisions) throughout the process.

1.2. Applicability

1.2.1. This GM is for an applicant that applies for changes to TCs under Subpart D, for STCs, or changes to STCs under Subpart E, or for changes to Military Technical Standard Order Authorisations (MTSOAs) for auxiliary power units (APUs) under Subpart O. This GM is also for approved design organisations that classify changes and approve minor changes under their SIM-To-Lt-035 21.A.263(c)(1) and (2) privileges.

1.2.2. This GM applies to major changes under SIM-To-Lt-035 21.A.101 for aeronautical products certified under SIM-To-Lt-035, and the airworthiness codes applicable to the changed product (e.g. EASA CS-23, CS-25, CS-27, CS-29, CS-MMEL, CS-FCD, CS-CCD, etc.). References to 'change' include the change and areas affected by the change pursuant to SIM-To-Lt-035 21. A.101.

1.2.3. Minor changes are within the scope of SIM-To-Lt-035 21.A.101 and this GM but are automatically considered to not be significant under the 'does not contribute materially to the level of safety' provision of SIM-To-Lt-035 21.A.101(b).

1.2.4. This GM also applies to changes to restricted type certificates.

1.2.5. The term 'aeronautical product', or 'product', means a type-certified aircraft, aircraft engine, or propeller and, for the purpose of this GM, an MTSOA'd APU.

1.2.6. This GM primarily provides guidance for the designation of applicable airworthiness codes and other airworthiness standards for the type-certification basis for the changed product. However, portions of this GM, as specified in GM1 21.A.101(g), can be applied by analogy to establish the operational suitability data (OSD) certification basis for the changed product. This GM is not intended to be used to determine the applicable environmental protection requirements (aircraft noise, fuel venting, and engine exhaust emissions and aeroplane CO₂ emissions requirements) for changed products, as they are designated by the Authority.

1.2.7. This GM is not mandatory and does not replace other requirements or acceptable means of compliance published by the Authority. An applicant who wishes to apply this GM to comply with SIM-To-Lt-035 21.A.101 shall seek the agreement and further guidance from the Authority.

1.3. Reserved.

1.4. GM Content

This GM contains 5 chapters and 10 appendices.

- 1.4.1. Chapter 1 (this chapter) clarifies the purpose of this GM, describes its content, specifies the intended audience affected by this GM, clarifies which changes are within the scope of this GM, and references the definitions and terminology used in this GM.
- 1.4.2. Chapter 2 provides a general overview of SIM-To-Lt-035 21.A.101 and 21.A.19, clarifies the main principles and safety objectives, and directs an applicant to the applicable guidance contained in subsequent chapters of this GM.
- 1.4.3. Chapter 3 contains guidance for the implementation of SIM-To-Lt-035 21.A.101(b) to establish the certification basis for changed aeronautical products. It describes in detail the various steps for developing the certification basis, which is a process that applies to all changes to aeronautical products. Chapter 3 also addresses SIM-To-Lt-035 21.A.19 considerations for identifying the conditions under which an applicant for a change is required to submit an application for a new TC, and it provides guidance regarding the stage of the process at which this assessment is performed.
- 1.4.4. Chapter 4 provides guidance about products excepted from the requirement of SIM-To-Lt-035 21.A.101(a).
- 1.4.5. Chapter 5 contains considerations for:
- design-related operating requirements,
 - defining a baseline product,
 - predecessor standards,
 - using special conditions under SIM-To-Lt-035 21.A.101(d),
 - documenting revisions to the TC basis,
 - incorporating STCs into the type design,
 - removing changes,
 - determining a certification basis after removing an approved change, and
 - sequential changes.
- 1.4.6. Appendix A contains a reference to examples of typical type design changes for products (small aeroplanes, large aeroplanes, rotorcraft, engines, and propellers), as categorised by the European Union Aviation Safety Agency (EASA) into individual tables according to the classifications of design change: ‘substantial’, ‘significant’, and ‘not significant’.
- 1.4.7. Appendix B contains the application chart for applying the SIM-To-Lt-035 21.A.101 process.
- 1.4.8. Appendix C contains a reference to the method proposed by the European Union Aviation Safety Agency (EASA) for determining the changed and affected areas of a product.
- 1.4.9. Appendix D contains additional guidance on affected areas that is not discussed in other parts of this GM.

1.4.10. Appendix E provides reference and military specific considerations for evaluating the ‘impracticality’ exception in the requirement.

1.4.11. Appendix F provides guidance and reference to examples on the use of relevant service experience in the certification process as one way to demonstrate that a later amendment may not contribute materially to the level of safety, allowing the use of earlier airworthiness codes or specifications.

1.4.12. Appendix G provides guidance on the structure of a CPR decision record.

1.4.13. Appendix H provides a reference to examples of documenting a proposed certification basis list.

1.4.14. Appendix I lists SIM-To-Lt-035 requirements related to this GM.

1.4.15. Appendix J lists the definitions and terminology applicable for the application of the requirement.

1.5. Terms Used in this GM.

1.5.1. The following terms are used interchangeably and have the same meaning: ‘codes’ ‘specifications’, ‘standards’, ‘airworthiness codes’, ‘certification specifications’ and ‘certification standards’ or ‘certification requirements’. They refer to the elements of the type-certification basis for airworthiness or OSD certification basis. Examples of such elements are EASA CS, FAA FAR, Mil Hdbk, JSSG, STANAG, Def-STAN, etc., as declared applicable by the Authority.

1.5.2. The term ‘certification basis’ refers to the type-certification basis for airworthiness

For more terms, consult Appendix J.

2. Chapter 2: Overview of SIM-To-Lt-035 21.A.19 and SIM-To-Lt-035 21.A.101

2.1. SIM-To-Lt-035 21.A.19.

2.1.1. SIM-To-Lt-035 21.A.19 requires an applicant to apply for a new TC for a changed product if the Authority finds that the change to the design, power, thrust, or weight is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

2.1.2. Changes that require a substantial re-evaluation of the compliance findings of the product are referred to as ‘substantial changes’. For guidance, see paragraph 3.3 in Chapter 3 of this GM. Appendix A of this GM provides a reference to examples of changes that will require a new TC for aircraft classes used in civil aviation.

2.1.3. If the Authority determines through SIM-To-Lt-035 21.A.19 that a proposed change does not require a new TC, SIM-To-Lt-035 21.A.101 defines the applicable requirements to develop the certification basis for the proposed change. For guidance, see Chapter 3 and the examples referred to in Appendix A of this GM.

2.2. SIM-To-Lt-035 21.A.101

2.2.1. SIM-To-Lt-035 21.A.101(a).

SIM-To-Lt-035 21.A.101(a) requires a change to a TC, and the areas affected by the change to comply with the airworthiness codes that are applicable to the changed product and that are in effect on the date of application for the change (i.e. the latest airworthiness codes in effect at the time of application), unless the change meets the criteria for the exceptions identified in SIM-To-Lt-035 21.A.101(b), or unless an applicant chooses to comply with amendments of the airworthiness codes that became effective after the date of application in accordance with SIM-To-Lt-035 21.A.101(f). The intent of SIM-To-Lt-035 21.A.101 is to enhance safety by incorporating the latest requirements into the certification basis for the changed product to the greatest extent practicable.

2.2.2.SIM-To-Lt-035 21.A.101(b).

SIM-To-Lt-035 21.A.101(b) pertains to when an applicant may show that a changed product complies with an earlier amendment of an airworthiness code or standard, provided that the earlier amendment is considered to be adequate and meets the criteria in SIM-To-Lt-035 21.A.101(b)(1), (2), or (3). When changes involve features or characteristics that are novel and unusual in comparison with the airworthiness code or standard at the proposed amendment, more recent airworthiness codes or standards and/or special conditions will be applied for these features.

Compliance with earlier amendments of the airworthiness codes or standards may be considered in accordance with SIM-To-Lt-035 21.A.101(b), when:

- a) a change is not significant (see SIM-To-Lt-035 21.A.101(b)(1));
- b) an area, system, part or appliance is not affected by the change (see SIM-To-Lt-035 21.A.101(b)(2));
- c) compliance with a later amendment for a significant change does not contribute materially to the level of safety (see SIM-To-Lt-035 21.A.101(b)(3)); or
- d) compliance with the latest amendment would be impractical (see SIM-To-Lt-035 21.A.101(b)(3)).

Earlier amendments may not precede the amendment level of the airworthiness codes or standards referred to in the certification basis of the identified baseline product.

SIM-To-Lt-035 21.A.101(b)(1)(i) and (ii) pertain to changes that meet the automatic criteria where the change is significant.

2.2.3.(reserved)

2.2.4.SIM-To-Lt-035 21.A.101(d).

SIM-To-Lt-035 21.A.101(d) provides for the use of special conditions, when the proposed certification basis and any later airworthiness codes or standards do not provide adequate requirements for the proposed change because of a novel or unusual design feature.

2.2.5. SIM-To-Lt-035 21.A.101(e).

SIM-To-Lt-035 21.A.101(e) provides the basis under which an applicant may propose to certify a change and the areas affected by the change against alternative requirements to the airworthiness codes or standards appointed or established by the Authority.

2.2.6. SIM-To-Lt-035 21.A.101(f).

SIM-To-Lt-035 21.A.101(f) requires that if an applicant chooses (elects) to comply with an airworthiness code or standard or an amendment to such codes and standards that is effective after the filing of the application for a change to a TC, the applicant shall also comply with any other requirements that the Authority finds are directly related. The requirements which are directly related must be, for the purpose of compliance demonstration, considered together at the same amendment level to be consistent.

2.2.7. SIM-To-Lt-035 21.A.101(g).

SIM-To-Lt-035 21.A.101(g) pertains to the designation of the applicable OSD certification basis when the application for a change to a type certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the OSD. It implies that the same requirements of paragraphs (a) and (f) that are applicable to the establishment of the airworthiness type-certification basis also apply to the establishment of the OSD certification basis. For specific guidance, see GM1 21.A.101(g).

3. Chapter 3: Process for establishing the certification basis for changed products

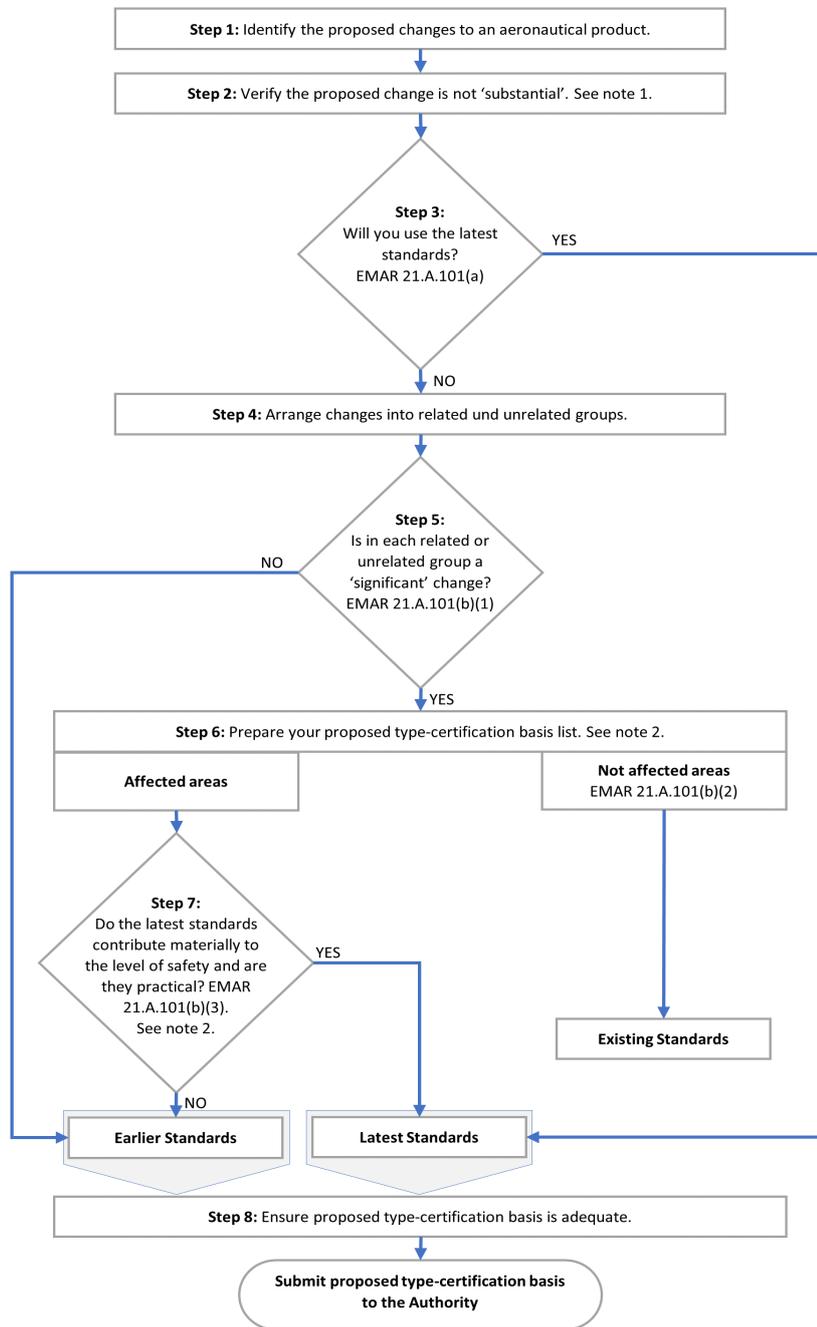
3.1. Overview.

3.1.1. The applicant and the Authority both have responsibilities under SIM-To-Lt-035 21.A.101(a) and (b). As an applicant for the certification of a change, the applicant must demonstrate that the change and areas affected by the change comply with the latest applicable airworthiness codes or standards unless the applicant proposes exception(s) under SIM-To-Lt-035 21.A.101(b). An applicant proposing exception(s) should make a preliminary classification whether the change is 'significant' or 'not significant', and propose an appropriate certification basis. The Authority is responsible for determining whether the applicant's classification of the change, and proposal for the certification basis, are consistent with the applicable regulations and their interpretation. This determination does not depend on whether the TC holder or applicant for an STC is originating the change. The certification basis can vary depending on the magnitude and scope of the change. The steps below present a streamlined approach for making this determination.

3.1.2. The tables referred to in appendix A of this GM are examples of classifications of typical type design changes. See paragraph 3.6.3 of this chapter for instructions on how to use those tables.

3.1.3. If a proposed change is not in the examples referred to in appendix A, the applicant may use the following steps in conjunction with the flow chart in Figure 1 of this GM to develop the appropriate certification basis for the change. For clarification, the change discussed in the flow chart also includes areas affected by the change. See paragraph 3.9.1 of this GM for guidance about affected areas.

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Notes:

1. Changed products that are substantially changed do not follow this flowchart. Refer to EMAR 21.A.19
2. Process and propose each applicable standard individually. If standards are linked together, then they should be assessed together.

Figure 1 – Developing a Proposed Certification Basis for a Changed Product Pursuant to SIM-To-Lt-035

3.2. Step 1. Identify the proposed changes to an aeronautical product.

- Identify the type design being changed (the baseline product).
- Identify the proposed change.
- Use high-level descriptors.

3.2.1. Identify the type design being changed (the baseline product).

Prior to describing the proposed change(s), it is important to clearly identify the specific type design configuration being changed.

Note: For additional guidance on the baseline product, see paragraph 5.3 of this GM.

3.2.2. Identify the proposed change.

3.2.2.1. The purpose of this process step is to identify and describe the change to the aeronautical product. Changes to a product can include physical design changes and functional changes (e.g. operating envelope or performance changes). An applicant must identify all changes and areas affected by the change, including those where they plan to use previously approved data. The Authority considers all of these changes and areas affected by the change to be part of the entire proposed type design and they are considered as a whole in the classification of whether the proposed change is substantial, significant, or not significant. The change can be a single change or a collection of changes. In addition to the proposed changes, an applicant should consider the cumulative effect of previous relevant changes incorporated since the last time the certification basis was upgraded. An applicant for a change must consider all previous relevant changes and the amendment level of the airworthiness codes or specifications in the certification basis used for these changes.

3.2.2.2. When identifying the proposed changes, an applicant should consider previous relevant changes that create a cumulative effect, as these may influence the decisions regarding the classification of the change later in the process. By 'previous relevant changes,' the Authority means changes where effects accumulate, such as successive thrust increases, incremental weight increases, or sectional increases in fuselage length. An applicant must account for any previous relevant changes to the area affected by the proposed change that did not involve an upgrade of the certification basis in the proposed change.

3.2.2.3. Example:

An applicant proposes a 5 per cent weight increase, but a previous 4 per cent and another 3 per cent weight increase were incorporated into this aircraft without upgrading the existing certification basis. In the current proposal for a 5 per cent weight increase, the cumulative effects of the two previous weight increases that did not involve an upgrade of the certification basis will now be accounted for as an approximate 12 per cent increase in weight. Note that the cumulative effects the applicant accounts for are only those incremental increases since the last time the airworthiness codes and specifications in the type-certification basis applicable to the area affected by the proposed change were upgraded.

3.2.3. Use High-Level Descriptors.

To identify and describe the proposed changes to any aeronautical product, an applicant should use a high-level description of the change that characterises the intent of, or the reason for, the change. No complex technical details are necessary at this stage. For example, a proposal to increase the maximum passenger-carrying capacity may require an addition of a fuselage plug, and as such, a 'fuselage plug' becomes one possible high-level description of this change. Similarly, a thrust increase, a new or complete interior, an avionics system upgrade, or a passenger-to-cargo conversion are all high-level descriptions that characterise typical changes to the aircraft, each driven by a specific goal, objective, or purpose.

3.2.4. Evolutionary changes that occur during the course of a certification program may require re-evaluation of the certification basis, and those changes that have influence at the product level may result in re-classification of the change.

3.3. Step 2. Verify the proposed change is not substantial.

3.3.1. SIM-To-Lt-035 21.A.19 requires an applicant to apply for a new TC for a changed product if the change to design, power, thrust, or weight is so extensive that a substantially complete investigation of compliance with the applicable regulations is required. A new TC could be required for either a single extensive change to a previously type-certified product or for a changed design derived through the cumulative effect of a series of design changes from a previously type-certified product.

3.3.2. A 'substantially complete investigation' of compliance is required when most of the existing substantiation is not applicable to the changed product. In other words, an applicant may consider the change 'substantial' if it is so extensive (making the product sufficiently different from its predecessor) that the design models, methodologies, and approaches used to demonstrate a previous compliance finding could not be used in a similarity argument. The Authority considers a change 'substantial' when these approaches, models, or methodologies of how compliance was shown are not valid for the changed product.

3.3.3. If it is not initially clear that a new TC is required, appendix A of this GM provides references to examples of substantial changes to aid in this classification. A substantial change requires an application for a new TC. See SIM-To-Lt-035 21.A.19. If the change is not substantial, proceed to step 3

3.4. Step 3. Will the applicant use the latest standards?

An applicant can use the latest airworthiness codes or specifications for their proposed change and the area affected by the change. If they use the latest airworthiness codes or specifications, they will have met the intent of SIM-To-Lt-035 21.A.101 and no further classification (significant or not significant) and justification is needed. Even though an applicant elects to use the latest airworthiness codes or specifications, the applicant will still be able to apply SIM-To-Lt-035 21.A.101 for future similar changes, and use the exceptions under SIM-To-Lt-035 21.A.101(b). However, the decision to comply with the latest air-worthiness codes or specifications sets a new basis for all future related changes to the same affected area for that amended TC.

- If using the latest airworthiness codes or specifications, an applicant should proceed to Step 6 (in paragraph 3.9 of this GM).
- If not using the latest airworthiness codes or specifications, an applicant should proceed to Step 4 below.

3.5. Step 4. Arrange changes into related and unrelated groups.

3.5.1. An applicant should now determine whether any of the changes identified in Step 1 are related to each other. Related changes are those that cannot exist without another, are co-dependent, or a prerequisite of another. For example, a need to carry more passengers could require the addition of a fuselage plug, which will result in a weight increase, and may necessitate a thrust increase. Thus, the fuselage plug, weight increase, and thrust increase are all related, high-level changes needed to achieve the goal of carrying more passengers. A decision to upgrade the flight deck to more modern avionics at the same time as these other changes may be considered unrelated, as the avionics upgrade is not necessarily needed to carry more passengers (it has a separate purpose, likely just modernisation). The proposed avionics upgrade would then be considered an unrelated (or a stand-alone) change. However, the simultaneous introduction of a new cabin interior is considered related since occupant safety considerations are impacted by a cabin length change. Even if a new cabin interior is not included in the product-level change, the functional effect of the fuselage plug has implications on occupant safety (e.g. the dynamic environment in an emergency landing, emergency evacuation, etc.), and thus the cabin interior becomes an affected area. Figure 2 below illustrates the grouping of related and unrelated changes using the example of increasing the maximum number of passengers.

Note: An applicant who plans changes in sequence over time should refer to the discussion on 'sequential design changes' in paragraph 5.13 of this GM.

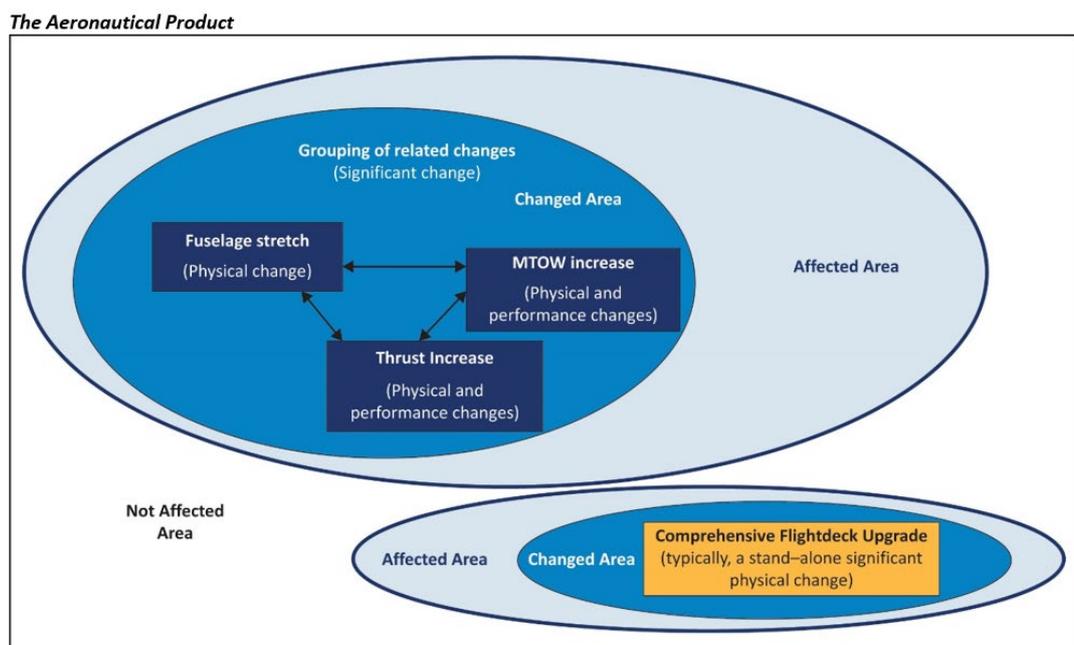


Figure 2 - Related and Unrelated Changes for Example of Increasing the Maximum Number of Passengers

3.5.2. Once the change(s) is (are) organised into groupings of those that are related and those that are unrelated (or stand-alone), an applicant should proceed to Step 5 below.

3.6. Step 5. Is each group of related changes or each unrelated (stand-alone) change a significant change?

3.6.1. The applicant is responsible for proposing the classification of groups of related changes or unrelated changes as 'significant' or 'not significant'. Significant changes are product-level changes that could result from an accumulation of changes, or occur through a single significant change that makes the changed product distinct from its baseline product. The grouping of related and unrelated changes is particularly relevant to the Authority's significant Yes/No decision (SIM-To-Lt-035 21.A.101(b)(1)) described in Step 1 of Figure 1. The Authority evaluates each group of related changes and each unrelated (stand-alone) change on its own merit for significance. Thus, there may be as many evaluations for significance as there are groupings of related and unrelated changes. Step 1 of Figure 1 explains the accumulation of changes that an applicant must consider. Additionally, SIM-To-Lt-035 21.A.101(b)(1) defines a change as 'significant' when at least one of the three automatic criteria applies:

3.6.1.1. Changes where the general configuration is not retained (significant change to general configuration).

A change to the general configuration at the product level is one that distinguishes the resulting product from other product models, for example, performance or interchangeability of major components. Typically, for these changes, an applicant will designate a new product model, although this is not required. For examples, see references provided in appendix A of this GM.

3.6.1.2. Changes where the principles of construction are not retained (significant change to principles of construction).

A change at the product level to the materials and/or construction methods that affects the overall product's operating characteristics or inherent strength and would require extensive reinvestigation to demonstrate compliance is one where the principles of construction are not retained. For examples, see references provided in appendix A of this GM.

3.6.1.3. Product-level changes that invalidate the assumptions used for certification of the baseline product.

Examples include:

- change of an aircraft from an unpressurised to pressurised fuselage,
- change of operation of a fixed-wing aircraft from land-based to water-based, and

- operating envelope expansions that are outside the approved design parameters and capabilities.

For additional examples, see references provided in appendix A of this GM.

3.6.2. The above criteria are used to determine whether each change grouping and each stand-alone change is significant. These three criteria are assessed at the product level. In applying the automatic criteria and the examples in appendix A of this GM, an applicant should focus on the change and how it impacts the existing product (including its performance, operating envelope, etc.). A change cannot be classified or reclassified as a significant change on the basis of the importance of a later amendment.

3.6.3. Appendix A of this GM includes references to tables of typical changes (examples) for various product classes (e.g. small aeroplanes, transport aeroplanes, rotorcraft, engines, and propellers) that would meet the criteria for a significant design change. These references also include tables of typical design changes that would not be classified as significant. The tables can be used in one of two ways:

3.6.3.1. To identify the classification of a proposed design change listed in the table, or

3.6.3.2. In conjunction with the three automatic criteria, to help classify a proposed design change not listed in the table by comparison to determinations made for changes with similar type and magnitude.

In any case, the final classification should be accepted by the Authority.

3.6.4. In many cases, a significant change may involve more than one of these criteria and will be obvious and distinct from other product improvements or production changes. There could be cases where a change to a single area, system, component, or appliance may not result in a product-level change. There could also be other cases where the change to a single system or component might result in a significant change due to its effect on the product overall. Examples may include the addition of winglets or leading-edge slats, or a change to primary flight controls of a fly-by-wire system.

3.6.5. If an unrelated (stand-alone) change or a grouping of related changes is classified as —

Significant (SIM-To-Lt-035 21.A.101(a)):

You must comply with the latest airworthiness codes or standards for certification of the change and areas affected by change, unless you justify use of one of the exceptions provided in SIM-To-Lt-035) 21.A.101(b)(2) or (3) to show compliance with earlier amendment(s). The final certification basis may consist of a combination of the requirements recorded in the certification basis ranging from the original aircraft certification basis to the most current regulatory amendments.

Not Significant (SIM-To-Lt-035 21.A.101(b)(1)):

You may comply with the existing certification basis unless the standards in the proposed certification basis are deemed inadequate. In cases where the existing certification basis is

inadequate or no regulatory standards exist, later requirements and/or special conditions will be required. See paragraph 3.11 of this GM for a detailed discussion.

3.6.6. A new model designation to a changed product is not necessarily indicative that the change is significant under SIM-To-Lt-035 21.A.101. Conversely, retaining the existing model designation does not mean that the change is not significant. Significance is determined by the magnitude of the change.

3.6.7. The Authority determines the final classification of whether a change is significant or not significant. To assist an applicant in its assessment, the Authority may predetermine the classification of several typical changes that an applicant could use for reference. Such examples are referred to in appendix A of this GM.

3.6.8. At this point, the determination of significant or not significant for each of the groupings of related changes and each stand-alone change is completed. For significant changes, an applicant that proposes to comply with an earlier airworthiness code or specification should use the procedure outlined in paragraph 3.7 below. For changes identified as not significant, see paragraph 3.8 below.

3.7. Proposing an amendment level for a significant change.

3.7.1. Without prejudice to the exceptions provided for in SIM-To-Lt-035 21.A.101(b) or (c), if the classification of a group of related changes or a stand-alone unrelated change is significant, all areas, systems, components, parts, or appliances affected by the change must comply with the airworthiness codes or specifications at the amendment level in effect on the date of application for the change, unless the applicant elects to comply with airworthiness codes or specifications that have become effective after that date (see SIM-To-Lt-035 21.A.101(a)).

3.7.2. In certain cases, an applicant will be required by the Authority to comply with airworthiness codes or specifications that have become effective after the date of application (see SIM-To-Lt-035 21.A.101(a)):

3.7.2.1. If an applicant elects to comply with a specific airworthiness code or specification or a subset of airworthiness codes or specifications at an amendment which has become effective after the date of application, the applicant must comply with any other airworthiness code or specification that the Authority finds is directly related (see SIM-To-Lt-035 21.A.101(f)).

3.7.2.2. In a case where the change has not been approved, or it is clear that it will not be approved under the time limit established, the applicant will be required to comply with an upgraded certification basis from airworthiness codes or specifications that have become effective since the date of the initial application.

3.7.3. Applicants can justify the use of one of the exceptions in SIM-To-Lt-035 21.A.101(b)(2) or (3) to comply with an earlier amendment, but not with an amendment introduced earlier than the existing certification basis. See paragraphs 3.9 and 3.10 of this GM. Applicants who elect to comply with a specific airworthiness code or specification or a subset of airworthiness codes or specifications at an earlier amendment will be required to comply with any other airworthiness code or specification that the Authority finds are directly related.

3.7.4. The final certification basis may combine the latest, earlier (intermediate), and existing airworthiness codes or specifications, but cannot contain airworthiness codes or specifications preceding the existing certification basis.

3.8. Proposing an amendment level for a not significant change.

3.8.1. When the Authority classifies the change as not significant, SIM-To-Lt-035 21.A.101(b) allows compliance with earlier amendments, but not prior to the existing certification basis. Within this limit, the applicant may propose an amendment level for each airworthiness code or specification for the affected area. However, each applicant should be aware that the Authority will review their proposals for the certification basis to ensure that the certification basis is adequate for the proposed change under Step 8. (See paragraph 3.11 of this GM.)

3.8.2. Even for a not significant change, an applicant may elect to comply with airworthiness codes or specifications which became applicable after the date of application. Applicants may propose to comply with a specific airworthiness code or specification or a subset of airworthiness codes or specifications at a certain amendment of their choice. In such a case, any other airworthiness codes or specifications of that amendment that are directly related should be included in the certification basis for the change.

3.9. Step 6. Prepare the proposed certification basis list.

As part of preparing the proposed certification basis list, an applicant must identify any areas, systems, parts or appliances of the product that are affected by the change and the corresponding certification specifications associated with these areas. For each group, the applicant must assess the physical and/or functional effects of the change on any areas, systems, parts or appliances of the product. The characteristics affected by the change are not only physical changes, but also functional changes brought about by the physical changes. Examples of physical aspects are structures, systems, parts and appliances, including software in combination with the affected hardware. Examples of functional characteristics are performance, handling qualities, aeroelastic characteristics, and emergency egress. The intent is to encompass all aspects where there is a need for re-evaluation, that is, where the substantiation presented for the product being changed should be updated or rewritten. Appendix H of this GM contains a reference to examples of how to document a proposed certification basis list.

3.9.1. An area affected by the change is any area, system, component, part, or appliance of the aeronautical product that is physically and/or functionally changed.

3.9.2. Figure 3 of this GM illustrates concepts of physical and functional changes of an affected area. Appendix C of this GM contains a reference to a method used by the European Union Aviation Safety Agency (EASA) to define the change and areas affected by the change. This Reference is meant to assist applicants when they propose large, complex changes. For each change, it is important for the applicant to properly assess the effects of such change on any areas, systems, parts or appliances of the product because areas that have not been physically changed may still be considered part of the affected area. If a new compliance finding is required, regardless of its amendment level, it is an affected area.

The Aeronautical Product

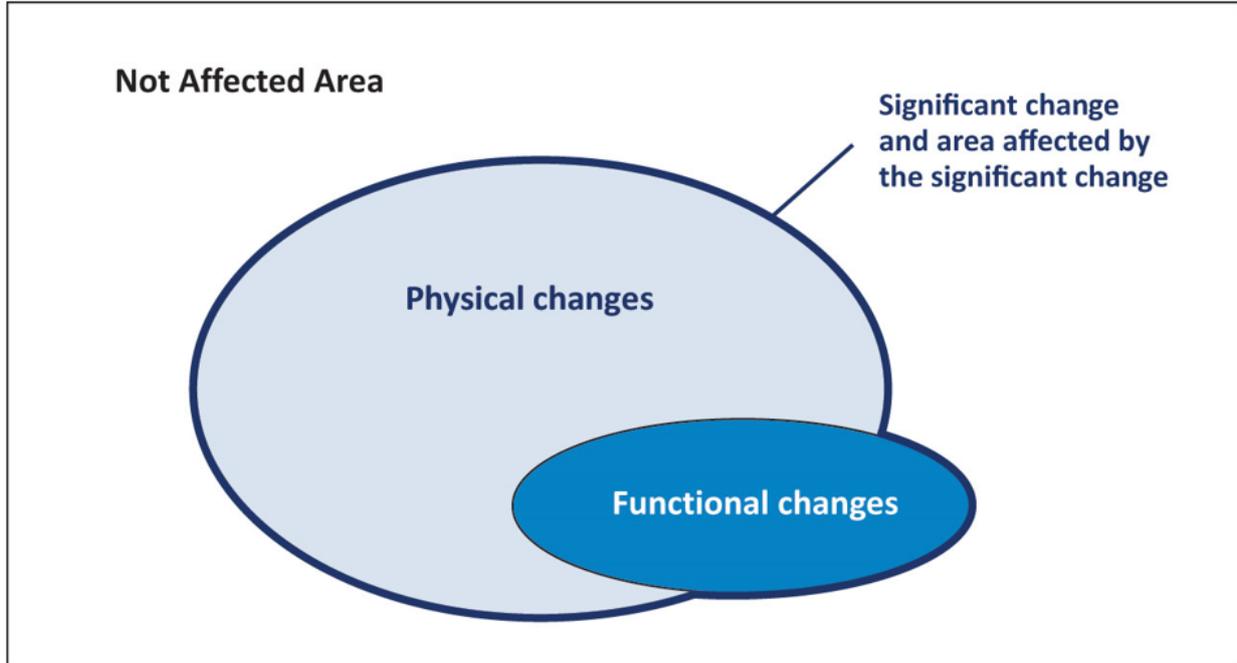


Figure 3 - Affected Areas versus Not Affected Areas

3.9.3. An area not affected by a change can remain at the existing certification basis, provided that the applicant presents to the Authority an acceptable justification that the area is not affected.

3.9.4. For sample questions to assist in determining affected areas, see paragraph D.1 of appendix D of this GM.

3.9.5. Consider the following aspects of a change: Physical aspects.

The physical aspects include direct changes to structures, systems, equipment, components, and appliances, and may include software/airborne electronic hardware changes and the resulting effects on systems functions.

3.9.5.1. Performance/functional characteristics.

The less obvious aspect of the word 'areas' covers general characteristics of the type-certified product, such as performance features, handling qualities, emergency egress, structural integrity (including load carrying), aeroelastic characteristics, or crashworthiness. A product-level change may affect these characteristics. For example, adding a fuselage plug could affect performance and handling qualities, and thus the airworthiness codes or standards associated with these aspects would be considered to be part of the affected area. Another example is the addition of a fuel tank and a new fuel conditioning unit. This change affects the fuel transfer and fuel quantity indication system, resulting in

the aircraft's unchanged fuel tanks being affected. Thus, the entire fuel system (changed and unchanged areas) may become part of the affected area due to the change to functional characteristics. Another example is changing turbine engine ratings and operating limitations, affecting the engine rotors' life limits.

3.9.6. All areas affected by the proposed change must comply with the latest airworthiness codes or standards, unless the applicant shows that demonstrating compliance with the latest amendment of an airworthiness code or standard would not contribute materially to the level of safety or would be impractical. Step 7 below provides further explanation.

3.9.7. The applicant should document the change and the area affected by the change using high-level descriptors along with the applicable air-worthiness codes or standards and their proposed associated amendment levels. The applicant proposes this change to the certification basis that the Authority will consider for documentation in the type certificate data sheet (TCDS) or STC, if they are different from that recorded for the baseline product in the TCDS.

3.10. Step 7. Do the latest airworthiness codes or standards contribute materially to the level of safety and are they practical?

Pursuant to SIM-To-Lt-035 21.A.101(a), compliance with the latest airworthiness codes or standards is required. However, exceptions may be allowed pursuant to SIM-To-Lt-035 21.A.101(b)(3). The applicant must provide justification to support the rationale for the application of earlier amendments for areas affected by a significant change in order to document that compliance with later airworthiness codes or standards in these areas would not contribute materially to the level of safety or would be impractical. Such a justification should address all the aspects of the area, system, part or appliance affected by the significant change. See paragraphs 3.10.1 and 3.10.1.4 of this GM.

3.10.1. Do the latest airworthiness codes or standards contribute materially to the level of safety?

Applicants could consider compliance with the latest airworthiness codes or standards to 'not contribute materially to the level of safety' if the existing type design and/or relevant experience demonstrates a level of safety comparable to that provided by the latest airworthiness codes or standards. In cases where design features provide a level of safety greater than the existing certification basis, applicants may use acceptable data, such as service experience, to establish the effectiveness of those design features in mitigating the specific hazards by a later amendment. Applicants must provide sufficient justification to allow the Authority to make this determination. An acceptable means of compliance is described in appendix E of this GM. Justification is sufficient when it provides a summary of the evaluation that supports the determination using an agreed evaluation method, such as that in appendix E of this GM. This exception could be applicable in the situations described in the paragraphs below.

Note: Compliance with later airworthiness codes or standards is not required where the amendment is of an administrative nature and made only to correct inconsequential errors or omissions, consolidate text, or to clarify an existing requirement.

3.10.1.1. Improved design features.

Design features that exceed the existing certification basis standards, but do not meet the latest airworthiness codes or standards, can be used as a basis for granting an

exception under SIM-To-Lt-035 21.A.101(b)(3) since complying with the latest amendment of the airworthiness codes or standards would not contribute materially to the level of safety of the product. If the Authority accepts these design features as justification for an exception, the applicant must incorporate them in the amended type design configuration and record them, where necessary, in the certification basis. The description of the design feature would be provided in the TCDS or STC at a level that allows the design feature to be maintained, but does not contain proprietary information. For example,¹ an applicant proposes to install winglets on a FAR-25 aeroplane, and part of the design involves adding a small number of new wing fuel tank fasteners. Assuming that the latest applicable amendment of FAR 25.981 is Amendment 25-102, which requires structural lightning protection, the applicant could propose an exception from these latest structural lightning protection requirements because the design change uses new wing fuel tank fasteners with cap seals installed. The cap seal is a design feature that exceeds the requirement of FAR 25.981 at a previous amendment level, but does not meet the latest Amendment 25-102. If the applicant can successfully substantiate that compliance with Amendment 25-102 would not materially increase the level of safety of the changed product, then this design feature can be accepted as an exception to compliance with the latest amendment.

3.10.1.2. Consistency of design.

This provision gives the opportunity to consider the consistency of design. For example, when a small fuselage plug is added, additional seats and overhead bins are likely to be installed, and the lower cargo hold extended. These components may be identical to the existing components. The level of safety may not materially increase by applying the latest airworthiness codes or standards in the area of the fuselage plug. Compliance of the new areas with the existing certification basis may be acceptable.

3.10.1.3. Service experience.

3.10.1.3.1. Relevant service experience, such as experience based on fleet performance or utilisation over time (relevant flight hours or cycles), is one way of showing that the level of safety will not materially increase by applying the latest amendment, so the use of earlier airworthiness codes or standards could be appropriate. Appendix F of this GM provides additional guidance on the use of service experience, along with examples.

3.10.1.3.2. When establishing the highest practicable level of safety for a changed product, the Authority has determined that it is appropriate to assess the service history of a product, as well as the later airworthiness codes or standards. It makes little sense to mandate changes to well-understood designs, whose service experience has been acceptable, merely to comply with new standards. The clear exception to this premise is if the new standards were issued to address a

¹ This example was used by the European Union Aviation Safety Agency (EASA) from the FAA experience gained prior to the establishment of EASA, therefore the references to the FAA sections and amendments are kept.

deficiency in the design in question, or if the service experience is not applicable to the new standards.

3.10.1.3.3. There may be cases where relevant data may not be sufficient or not available at all because of the low utilisation and the insufficient amount and type of data available. In such cases, other service history information may provide sufficient data to justify the use of earlier airworthiness codes or standards, such as: warranty, repair, and parts usage data; accident, incident, and service difficulty reports; service bulletins; airworthiness directives; or other pertinent and sufficient data collected by the manufacturers, authorities, or other entities.

3.10.1.3.4. The Authority will determine whether the proposed service experience levels necessary to demonstrate the appropriate level of safety as they relate to the proposed design change are acceptable.

3.10.1.4. Secondary changes.

3.10.1.4.1. The change proposed by the applicant can consist of physical and/or functional changes to the product. See Figure 4 below. There may be aspects of the existing type design of the product that the applicant may not be proposing to change directly, but that are affected by the overall change. For example, changing an airframe's structure, such as adding a cargo door in one location, may affect the frame or floor loading in another area. Further, upgrading engines with new performance capabilities could require additional demonstration of compliance for minimum control speeds and aeroplane performance requirements.

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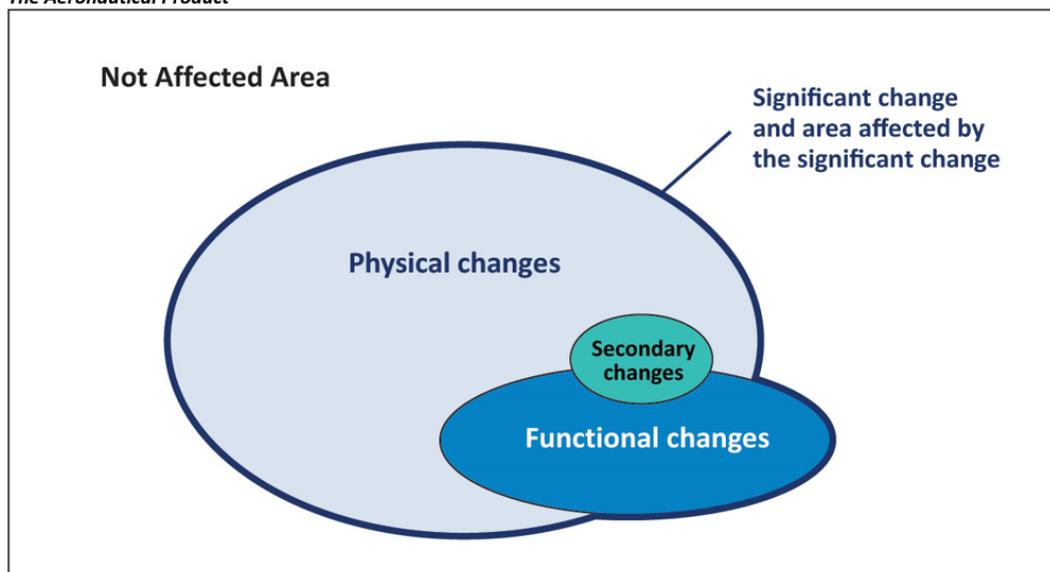


Figure 4 - Change-Affected Areas with Secondary Changes

- 3.10.1.4.2. For each change, it is important that the effects of the change on other systems, components, equipment, or appliances of the product are properly identified and assessed. The intent is to encompass all aspects where there is a need for re-evaluation, that is, where the substantiation presented for the product being changed should be reviewed, updated, or rewritten.
- 3.10.1.4.3. In assessing the areas affected by the change, it may be helpful to identify secondary changes. A secondary change is a change to physical and/or functional aspects that is part of, but consequential to, a significant physical change, whose only purpose is to restore, and not add or increase, existing functionality or capacity. The term 'consequential' is intended to refer to:
- a change that would not have been made by itself; it achieves no purpose on its own;
- a change that has no effect on the existing functionality or capacity of areas, systems, structures, components, parts, or appliances affected by the change; or
- a change that would not create the need for: (1) new limitations or would affect existing limitations; (2) a new aircraft flight manual (AFM) or instructions for continuing airworthiness (ICA) or a change to the AFM or ICA; or (3) special conditions, equivalent safety findings, or deviations.
- 3.10.1.4.4. A secondary change is not required to comply with the latest airworthiness codes or standards because it is considered to be 'not contributing materially to the level of safety' and, therefore, eligible for an exception under SIM-To-Lt-035 21.A.101. Determining whether a change meets the description for a secondary change, and is thus eligible for an exception, should be straightforward. Hence, the substantiation or justification need only be minimal. If this determination is not straightforward, then the proposed change is not a secondary change.
- 3.10.1.4.5. In some cases, a secondary area of change that restores functionality may in fact contribute materially to the level of safety by meeting a later amendment. If this is the case, it is not considered a secondary change.

3.10.2. Are the latest airworthiness codes or standards practical?

The intent of SIM-To-Lt-035 21.A.101 is to enhance safety by applying the latest airworthiness codes or standards to the greatest extent practicable. The concepts of contributing materially and practicality are linked. If compliance with the latest airworthiness codes or standards does contribute materially to the level of safety, then the applicant may assess the incremental costs to see whether they are commensurate with the increase in safety. The additional resource requirements could include those arising from changes required for compliance and the effort required to demonstrate compliance, but excluding resource expenditures for prior product changes. The cost of changing compliance documentation and/or drawings is not an acceptable reason for an exception.

- 3.10.2.1. Applicants should support their position that compliance is impractical with substantiating data and analyses. While evaluating that position and the substantiating data regarding impracticality, the Authority may consider other factors (e.g. the costs and safety benefits for a comparable new design).
- 3.10.2.2. The European Union Aviation Safety Agency (EASA) re-viewed large aeroplane projects. It was shown that, in certain cases where EASA allowed an earlier amendment of applicable EASA certification specifications (CS), the applicants made changes that nearly complied with the latest amendments. In these cases, the applicants successfully demonstrated that full compliance would require a substantial increase in the outlay or expenditure of resources with a very small increase in the level of safety. These design features can also be used as a basis for granting an exception under SIM-To-Lt-035 21.A.101(b)(3) on the basis of ‘impracticality.’
- 3.10.2.3. Appendix E of this GM provides additional guidance and examples for evaluating the impracticality of applying the latest airworthiness codes or standards to a changed product for which compliance with the latest airworthiness codes or standards would contribute materially to the level of safety of the product.

- 3.10.2.3.1. The exception of impracticality is a qualitative and quantitative cost–safety benefit assessment for which it is difficult to specify clear criteria. Experience from Authorities to date with applicants has shown that a justification of impracticality is more feasible when both the applicant and the Authority agree during a discussion at an early stage that the effort (in terms of cost, changes to manufacturing, etc.) required to comply would not be commensurate with a small incremental safety gain. This would be clear even without the need to perform any detailed cost–safety benefit analysis (although an applicant could always use cost analysis to support an appropriate amendment level). However, there should be enough detail in the applicant’s rationale to justify the exception.

Note: An applicant should not base an exception due to impracticality on the size of the applicant’s company or their financial resources. The applicant must evaluate the costs to comply with a later amendment against the safety benefit of complying with the later amendment.

- 3.10.2.3.2. For example, a complex redesign of an area of the baseline aircraft may be required to comply with a new requirement, and that redesign may affect the commonality of the changed product with respect to the design and manufacturing processes of the existing family of models. Relevant service experience of the existing fleet of the baseline aircraft family would be required to show that there has not been a history of problems associated with the hazard that the new amendment in question was meant to address. In this way, the incremental cost/impact to the applicant is onerous, and the incremental safety benefit realised by complying with the later amendment would be minimal. This would be justified by demonstrated acceptable service experience in relation to the hazard that the new rule addresses.

- 3.11. Step 8. Ensure the proposed certification basis is adequate.

The Authority considers a proposed certification basis for any change (whether it is significant or not significant) to be adequate when:

- the airworthiness codes or standards provide an appropriate level of safety for the intended change, and
- the change and the areas affected by the change do not result in unsafe design features or characteristics for the intended use.

3.11.1. For a change that contains new design features that are novel and unusual for which there are no later applicable airworthiness codes or standards at a later amendment level, the Authority will designate special conditions pursuant to EMAR 21.B.75. The Authority will impose later airworthiness codes or standards that contain adequate or appropriate safety standards for this feature, if they exist, in lieu of special conditions. An example is adding a flight-critical system, such as an electronic air data display on a EASA CS-25 large aeroplane whose existing certification basis does not cover protection against lightning and high-intensity radiated fields (HIRF). In this case, compliance with the EASA certification specifications for lightning and HIRF protection will be required, even though it has been determined that the change is not significant.

3.11.2. For new design features or characteristics that may pose a potential unsafe condition for which there are no later applicable airworthiness codes or standards, new special conditions may be required to address Authority. EMAR 21.B.107(a)(3) or 21.B.111(a)(3).

3.11.3. In cases where inadequate or no requirements exist for the change to the existing certification basis, but adequate requirements exist in a later amendment of the applicable airworthiness codes or standards, the later amendment will be made part of the certification basis to ensure the adequacy of the certification basis.

3.11.4. The Authority determines the final certification basis for a product change. This may consist of a combination of those requirements of applicable airworthiness codes or standards ranging from the existing certification basis of the baseline product to the latest amendments and special conditions.

4. Reserved

5. Other considerations

5.1. Design-related requirements from other aviation domains.

Some implementing rules in other aviation domains (air operations, ATM/ANS) (e.g. Commission Regulation (EU) No 965/2012 on air operations or Commission Regulation (EU) 2015/640 on additional airworthiness specifications for a given type of operations (Annex I (Part-26)) impose airworthiness standards that are not required for the issue of a TC or STC (e.g. EASA CS-26, EASA CS-ACNS, etc.). If not already included in the certification basis, any such applicable airworthiness standard may be added to the type certification basis by mutual agreement between the applicant and the Authority. The benefit of adding these airworthiness codes and standards to the type certification basis is to increase awareness of these standards, imposed by other implementing rules, during

design certification and future modifications to the aircraft. The use of exceptions under SIM-To-Lt-035 21.A.101(b) is not intended to alleviate or preclude compliance with operating regulations.

5.2. Reserved

5.3. Baseline product

A baseline product consists of one unique type design configuration, an aeronautical product with a specific, defined, approved configuration and certification basis that the applicant proposes to change. As mentioned in paragraph 3.2.1 of this GM, it is important to clearly identify the type design configuration to be changed. The Authority does not require an applicant to assign a new model name for a changed product. Therefore, there are vastly different changed products with the same aircraft model name, and there are changed products with minimal differences that have different model names. Since the assignment of a model name is based solely on an applicant's business decision, the identification of the baseline product, for the purposes of SIM-To-Lt-035 21.A.101, is, as defined below.

The baseline product is an approved type design that exists at the date of application and is representative of:

- a single certified build configuration, or
- multiple approvals over time (including STC(s) or service bulletins) and may be representative of more than one product serial number.

Note: The type design configuration, for this purpose, could also be based on a proposed future configuration that is expected to be approved at a later date but prior to the proposed changed product.

5.4. Reserved

5.5. Special conditions, SIM-To-Lt-035 21.A.101(d).

SIM-To-Lt-035 21.A.101(d) allows for the application of special conditions, or for changes to existing special conditions, to address the changed designs where neither the proposed certification basis nor any later airworthiness codes or standards provide adequate requirements for an area, system, part or appliance related to the change. The objective is to achieve a level of safety consistent with that provided for other areas, systems, parts or appliances affected by the change by the other airworthiness codes or standards of the proposed certification basis. The application of special conditions to a design change is not, in itself, a reason to classify it as either a substantial change or a significant change. Whether the change is significant, with earlier airworthiness codes or standards allowed through exceptions, or not significant, the level of safety intended by the special conditions must be consistent with the agreed certification basis.

5.6. Reserved.

5.7. Reserved.

5.8. Reserved.

5.9. Documentation.

5.9.1. Documenting the proposal.

In order to efficiently determine and agree upon a certification basis with the Authority, the following information is useful to understand the applicant's position:

- The current certification basis of the product being changed, including the amendment level.
- The amendment level of all the applicable airworthiness codes or standards at the date of application.
- The proposed certification basis, including the amendment levels.
- Description of the affected area.
- Applicants who propose a certification basis that includes amendment levels earlier than what was in effect at the date of application should include the exception as outlined in SIM-To-Lt-035 21.A.101(b) and their justification if needed.

Please see appendix H for examples of optional tools an applicant can use to document your proposed certification basis.

5.9.2. Documenting the significant/not significant decision.

5.9.2.1. The Authority determines and documents whether the changes are significant or not significant. However, applicants could make a written predetermination to facilitate the Authority's decision. Such document should follow the flow chart in Figure 1 of this GM and should be submitted along with the certification plan. Appendix G provides further guidance on the document content and structure expected by the Authority.

5.9.2.2. Changes that are determined to be significant changes under SIM-To-Lt-035 21.A.101, the exceptions, and the agreement of affected and unaffected areas are typically documented through the Certification Review Item (CRI) A-01 process. An example tool is provided in appendix H of this GM. Appendix H refers to further guidance on the documentation of changes that are determined to be significant changes under SIM-To-Lt-035 21.A.101, the exceptions, and the agreement of affected and unaffected areas.

5.9.3. Documenting the certification basis.

5.9.3.1. The Authority will amend the certification basis for all changes that result in a revision to the product's certification basis on the amended TCDS or STC. In case of a significant change, the Authority will document the resulting certification basis (e.g. EASA CRI-A-01).

5.9.3.2. The Authority will document the certification basis of each product model on all STCs, including approved model list STCs.

5.10. Incorporation of STCs into the Type Design.

The incorporation of STCs into the product type design may generate an additional major change when that change is needed to account for incompatibility between several STCs that were initially not intended to be applied concurrently.

- 5.10.1. If the incorporation of the STC(s) does not generate an additional major change, the incorporation is not evaluated pursuant to SIM-To-Lt-035 21.A.101. The existing certification basis should be updated to include the later amendments of the STC(s) being incorporated.
- 5.10.2. If the incorporation of the STC(s) generates an additional major change, the change must be evaluated pursuant to SIM-To-Lt-035 21.A.101, and the existing certification basis should be updated to include the amendments resulting from the application of SIM-To-Lt-035 21.A.101.

5.11. Removing changes.

Approved changes may be removed after incorporation in an aeronautical product. These changes will most commonly occur via an STC or a service bulletin kit.

- 5.11.1. The applicant should identify a product change that they intend at its inception to be removable as such and should develop instructions for its removal during the initial certification. The Authority will document the certification basis for both the installed and removed configuration separately on the TCDS or STC.
- 5.11.2. If specific removal instructions and a certification basis corresponding to the removed condition are not established at the time of the initial product change certification, the removal of changes or portions of those changes may constitute a significant change to type design. A separate STC or an amended TC may be required to remove the modifications and the resulting certification basis established for the changed product.

5.12. The certification basis is part of the change.

A new change may be installed in a product during its production or via a service bulletin or STC. In terms of SIM-To-Lt-035 21.A.101, each of the approved changes has its own basis of certification. If an applicant chooses to remove an approved installation (e.g. an interior installation, avionics equipment) and install a new installation, a new certification basis may be required for the new installation, depending on whether the change associated with the new installation is considered significant compared to the baseline configuration that the applicant chooses. If the new installation is a not significant change, the unmodified product's certification basis may be used (not the previous installation certification basis), provided the certification basis is adequate.

For example, a large aeroplane is certified by EASA in a 'green' configuration. The aeroplane certification basis does not include EASA CS 25.562. An interior is installed under an STC, and the applicant elects to include EASA CS 25.562 (dynamic seats) in the certification basis to meet specific operational requirements. Later, the aeroplane is sold to another operating organisation who does not have the same operational requirements. A new interior is installed; there will be no requirement for EASA CS 25.562 to be included in the new certification basis.

5.13. Sequential changes — cumulative effects.

- 5.13.1. Any applicant who intends to accomplish a product change by incorporating several changes in a sequential manner should identify this to the Authority up front when the first application is made. In addition, the cumulative effects arising from the initial change, and from all

of the follow-on changes, should be included as part of the description of the change in the initial proposal. The classification of the intended product change will not be evaluated solely on the basis of the first application, but rather on the basis of all the required changes needed to accomplish the intended product change. If the Authority determines that the current application is a part of a sequence of related changes, then it will re-evaluate the determination of significance and the resulting certification basis as a group of related changes.

5.13.2. Example: Cumulative effects — advancing the certification basis.

The type certificate for aeroplane model X lists three models, namely X-300, X-200, and X-100. The X-300 is derived from the X-200, which is derived from the original X-100 model. An applicant proposes a change to the X-300 aeroplane model. During the review of the X-300 certification basis and the requirements of airworthiness codes or standards affected by the proposed change, it was identified that one requirement, EASA CS 25.571 (damage tolerance requirements), remained at the same amendment level as the X-100 original certification basis (exception granted on the X-200). Since the amendment level for this particular code was not changed for the two subsequent aero-plane models (X-200 and X-300), the applicant must now examine the cumulative effects of these two previous changes that are related to the proposed change and the damage tolerance requirements to determine whether the amendment level needs to advance.

Appendix A to GM 21.A.101 Classification of design changes

Appendix A to EASA GM 21.A.101 Classification of design changes, as per ED Decision 2017/024/R contains tables of 'substantial', 'significant', and 'not significant' changes, that are adopted by the FAA, Agência Nacional de Aviação Civil (ANAC), the European Aviation Safety Agency (EASA), and Transport Canada Civil Aviation (TCCA) through international collaboration. These tables should be used as a reference for the classification of design changes to military aircraft. In any case, the aircraft category to be used should be confirmed by the Authority and the final classification may change due to cumulative effects and/or combinations of individual changes.

Appendix B to GM 21.A.101 Application charts for changed product rule

This appendix contains the application chart for applying the SIM-To-Lt-035 21.A.101 process.

Substantial (21.A.19)	Significant (21.A.101(a) and (b))			Not Significant (21.A.101)(b)(1))		
<p>Substantially changed product Compliance with all latest airworthiness codes and standards required for product certification. Previously approved type design and compliance data may be allowed if valid for the changed product.</p>	<p>Affected area (Changed and/or affected areas) New demonstration of compliance is required Previously approved type design and compliance data may be allowed if valid for the changed product.</p>		<p>Unaffected area No new demonstration of compliance is required. Unaffected area continues to comply with the existing certification basis.</p>	<p>Affected area (Changed and/or affected areas) New demonstration of compliance is required. The applicant may propose a certification basis using an earlier amendment but not earlier than in the existing TC basis. Previously approved type design and compliance data may be allowed if valid for the changed product.</p>		<p>Unaffected area No new demonstration of compliance is required. Unaffected area continues to comply with the existing certification basis.</p>
	<p>Compliance with the latest amendment materially contributes to safety</p>			<p>No material contribution to safety</p>		
	<p>Practical —</p>	<p>Impractical The applicant may propose a certification basis using earlier airworthiness codes and standards, but not earlier than the existing TC basis.</p>		<p>The applicant may propose a certification basis using earlier airworthiness codes and standards, but not earlier than the existing TC basis.</p>		
	<p>Certification Basis Proposed by the Applicant</p>					
<p>New certification basis using latest airworthiness codes and standards.</p>	<p>Airworthiness codes and standards at earlier amendments with supporting rationale.</p>		<p>Existing certification basis.</p>	<p>Existing certification basis including 'elects to comply'.</p>	<p>Existing certification basis.</p>	
<p>Resultant Type-Certification Basis, subject to acceptance by the Authority</p>						
<p>New certification basis using the latest airworthiness codes and standards, and special conditions if required.</p>	<p>New certification basis using the airworthiness codes and standards at earlier approved amendments, and special conditions if required.</p>		<p>Existing certification basis.</p>	<p>Existing certification basis (if adequate); if not, first appropriate later amendment(s) and/or special conditions including 'elects to comply'.</p>		<p>Existing certification basis.</p>

Appendix C to GM 21.A.101 A method to determine the changed and affected areas

When a product is changed, some areas may change physically, while others may change functionally. GM 21.A.101 refers to this combination as changed and affected areas. Appendix C to EASA GM 21.A.101 as per ED Decision 2017/024/R contains a process to determine physical and functional changes, including affected areas, and to develop the combined list of physical and functional changes with applicable requirements of airworthiness codes or standards. In principle, this process may also be applied where airworthiness codes and standards other than EASA Certification Specifications (CS) are used.

Appendix D to GM 21.A.101 Other guidance for affected areas

D.1 Sample Questions in Determining Affected Areas.

Below are sample questions to assist in determining whether an area is affected by the change. If the answer to any of these questions is yes, then the area is considered to be affected.

1. Is the area changed from the identified baseline product?
2. Is the area impacted by a significant product-level change?
3. Is there a functional effect on the unchanged area by a change to the system or system function that it is a part of?
4. Does the unchanged area need to comply with a system or product-level airworthiness code or standard that is part of the change?
5. Are the product-level characteristics affected by the change?
6. Is the existing compliance for the area invalidated?

D.2 Sub-Areas within an Affected Area.

Within areas affected by a change, there may be 'sub-areas' of the area that are not affected. For those sub-areas, the amendment levels at the existing certification basis remain valid, along with the previous compliance findings.

For example, if a passenger seat fitting is changed as part of a significant change, then the structure of the seat is affected. Thus, the amendment level for all applicable structural requirements (e.g. EASA CS 25.561 and EASA CS 25.562) would be at the amendment level on the date of application (unless an exception is granted). However, the seat fabric is not affected, so the amendment level of flammability requirements (e.g.

EASA CS 25.853) may remain at the existing certification basis, and a new compliance finding would not be required.

Appendix E to GM 21.A.101 Procedure for evaluating material contribution to safety or impracticality of applying latest airworthiness codes to a changed product

Appendix E to EASA GM 21.A.101 as per ED Decision 2019/018/R proposes a procedure for evaluating material contribution to safety or impracticality of applying latest airworthiness codes to a changed product and could be applied for military products, regardless of the airworthiness codes or standards used.

Appendix F to GM 21.A.101 The use of service experience in the exception process

F.1 Introduction.

Service experience may support the application of an earlier airworthiness codes or standards pursuant to SIM-To-Lt-035 21.A.101(b)(3) if, in conjunction with the applicable service experience and other compliance measures, the earlier airworthiness code or standard provides a level of safety comparable to that provided by the latest airworthiness codes or standards. The applicant must provide sufficient substantiation to allow the Authority to make this determination. A statistical approach may be used, subject to the availability and relevance of data, but sound engineering judgment must be used. For service history to be acceptable, the data must be both sufficient and pertinent. The essentials of the process involve:

- A clear understanding of the change of the airworthiness code or standard, and the purpose for the change,
- A determination based on detailed knowledge of the proposed design feature,
- The availability of pertinent and sufficient service experience data, and
- A comprehensive review of that service experience data.

In case that civil service experience is used in the process, military specific kinds of operations and operational conditions must be sufficiently addressed and factored in. Similarly, it needs to be ensured that service experience from different operating organisations is relevant or representative for the intended use.

F.2 Guidelines.

The substantiation by the applicant and the determination by the Authority should be documented together with the type-certification basis.

Note: Special conditions (SCs), equivalent safety findings (ESFs) / equivalent level of safety (ELOSs), deviations, reversions, and most elects to comply (ETC) are formally part of the type-certification basis (TCB). A process like the Certification Review Item (CRI) process of the European Union Aviation Safety Agency (EASA) may be used to keep record of the applicant's substantiation and the Authority's determination, either as a stand-alone CRI or included in the type-certification basis CRI A-01.

The documentation provided by the applicant should support the following:

- F.2.1 The identification of the differences between the airworthiness codes or standards in the existing basis and the airworthiness codes or standards as amended, and the effect of the change to the requirements.
- F.2.2 A description as to what aspect(s) of the latest airworthiness codes or standards the proposed changed product would not meet.
- F.2.3 Evidence showing that the proposed certification basis for the changed product, together with applicable service experience, relative to the hazard, provides a level of safety that approaches the latest airworthiness codes or standards, yet is not fully compliant with the latest airworthiness codes or standards.
- F.2.4 A description of the design feature and its intended function.
- F.2.5 Data for the product pertinent to the requirement.
 - F.2.5.1 Service experience from such data sources, such as:
 - Accident reports,
 - Incident reports,
 - Service bulletins,
 - Airworthiness directives,
 - Repairs,
 - Modifications,
 - Flight hours/cycles for fleet leader and total fleet,
 - World airline / operating organisation accident summary data,
 - Service difficulty reports,
 - Accident Investigation Board reports, and
 - Warranty, repair, and parts usage data.
 - F.2.5.2 Show that the data presented represent all relevant service experience for the product, including the results of any operator surveys, and is comprehensive enough to be representative.
 - F.2.5.3 Show that the service experience is relevant to the hazard.

F.2.5.4 Identification and evaluation of each of the main areas of concern with regard to:

- Recurring and/or common failure modes,
- Cause,
- Probability by qualitative reasoning, and
- Measures already taken and their effects.

F.2.5.5 Relevant data pertaining to aircraft of similar design and construction may be included.

F.2.5.6 Evaluation of failure modes and consequences through analytical processes. The analytical processes should be supported by:

- A review of previous test results,
- Additional detailed testing as required, or
- A review of aircraft functional hazard assessments (FHA) and any applicable system safety assessments (SSA) as required.

F.2.6 A conclusion that draws together the data and the rationale.

F.2.7 These guidelines are not intended to be limiting, either in setting the required minimum elements or in precluding alternative forms of submission. Each case may be different, based on the particulars of the system being examined and the requirement to be addressed.

F.3 Example: EASA CS/FAA FAR.25.1141(f) for Transport Category Aeroplanes.

NOTE: This example is taken from the certification experience of the Federal Aviation Administration (FAA), so references to FAR sections and amendments are kept.

F.3.1 The following example, for transport category aeroplanes (§ 25.1141(f), APU Fuel Valve Position Indication System), illustrates the typical process an applicant follows. The process will be the same for all product types.

F.3.2 This example comes from a derived model transport aeroplane where significant changes were made to the main airframe components, engines and systems, and APU. The baseline aeroplane has an extensive service history. The example shows how the use of service experience supports a finding that compliance with the latest certification specifications would not contribute materially to the level of safety and that application of the existing certification basis (or earlier amendment) would be appropriate. The example is for significant derived models of transport aeroplanes with extensive service history. It illustrates the process, following the guidelines in this Appendix, but does not include the level of detail normally required.

F.3.2.1 Determine the differences between the certification specifications applied in the original certification basis and the latest certification specification, and the effect of the change to the certification specifications. The original certification basis of the aeroplane that is being changed is the initial release of Part 25. Amendment 25-40 added requirement § 25.1141(f), which mandates that power-assisted valves

must have a means to indicate to the flight crew when the valve is in the fully open or closed position, or is moving between these positions. The addressed hazard would be risk of APU fire due to fuel accumulation caused by excessive unsuccessful APU start attempts.

- F.3.2.2 What aspect of the proposed changed product would not meet the latest certification specifications? The proposed APU fuel valve position indication system does not provide the flight crew with fuel valve position or transition indication and, therefore, does not comply with the requirements of § 25.1141(f).
- F.3.2.3 The applicant provides evidence that the proposed certification basis for the changed product, together with applicable service experience of the existing design, provide a level of safety that approaches, yet is not fully compliant with, the latest certification specifications. The APU fuel shut-off valve and actuator are unchanged from those used on the current family of aeroplanes, and have been found to comply with the earlier Amendment 25-11 of § 25.1141. The existing fleet has achieved approximately (#) flights during which service experience of the existing design has been found to be acceptable. If one assumes a complete APU cycle, i.e. start-up and shutdown for each flight, the number of APU fuel shut-off valve operations would be over 108 cycles, which demonstrates that the valve successfully meets its intended function and complies with the intent of the certification specification.
- F.3.2.4 The applicant provides a description of the design feature and its intended function. The fuel shut-off valve, actuator design, and operation is essentially unchanged with the system design ensuring that the valve is monitored for proper cycling from closed to open at start. If the valve is not in the appropriate position (i.e. closed), then the APU start is terminated, an indication is displayed on the flight deck, and any further APU starts are prevented. Design improvements using the capability of the APU electronic control unit (ECU) have been incorporated in this proposed product change. These design changes ensure that the fuel valve indication system will indicate failure of proper valve operation to the flight crew, and these features increase the level of functionality and safety, but the system does not indicate valve position as required by § 25.1141(f).
- F.3.2.5 The FAA and the applicant record this in an issue paper. The FAA can use the G-1 or a technical issue paper for this purpose. An issue paper was coordinated, included data, or referenced reports documenting relevant service experience compiled from incident reports, fleet flight hour/cycle data, and maintenance records. The issue paper also discussed existing and proposed design details, failure modes, and analyses showing to what extent the proposed aeroplane complies with the latest amendment of § 25.1141. Information is presented to support the applicant's argument that compliance with the latest amendment would not materially increase the level of safety. Comparative data pertaining to aircraft of similar design and construction are also presented.

- F.3.2.6 The conclusion, drawing together the data and rationale, is documented in the G-1 issue paper. The additional features incorporated in the APU fuel shut-off valve will provide a significant increase in safety to an existing design with satisfactory service experience. The applicant proposes that compliance with the latest amendment would not materially increase the level of safety and that compliance with § 25.1141 at Amendment 25-11 would provide an acceptable level of safety for the proposed product change.

Appendix G to GM 21.A.101 Changed product rule (CPR) decision record

The changed product rule (CPR) decision should be recorded following the instructions and templates provided by the Authority. In case that no template is available, Appendix G to EASA GM 21.A.101 as per ED Decision 2017/024/R should be used to determine the general structure and information that is expected for a changed product rule (CPR) decision record.

Generally, the decision sheet should

- identify the project,
- identify the related TC/STC No,
- document each step of the process outlined in GM to 21.A.101 with appropriate justification and decision (YES/NO),
- detail the reference to the proposed certification basis to be accepted by the Authority.

Appendix H to GM 21.A.101 Examples of documenting the proposed certification basis list

Appendix H to EASA GM 21.A.101 as per ED Decision 2017/024/R provides examples for establishing the applicable airworthiness and OSD codes or standards that will become part of the type-certification basis for airworthiness or OSD certification basis as well as for documenting a proposed certification basis.

Appendix I to GM 21.A.101 Related documents

I.1 Related SIM-To-Lt-035 requirements.

- 21.A.15, Application

- 21.A.19, Changes requiring a new type certificate
- 21.A.31, Type design
- 21.A.41, Type certificate
- 21.A.91, Classification of changes to a type certificate
- 21.A.93, Application
- 21.A.97, Requirements for approval of a major change
- 21.A.101, Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate
- 21.A.113, Application for a supplemental type-certificate
- 21.A.115, Requirements for approval of major changes in the form of a supplemental type-certificate

Appendix J to GM 21.A.101 Definitions and terminology

J.1 Aeronautical product.

The terms 'aeronautical product' or 'product' used in this guidance material include type-certified aircraft, engines, or propellers and, for the purpose of this GM, an MTSOA'd APU.

J.2 Assumptions used for certification.

The assumptions used for certification are the evaluations and decisions that led to the approval of the baseline product's characteristics. Examples of the product's baseline characteristics include but are not limited to the following:

- Design methodologies, methods of compliance, and standards used to achieve compliance with the airworthiness codes or standards making up the certification basis;
- Structural, mechanical, electrical, propulsion, aerodynamic, performance, operational, and maintenance characteristics;
- Operational and flight envelopes defining the product performance and capabilities at specified weights, speeds, altitudes, load factors, and centres of gravity;
- Crashworthiness;
- Role or mission;
- Airworthiness and operational limitations; or
- Pilot training, if necessary.

J.3 Baseline product.

It is an aeronautical product with a specific, defined approved configuration and certification basis that the applicant proposes to change.

J.4 Certification basis.

The combination of the:

- airworthiness codes or standards
- OSD certification codes or standards
- environmental protection requirements as established for the change according to SIM-To-Lt-035 21.A.101, as well as the:
- special conditions (SC);
- equivalent safety findings (ESF);
- elects to comply (ETC); and
- deviations, applicable to the product to be certified.

J.5 Change.

The term ‘change’ refers to a change to a product type-certificate (as defined in SIM-To-Lt-035 21.A.41) approved or to be approved under Subpart D or Subpart E (as a supplemental type-certificate) of SIM-To-Lt-035, including a change to an STC or a change to the MTSOA for auxiliary power units (APUs) under Subpart O. A change may consist of a single stand-alone change to one TC component or several interrelated changes to different TC components (e.g. the type design, operating characteristics, OSD, environmental protection characteristics, etc. (see SIM-To-Lt-035 21.A.41 and GM to SIM-To-Lt-035 21.A.90A)).

J.6 Design change.

The term ‘design change’ refers to a change to the type design (as defined in SIM-To-Lt-035 21.A.31) of an aeronautical product. In the context of this document, the terms ‘change to the type design’, ‘modification’, ‘design change’, and ‘type design change’ are synonymous.

J.7 Earlier standards.

The airworthiness codes or standards in effect prior to the date of application for the change, but not prior to the existing certification basis.

J.8 Existing certification basis.

The airworthiness codes or standards incorporated by reference in the type certificate of the baseline product to be changed.

J.9 Latest standards.

The airworthiness codes or standards in effect on the date of application for the change.

J.10 Previous relevant design changes.

Previous design changes, the cumulative effect of which could result in a product significantly or substantially different from the original product or model, when considered from the last time the latest standards were applied.

J.11 Product-level change.

A change or combination of changes that makes the product distinct from other models of the product (e.g. range, payload, speed, design philosophy). Product-level change is defined at the aircraft, aircraft engine, or propeller level of change.

J.12 Secondary change.

A change that is part of a significant physical change that does not contribute materially to the level of safety. Guidance is contained in paragraph 3.10.1.4 of GM 21.A.101.

J.13 Significant change.

A change to the type certificate to the extent that it changes one or more of the following, but not to the extent to be considered a substantial change: the general configuration, principles of construction, or the assumptions used for certification. The significance of the change is considered in the context of all previous relevant design changes and all related revisions to the applicable standards. Not all product-level changes are significant.

J.14 Significant change to area.

not used in the context of SIM-To-Lt-035

J.15 Substantial change.

A change that is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required, and consequently a new type-certificate is required pursuant to SIM-To-Lt-035 21.A.19.

GM No 1 to 21.A.101(g) Establishment of the operational suitability data (OSD) certification basis for changes to type certificates (TCs)

This GM provides guidance on the application of SIM-To-Lt-035 21.A.101(g) in order to determine the applicable OSD certification basis in accordance with SIM-To-Lt-035 21.A.101(a), (b), (d), (e) and (f) for major changes to the OSD of type-certified aircraft.

1. Minor changes

Minor changes to the OSD are automatically outside the scope of SIM-To-Lt-035 21.A.101. See GM 21.A.95 for their certification basis.

2. Major changes

- a) If the design change that triggered the change to the OSD constituent is classified as non-significant, the change to the OSD constituent is also non-significant.
- b) If the design change that triggered the change to the OSD constituent is classified as significant, the change to the OSD constituent should comply with the latest amendment of the applicable airworthiness codes or standards (e.g. EASA certification specifications for OSD, such as CS-MMEL), unless the exceptions of SIM-To-Lt-035 21.A.101(b)(3) apply or unless the OSD change can be classified as minor as per SIM-To-Lt-035 21.A.91. The guidance of GM 21.A.101 Section 3.10 regarding the exceptions 'impractical' and 'not contributing materially to the level of safety', can be applied by analogy and as far as it is applicable to OSD changes.
- c) Stand-alone changes to an OSD constituent are considered to be non-significant.
- d) When a new OSD constituent is added or required to be added, it should comply with the latest amendment of the applicable airworthiness codes or standards.
- e) Reserved.
- f) Reserved.
- g) Reserved.

Note: Refer to GM No 1 to 21.A.15(d) for the applicability of the OSD to other-than-complex motor-powered aircraft.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

- a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.
- b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

SUBPART E - MILITARY SUPPLEMENTAL TYPE-CERTIFICATES

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b)
Flight Test Operations Manual (FTOM)

1. General

- a) Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

- b) Format

The FTOM may:

- be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (ADOA)¹ documents, or
- be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

- c) Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

- a) Exposition (not applicable in the case of ADOA)¹:

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

- b) Risk and safety management:

¹ Also referred to as APDOA by EASA

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c) Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d) Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e) Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f) Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

i. documents associated with a Flight Test Programme:

– Flight Order for a given flight, which should include:

- a list of the tests to be performed and associated conditions;
- safety considerations relevant to the flight;
- category of the flight (e.g. Category 1);
- composition of the crew;
- names of persons other than crew members;
- aircraft configuration items relevant to the test to be highlighted to the crew;
- loading of the aircraft;

- reference to approved flight conditions; and
 - restrictions relevant to the flight to be highlighted to the crew.
- Flight crew report.
- ii. documentation and information to be carried on the aircraft during flight test;
 - iii. record-keeping: the FTOM should describe the policy relative to record-keeping.
- g) Permit to fly:
- The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.
- h) Currency and training:
- The FTOM should describe how training for flight test is organised.
- Currency of the flight test crew may be ensured either through recent experience or refresher training.
- The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.
- A system should be established to record the currency of the flight test crew's training.

AMC 21.A.112B (d) Alternative Demonstration

In some countries, a government organisation is approved by the Authority to execute the Military Supplemental Type Certificate Holder's (MSTCH) responsibilities. This government organisation may apply for a military supplemental type certificate, without being the original design organisation. In this case, the government organisation should, in accordance with SIM-To-Lt-035 21.A.2, enter an agreement with a design organisation which has access to the Type Design data to ensure the undertaking of specific actions and obligations. Alternative procedures (refer to SIM-To-Lt-035 21.A.14(b)) for establishing a Design Assurance System to fulfil the obligations required under SIM-To-Lt-035 21.A.118A must be acceptable to the Authority.

GM to 21.A.112B Demonstration of capability for supplemental type-certificate (STC) cases

See also AMC 21.A.14(b) for the details of the alternative procedures.

AMC&GM
ACCEPTABLE MEANS OF COMPLIANCE AND GUIDANCE MATERIAL TO
SIM-To-Lt-035 (FIN EMAR 21)

The following examples of major changes to type design (ref.: SIM-To-Lt-035 21.A.91) are classified in two groups. Group 1 contains cases where a design organisation approved under SIM-To-Lt-035 Subpart J ('Subpart J DOA') should be required, and Group 2 cases where the alternative procedure to design organization approval may be accepted. They are typical examples, taken from EASA GM1 to 21.A.112B, but each STC case should be addressed on its merits and there would be exceptions in practice. This classification is valid for new STCs, not for evolution of STCs, and may depend upon the nature of the STC (complete design or installation).

Product	Discipline	Kind of STC	Group
All aircraft			
	OSD		
		Major stand-alone change to any OSD constituent	1
Small Aircraft, e.g. EASA CS-23 (products where a Subpart J DOA is required for TC)			
Notes:			
1) An STC which leads to a reassessment of the loads on large parts of the primary structure should be in Group 1.			
2) '2/1' means that an assessment of consequences in terms of handling qualities, performance or complexity of demonstration of compliance may lead to classification in Group 1.			
	Aircraft		
		Conversion to tail wheel configuration	1
		Auxiliary fuel tank installations	2/1
		Glass fibre wing tips	2/1
		Fairings: nacelle, landing gear	2
		Gap seals: aileron, flap, empennage, doors	2
		Vortex generators	2/1
		Spoiler installation	1
		Increase in MTOW	1
	Structures		
		Stretcher installation	2
		Change to seating configuration	2
		Windshield replacement (heated, single piece, etc.)	2
		Lightweight floor panels	2
		Ski installations	2/1
	Propulsion		
		Engine model change	1
		Fixed pitch propeller installation	2
		Constant speed propeller installation	2/1
		Installation of exhaust silencer	2
		Installation of graphic engine monitor	2
		Installation of fuel flow meter	2
		Accessory replacement (alternator, magnetos, etc.)	2
		Inlet modifications: oil cooler; induction air	2

AMC&GM
ACCEPTABLE MEANS OF COMPLIANCE AND GUIDANCE MATERIAL TO
SIM-To-Lt-035 (FIN EMAR 21)

Product	Discipline	Kind of STC	Group
	Equipment		
		Avionics upgrades (EFIS, GPS, etc.)	2/1
		Engine instrument replacements	2
		Carburettor ice detection system	2
		Autopilot system installation	1
		Wing tip landing light; recognition lights	2
		WX radar installation	2
		Aeromedical system installations	2
		De-icing and anti-icing system installations	1
		Emergency power supply installations	2
Large aircraft, e.g. EASA CS-25			
	Cabin Safety		
<u>Note:</u> Basically, all changes related to cabin configuration should be in Group 2.		Cabin layout (installation of seats (16G), galleys, single class or business / economy class, etc.)	2
		Floor path marking	2
		Crew rest compartment	1
		Change of cargo compartment classification (from class D to class C)	1
	Structure		
<u>Note:</u> An STC which leads to a reassessment of the loads on large parts of the primary structure should be in Group 1.		Cargo door	1
		Change from passenger to freighter configuration	1
	Avionics		
<u>Notes:</u> For large aircraft, the existence of an (M)TSO is not taken into account for the classification. The impact on aircraft performance, and influence of aircraft performance are criteria to assess the classification. Subjective assessment of human factors is considered for determination of the classification.		CVR	2
		VHF	2
		NAV (ADF, VOR, GPS, BRNAV)	2
		Autopilot, HUD, EFIS, FMS	1
		DFDR	2/1
		Meteo radar	2
		ILS Cat 3	1
		RVSM	1
		TCAS, EGPWS	1
		GPWS	2

AMC&GM
ACCEPTABLE MEANS OF COMPLIANCE AND GUIDANCE MATERIAL TO
SIM-To-Lt-035 (FIN EMAR 21)

Product	Discipline	Kind of STC	Group
	Powerplant		
		Auxiliary fuel tanks	1
		Thrust reverser system	1
		Hushkit	1
		Fire detection	1
		Fuel gauging	1
		Change of engine or propeller	1
Helicopters, e.g. EASA CS-27 or CS-29	All disciplines		
<u>Note:</u> 2/1 means that an assessment of consequences in terms of handling qualities and performance may lead to classification in Group 1.		Replacement of main rotor or tail rotor blades	1
		Autopilot	1
		Engine type change	1
		GPS installation	2
		Jettisonable overhead raft installation	2
		Utility basket installation	2/1
		Nose or side mount camera installation	2/1
		Passenger access step installation	2/1
		Protection net & handle installation (parachuting)	2
		VIP cabin layout	2
		Navigation system installation	2
		Fuel boost pump automatic switch-on installation	2
		Decrease of maximum seating capacity	2
		Agricultural spray kit installation	2/1
		Long exhaust pipe installation	2
		Flotation gear installation	2/1
		Wipers installation	2
		Engine oil filter installation	2
		Skid gear covering installation	2/1
		Gutter installation (top pilot door)	2
		Cable cutter installation	2
		Auxiliary fuel tank fixed parts installation	2
		Cabin doors windows replacement	2
		Radio altimeter aural warning installation	2
		Standby horizon autonomous power supply	2
		Fire attack system	2/1
		Hoisting system installation	2/1
		External loads hook installation	2
		Emergency flotation gear installation	2/1
		Heating/demisting (P2 supply)	2

AMC 21.A.15(a), 21.A.93(a), 21.A.113(a), 21.A.432C(a) Form and manner

The applicant should file an application using the forms or tools specified by the Authority. In doubt, the applicant should consult with the Authority to get informed about the relevant forms, tools, and procedure.

The application should be completed in accordance with the instructions given in the forms or tools or as received from the authority and sent to the addressee nominated by the Authority by fax, email, or regular mail.

AMC 21.A.115 Requirements for the approval of major changes in the form of a supplemental type certificate (STC)

- a) For STCs approved by the Authority, the AMC and GM 21.A.20 should be followed by the applicant.
- b) For an application under SIM-To-Lt-035 21.A.115(c), see GM 21.A.21(b), 21.A.95(c), 21.A.97(c) and 21.A.115(c).
- c) In accordance with SIM-To-Lt-035 21.A.115(d), the compliance demonstration process must always cover the specific configuration(s) in the type certificate (TC) to which the STC under approval is applied. These configurations should be defined by the change to the type certificate considering the type certificate data sheet (TCDS) and the relevant optional installations. The demonstration of compliance should cover these specific applicable configurations. Consequently, the approval of the STC excludes any other configuration, in particular those that already existed, but were not considered in the compliance demonstration process, and those that may be certified in future.
- d) For STCs approved by the design organisation approval (DOA) holder under their privilege as per SIM-To-Lt-035 21.A.263(c)(9), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

AMC 21.A.118(a) Continue to meet the criteria of SIM-To-Lt-035 21.A.112B

To ensure that the holder of a supplemental type-certificate remains capable to undertake the required actions and obligations, SIM-To-Lt-035 21.A.118(a) also requires the holder to continue to meet the criteria of SIM-To-Lt-035 21.A.112B.

To comply with this requirement, the holder of a supplemental type-certificate shall inform the Authority without undue delay of any circumstances that significantly affect the ability of the holder to effectively discharge its obligations.

If the actions and obligations of the holder of a supplemental type-certificate are undertaken on its behalf by another person or organisation in accordance with SIM-To-Lt-035 21.A.2, these circumstances shall include any changes to the relevant arrangements with the other organisation or findings regarding its safety performance.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

- a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.
- b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

SUBPART F - PRODUCTION WITHOUT MILITARY PRODUCTION ORGANISATION APPROVAL

GM No. 1 to 21.A.121 Applicability - Individual product, part or appliance

In this context, “demonstrating the conformity with the applicable design data of a product, part and appliance” means that conformity with the applicable design data has to be established and shown for each and every product, part or appliance.

GM No. 2 to 21.A.121 Applicability – Applicable design data

Applicable design data is defined as all necessary drawings, specifications and other technical information provided by the applicant for, or holder of a design organisation approval, MTC, MSTC, approval of repair or minor change design, or MTSO authorisation (or equivalent when SIM-To-Lt-035 Section A Subpart F is used for production of products, parts or appliances, the design of which has been approved other than according to SIM-To-Lt-035), and released in a controlled manner to the manufacturer producing under SIM-To-Lt-035 Section A Subpart F. This will be sufficient for the development of production data to enable manufacture in conformity with the design data.

Prior to issue of the MTC, MSTC, approval of repair or minor change design or MTSO authorisation, or equivalent, design data is defined as ‘not approved’, but parts and appliances may be released with an EMAR Form 1(SVY901) as a certificate of conformity.

After issue of the MTC, MSTC, approval of repair or minor change or MTSO authorisation, or equivalent, this design data is defined as ‘approved’ and items manufactured in conformity are eligible for release on an EMAR Form 1 (SVY901) for airworthiness purposes.

For the purpose of Subpart F of SIM-To-Lt-035, the term ‘applicable design data’ includes the information related to the applicable engine exhaust emissions and aeroplane CO₂ emissions production cut-off requirements.

AMC No. 1 to 21.A.122 Eligibility – Link between design and production

An “arrangement” is considered suitable if it is documented and satisfies the Authority that co-ordination is satisfactory.

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To achieve satisfactory co-ordination, the documented arrangements should at least define the following aspects irrespective of whether the design organisation and the person producing or intending to produce under SIM-To-Lt-035 Section A Subpart F are separate legal entities or not:

- a) The responsibilities of a design organisation which assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);
- b) The responsibilities and procedures of the manufacturer for receiving, managing and using the applicable design data provided by the design organisation;
- c) The responsibilities and procedures of the manufacturer for developing, where applicable, its own manufacturing data in compliance with the applicable design data package;
- d) The responsibilities of the manufacturer to assist the design organisation in dealing with continuing airworthiness matters and for required actions (e.g., traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.);
- e) The scope of the arrangements covering SIM-To-Lt-035 Section A Subpart F requirements, in particular: SIM-To-Lt-035 21.A.126(a)(4) and SIM-To-Lt-035 21.A.129(d) and (f) and any associated GM or AMC;
- f) f)The responsibilities of the manufacturer, in case of products prior to type certification to assist a design organisation in demonstrating compliance with Certification Basis (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);
- g) The procedures to deal adequately with production deviations and non-conforming parts;
- h) The means to achieve adequate configuration control of manufactured parts, to enable the manufacturer to make the final determination and identification for conformity or airworthiness release and eligibility status;
- i) The identification of responsible persons/offices who controls the above;
- j) The acknowledgment by the holder of the MTC/MSTC/repair or change approval / MTSO authorisation that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved.

In many cases the person producing or intending to produce under SIM-To-Lt-035 Section A Subpart F may receive the approved design data through an intermediate production organisation. This is acceptable provided an effective link between the design approval holder and the production organisation can be maintained to satisfy the intent of SIM-To-Lt-035 21.A.122.

When the design organisation and the manufacturer are two separate legal entities a Direct Delivery Authorisation should be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

Where there is no general agreement for Direct Delivery Authorisation, specific permissions may be granted (see AMC 21.A.4).

AMC No. 2 to 21.A.122 Eligibility – Link between design and production

In accordance with AMC No.1 to 21.A.122 the person producing or intending to produce under SIM-To-Lt-035 Section A Subpart F should demonstrate to the Authority that it has entered into an arrangement with the design organisation. The arrangement should be documented irrespective of whether the two organisations are separate legal entities or not.

The documented arrangement should facilitate the person producing or intending to produce under SIM-To-Lt-035 Section A Subpart F to demonstrate compliance with the requirement of SIM-To-Lt-035 21.A.122 by means of written documents agreed.

In the case where the design organisation and the person producing or intending to produce under SIM-To-Lt-035 Section A Subpart F are part of the same legal entity these interfaces may be demonstrated by company procedures accepted by the Authority.

In all other cases to define such a design/production interface the following sample format is offered:

Arrangement Sample Form

ARRANGEMENT in accordance with SIM-To-Lt-035 21.A.122	
The undersigned agree on the following commitments:	Relevant interface procedures
The design organisation [NAME] takes responsibility to: <ul style="list-style-type: none"> – assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the person producing under SIM-To-Lt-035 Section A Subpart F [NAME] – provide visible statement(s) of approved design data. 	
The person producing under SIM-To-Lt-035 Section A Subpart F [NAME] takes responsibility to <ul style="list-style-type: none"> – assist the design organisation [Name] in dealing with continuing airworthiness matter and for required actions – assist the design organisation [NAME] in case of products prior to type certification in demonstrating compliance with certification specifications – develop, where applicable, its own manufacturing data in compliance with the airworthiness data package. 	
The design organisation [NAME] and the person producing under SIM-To-Lt-035 Section A Subpart F [NAME] take joint responsibility to: <ul style="list-style-type: none"> – deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the manufacturer producing under SIM-To-Lt-035 Section A Subpart F. – achieve adequate configuration control of manufactured parts, to enable the manufacturer producing under SIM-To-Lt-035 Section A Subpart F to make the final determination and identification for conformity. 	

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<p>The scope of production covered by this arrangement is detailed in <i>[DOCUMENT REFERENCE/ATTACHED LIST]</i></p>	
<p><i>[When the design organisation is not the same legal entity as the manufacturer producing under SIM-To-Lt-035 Section A Subpart F]</i></p>	
<p>Transfer of approved design data: The TC/STC/MTSO authorisation holder <i>[NAME]</i> acknowledges that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved by the Authority and therefore the parts and appliances manufactured in accordance with these data and found in a condition for safe operation may be released certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation.</p>	
<p><i>[When the design organisation is not the same legal entity as the manufacturer producing under SIM-To-Lt-035 Section A Subpart F]</i></p>	
<p>Direct Delivery Authorisation: This acknowledgment includes also <i>[OR does not include]</i> the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.</p>	
<p>For the <i>[NAME of the design organisation/DOA holder]</i></p>	<p>For the <i>[NAME of the person producing under Part 21 Subpart F]</i></p>
<p>Date: xx.xx.xxxx</p>	<p>Date: xx.xx.xxxx</p>
<p>Signature: ((NAME in block letters))</p>	<p>Signature: ((NAME in block letters))</p>

Instructions for completion:

Title: The title of the relevant document should clearly indicate that it serves the purpose of a design/production interface arrangement in accordance with SIM-To-Lt-035 21.A.122.

Commitment: The document should include the basic commitments between the design organisation and the manufacturer producing under SIM-To-Lt-035 Section A Subpart F as addressed in AMC 21.A.4 and AMC No. 1 to SIM-To-Lt-035 21.A.122.

Relevant Procedures: Identify an entry point into the documentary system of the organisations with respect to the implementation of the arrangement (for example a contract, quality plan, handbooks, common applicable procedures, working plans etc.).

Scope of arrangement: The scope of arrangement should state by means of a list or reference to relevant documents those products, parts or appliances that are covered by the arrangement.

Transfer of approved design data: Identify the relevant procedures for the transfer of the applicable design data required by SIM-To-Lt-035 21.A.122 and AMC No. 1 to SIM-To-Lt-035 21.A.122 from the design organisation to the person producing under SIM-To-Lt-035 Section A Subpart F. The means by which the design organisation advises the person producing under SIM-To-Lt-035 Section A Subpart F whether such data is approved or not approved should also be identified (ref. SIM-To-Lt-035 21.A.4 / AMC 21.A.4).

Direct Delivery Authorisation: Where the design organisation and the person producing under SIM-To-Lt-035 Section A Subpart F are separate legal entities the arrangement should clearly identify whether authorisation for direct delivery to end users is permitted or not.

Where any intermediate production/design organisation is involved in the chain between the original design organisation and the person producing under SIM-To-Lt-035 Section A Subpart F, evidence should be available that this intermediate organisation has received authority from the design organisation to grant Direct Delivery Authorisation.

Signature: AMC No. 1 to SIM-To-Lt-035 21.A.122 requests the identification of the responsible persons/offices who control the commitments laid down in the arrangement. Therefore, the basic document should be signed mutually by the authorised representatives of the design organisation and the manufacturer producing under SIM-To-Lt-035 Section A Subpart F in this regard.

GM 21.A.124(a) Application – Application form

SVY960 (EMAR Form 60) is to be completed by the applicant.

An application may be accepted from:

- a) an individual applying on his or her own behalf, or
- b) in the case of an organisation, an individual with the authority to make agreements on behalf of the organisation.

The completed form is to be forwarded to the Authority.

GM to 21.A.124(b)(1) Re-use of evidence

Organisations recognised by competent civil aviation authorities or certified as per AS/EN 9100 or the equivalent Allied Quality Assurance Publications (AQAP), may re-use part or all of the same process evidence in the demonstration of compliance with SIM-To-Lt-035 Section A Subpart F, as agreed by the Authority.

GM 21.A.124(b)(1)(i) Applicability - Inappropriate approval under Subpart G

The issue of a letter of agreement of production under SIM-To-Lt-035 Section A Subpart F may be agreed by the Authority when:

- a) The applicant produces or intends to produce aeronautical products, parts and/or appliances intended for airborne use as part of a type-certificated product (this excludes simulators, ground equipment and tools), and
- b) The Authority determines that SIM-To-Lt-035 Section A Subpart G would be inappropriate, and consequently SIM-To-Lt-035 Section A Subpart F applies. The main difference between SIM-To-Lt-035 Section A Subparts G and F is that Subpart G requires the existence of a Quality System

which provides the Authority with the necessary confidence to grant to the manufacturer the privileges of certifying its own production. There are situations where a Quality System, including independent monitoring and continuous internal evaluation functions, is not justified and /or feasible. In making the determination that Subpart F may apply, the Authority may take into account one or a combination of parameters such as the following:

- i. no flow production (infrequent or low volume of production);
- ii. simple technology (enabling effective inspection phases during the manufacturing process);
- iii. very small organisation.

GM 21.A.124(b)(1)(ii) Certification or approval needed in advance of the issue of a POA

In cases where SIM-To-Lt-035 Section A Subpart G is applicable, but when some time is needed for the organisation to achieve compliance with Subpart G, i.e., to establish the necessary documented quality system, the Authority may agree to use SIM-To-Lt-035 Section A Subpart F for a limited period (transient phase).

In cases where SIM-To-Lt-035 Section A Subpart G is applicable, such as to produce TSO articles, a letter of agreement to produce under SIM-To-Lt-035 Section A Subpart F will not be given unless an application has been made for organisation approval under Subpart G, and reasonable progress is being made towards compliance with Subpart G. Long-term production under SIM-To-Lt-035 Section A Subpart F will not be permitted.

GM 21.A.124(b)(2) Application - Minimum information to include with the application

At this early stage, provision of the complete manual is not necessary, but at least the following items are to be covered:

- a) Table of Contents of the Manual (including list of existing inspection system documents or procedures);
- b) Description of items to be manufactured (including intended quantities /deliveries);
- c) List of possible suppliers;
- d) General description of facilities;
- e) General description of production means;
- f) Human resources.

GM No 1 to 21.A.125A Letter of agreement – Meaning of individual

‘Individual’ means that each part number or type of item (i.e., product, part or appliance) to be produced should be specifically referenced, either directly or through a referenced capability list, in the letter of agreement from the competent authority. The letter may also specify any limitation in the production rate.

GM No. 1 to 21.A.125A(b) Letter of agreement - Contents of the Manual

The manual referred in SIM-To-Lt-035 21.A.125A(b) should include, at least the following information:

- a) Declaration by the applicant of undertaking in respect of:
 - i. the requirements defined in SIM-To-Lt-035 Section A Subpart F;
 - ii. the procedures contained in the manual and in the documentation mentioned herein;
 - iii. every legal provision laid down for the carrying on of the business activities (statutory declaration).
- b) Declaration by the applicant certifying the conformity of the manual to the requirements defined in SIM-To-Lt-035 Section A Subpart F;
- c) Jobs, power and responsibilities of the accountable personnel;
- d) Organisation chart, if required by the Authority;
- e) Description of the resources, including human resources, with an indication of the personnel qualification criteria;
- f) Description of location and equipment;
- g) Description of the scope of work, the production processes and techniques, and reference to the “capability list”;
- h) Communications with the Authority, and specifically those required by SIM-To-Lt-035 21.A.125A(c);
- i) Assistance and communication with the design approval holder, and the means of compliance with SIM-To-Lt-035 21.A.125A(c);
- j) Amendments to the Manual;
- k) Description of the Inspection System (including test, see GM No. 2 to SIM-To-Lt-035 21.A.125A(b), and SIM-To-Lt-035 21.A.127 and SIM-To-Lt-035 21.A.128), and the procedures to meet SIM-To-Lt-035 21.A.126 and associated GM;
- l) List of suppliers;
- m) Issuing of the Statement of Conformity and Authority inspection for validation.

If the information is listed in the Manual in a different order a cross reference to the above list is to be made available in the Manual.

GM No. 2 to 21.A.125A(b) Letter of agreement - Production Inspection System: Functional Tests

All items produced should be subject to inspection to be carried out at suitable phases which permit an effective verification of conformity with the design data.

These inspections may provide for the execution of tests to measure performances as set out in the applicable design data.

Considerations of complexity of the item and/or its integration in the next level of production will largely determine the nature and time for these tests, for example:

- a) appliances - will require full functional testing to the specifications;
- b) parts - will at least require basic testing to establish conformity, but due allowance may be made for further testing carried out at the next level of production;
- c) material - will require verification of its stated properties.

GM 21.A.125A(c) Letter of agreement – Assistance

The Authority should be provided with material which defines the means of providing assistance as required by SIM-To-Lt-035 21.A.125A(c). Suitable descriptive material is to be included in the Manual, as described in GM No. 1 to SIM-To-Lt-035 21.A.125A(b).

GM No. 1 to 21.A.125B(a) Uncontrolled non-compliance with applicable design data

An uncontrolled non-compliance with applicable design data is a non-compliance:

- a) that cannot be discovered through systematic analysis; or
- b) that prevents identification of affected products, parts, appliances, or material.

GM No. 2 to 21.A.125B(a) Examples for level one findings

Examples for level 1 findings are non-compliances with any of the following paragraphs, that could affect the safety of the aircraft:

SIM-To-Lt-035 21.A.126, SIM-To-Lt-035 21.A.127, SIM-To-Lt-035 21.A.128, SIM-To-Lt-035 21.A.129.

It should be anticipated that a non-compliance with these paragraphs is only considered a level one finding when objective evidence has been found that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.

GM 21.A.126 Production Inspection System

GM 21.A.126 (a) and (b) have been developed for persons producing under SIM-To-Lt-035 Section A Subpart F on the long-term basis as defined in SIM-To-Lt-035 21.A.124(b)(1)(i).

For those persons producing under SIM-To-Lt-035 Section A Subpart F as a transient phase under SIM-To-Lt-035 21.A.124(b)(1)(ii), compliance with SIM-To-Lt-035 21.A.126 may also be demonstrated to the satisfaction of the Authority by using the equivalent SIM-To-Lt-035 Section A Subpart G AMC/GM.

GM 21.A.126(a)(1) Production Inspection System – Conformity of supplied parts, appliances and material

- a) The person producing under SIM-To-Lt-035 Section A Subpart F is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity, as appropriate, of raw materials, subcontracted works, and supplied products, parts, appliances or material, whether to be used in production or delivered to customers as spare parts. This responsibility also includes Government Furnished Equipment (GFE) items.
- b) Control may be based upon use of the following techniques, as appropriate:
 - i. first article inspection, including destruction if necessary, to verify that the article conforms to the applicable data for new production line or new supplier,
 - ii. incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt,
 - iii. identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents,

- iv. any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subject to the checks normally provided by subsequent production or inspection stages.
- c) The person producing under SIM-To-Lt-035 Section A Subpart F may rely upon an EMAR Form 1 (SVY901) issued in accordance with SIM-To-Lt-035 if provided as evidence of conformity with applicable design data.
- d) For suppliers not holding a POA the inspection system of the person producing under SIM-To-Lt-035 Section A Subpart F should establish a system for control of incoming materials and bought or subcontracted items which provides for inspections and tests of such items by the person producing under SIM-To-Lt-035 Section A Subpart F at the supplier's facility, if the item cannot or will not be completely inspected upon receipt.

GM 21.A.126(a)(2) Production Inspection System - Identification of incoming materials and parts

All parts and materials coming from external parties should be identified and inspected to ascertain that they have not been damaged during transport or unpacking, that the incoming parts and materials have the appropriate and correct accompanying documentation and that the configuration and condition of the parts or materials is as laid down in that documentation.

Only on completion of these checks and of any incoming further verifications laid down in the procurement specification, may the part or material be accepted for warehousing and used in production.

This acceptance should be certified by an inspection statement.

A suitable recording system should allow reconstruction at any time of the history of every material or part.

The areas where the incoming checks are carried out and the materials or parts are stored pending completion of the checks should be physically segregated from other departments.

GM No. 1 to 21.A.126(a)(3) Production Inspection System - List of specifications

It is the responsibility of:

- a) The designer, to define all necessary processes, techniques and methods to be followed during manufacture (SIM-To-Lt-035 21.A.31) and this information will be provided as part of the applicable design data.
- b) The manufacturer, to ensure that all processes are carried out strictly in accordance with the specifications provided as part of the applicable design data.

GM No. 2 to 21.A.126(a)(3) Production Inspection System - Means of checking of the production processes

The Production Inspection System should be provided with appropriate means of checking that production processes, whether performed by the person producing under SIM-To-Lt-035 Section A Subpart F or by sub-contractors under its control, are carried out in accordance with applicable data, including:

- a) A system for the control and authorised amendment of data provided for the production, inspection and test to ensure that it is complete and up-to-date at the point of use;
- b) Availability of personnel with suitable qualification, experience, and training for each required production, inspection, and test task. Special attention is to be paid to tasks requiring specialised knowledge and skill, e.g., NDT/NDI, welding...;
- c) A working area where the working conditions and environment are controlled as appropriate in respect of: cleanliness, temperature, humidity, ventilation, lighting, space/access, protection against noise and pollution;
- d) Equipment and tools sufficient to enable all specified tasks to be accomplished in a safe and effective manner without detrimental effect on the items under production. Calibration control of equipment and tools which affect critical dimensions and values are to demonstrate compliance with, and be traceable to, recognised national or international standards.

GM 21.A.126(a)(4) Production Inspection System – Applicable design/production data procedures

- a) When a person producing under SIM-To-Lt-035 Section A Subpart F is developing its own manufacturing data from the design data package delivered by a Design holder, procedures should demonstrate the correct transcription of the original design data.
- b) Procedures should define the manner in which applicable design data is used to issue and update the production/inspection data, which determines the conformity of products, parts, appliances and materials. The procedure should also define the traceability of such data to each individual product, part, appliance or material for the purpose of stating the condition for safe operation and for issuing a Statement of Conformity.
- c) During execution, all works should be accompanied by documentation giving either directly or by means of appropriate references, the description of the works as well as the identification of the personnel in charge of inspection and execution tasks for each of the different work phases.

GM 21.A.126(b)(1) Production Inspection System - Inspection of parts in process

The purpose of the Production Inspection System is to check at suitable points during production and provide objective evidence that the correct specifications are used, and that processes are carried out strictly in accordance with the specification.

During the manufacturing process, each article should be inspected in accordance with a plan which identifies the nature of all inspections required and the production stages at which they occur. The plan is to also identify any particular skills or qualification required of person(s) carrying out the inspections (e.g., NDT personnel). A copy of the plan is to be included in, or referenced by, the manual required by SIM-To-Lt-035 21.A.125A(b).

If the parts are such that, if damaged, they could compromise the safety of the aircraft, additional inspections for such damage should be performed at the completion of each production stage.

GM 21.A.126(b)(2) Production Inspection System – Suitable storage and protection

- a) Storage areas should be protected from dust, dirt, or debris, and adequate blanking and packaging of stored items is to be practised.
- b) All parts should be protected from extremes of temperatures and humidity and, where needed, temperature-controlled or full air-conditioned facilities are to be provided.
- c) Racking and handling equipment should be provided such as to allow storage, handling and movement of parts without damage.
- d) Lighting should be such as to allow safe and effective access and handling, but is to also cater for items which are sensitive to light e.g., rubber items.
- e) Care should be taken to segregate and shield items which can emit fumes (e.g., wet batteries), substances or radiation (e.g., magnetic items) which are potentially damaging to other stored items.
- f) Procedures should be in place to maintain and record stored parts identities and batch information.
- g) Access to storage areas is should restricted to authorised personnel who are fully trained to understand and maintain the storage control arrangements and procedures.
- h) Provisions should be made for segregated storage of non-conforming items pending their disposition (see GM SIM-To-Lt-035 21.A.126(b)(4)).

GM 21.A.126(b)(3) Production Inspection System – Use of derived data instead of original design data

Where derived data, e.g., worksheets, process sheets, fabrication/inspection instructions, etc., is used instead of original design drawings, documents identification and control procedures should be used to ensure that the documentation in use is always accurate and current.

GM 21.A.126(b)(4) Production Inspection System – Segregation of rejected material

All materials and parts which have been identified at any stage in the manufacturing process as not conforming to the specific working and inspection instructions must be suitably identified by clearly marking or labeling, to indicate their non-conforming status.

All such non-conforming material or parts should be removed from the production area and held in a restricted access segregated area until an appropriate disposition is determined in accordance with SIM-To-Lt-035 21.A.126(b)(5).

GM 21.A.126(b)(5) Production Inspection System – Engineering and manufacturing review procedure

- a) The procedure should permit to record the deviation, to present it to the Design holder under the provisions of SIM-To-Lt-035 21.A.122, and to record the results of the re-view and actions taken consequently as regards the part/product.
- b) Any unintentional deviation from the manufacturing/inspection data should be recorded and handled in accordance with SIM-To-Lt-035 Section A Subpart D or E as changes to the approved design.

GM 21.A.126(b)(6) Production Inspection System – Recording and record keeping

- a) Records within a production environment satisfy two purposes. Firstly, they should, during the production process, ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the

production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.

Therefore, the person producing under SIM-To-Lt-035 Section A Subpart F should implement a system for the compilation and retention of records during all stages of manufacture, covering short-term and long-term records appropriate to the nature of the product and its production processes.

The management of such information should be subject to appropriate documented procedures in the Manual required by SIM-To-Lt-035 21.A.125A(b).

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

- b) The related procedures should:
- i. Identify records to be kept.
 - ii. Describe the organisation of and responsibility for the archiving system (location, compilation, format) and conditions for access to the information (e.g., by product, subject).
 - iii. Control access and provide effective protection from deterioration or accidental damage.
 - iv. Ensure continued readability of the records.
 - v. Demonstrate to the Authority proper functioning of the records system.
 - vi. Clearly identify the persons involved in conformity determination.
 - vii. Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:
 1. Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate.
 2. Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.
 - viii. Data related to supplied parts may be retained by the supplier if the supplier has a system agreed under SIM-To-Lt-035 Section A Subpart F by the Authority. The manufacturer should, in each case, define the archiving period and satisfy himself or herself and the Authority that the recording media are acceptable.

GM 21.A.127 Approved production ground and flight tests

The production ground and flight tests for new aircraft will be specified by the aircraft design organisation.

GM No. 1 to 21.A.128 Acceptable functional test – Engines

The functional test required for a new engine will be specified by the engine design organisation and will normally include at least the following:

- a) Break-in runs that include a determination of fuel and oil consumption and a determination of power characteristics at rated maximum continuous power or thrust and, if applicable, at rated take-off power or thrust;
- b) A period of operation at rated maximum continuous power or thrust. For engines having a rated take-off power or - thrust, part of that period is to be at rated take-off power or - thrust.

The test equipment used for the test run should be capable of output determination of accuracy sufficient to assure that the engine output delivered complies with the specified rating and operation limitations.

GM No. 2 to 21.A.128 Acceptable functional test – Variable pitch propellers

The functional tests required for a new propeller will be specified by the propeller design organisation and should normally include a number of complete cycles of control through-out the propeller pitch and rotational speed ranges. In addition, for feathering and/or reversing propellers, several cycles of feathering operation and reversing operation from the lowest normal pitch to the maximum reverse pitch, should normally be required.

GM No. 3 to 21.A.128 Acceptable functional test - Engines and Propellers

After functional test, each engine or propeller should be inspected to determine that the engine or propeller is in condition for safe operation. Such inspection will be specified by the design organisation and should normally include internal inspection and examination. The degree of internal inspections will normally be determined on the basis of the positive results of previous inspections conducted on the first production engines, and on the basis of service experience.

GM 21.A.129(a) Availability for inspection by the Authority

Each product, part or appliance should be made available for inspection at any time at the request of the Authority.

It is recommended that a pre-defined plan of inspection points be established and agreed with the Authority to be used as a basis for such inspections.

The manufacturer should provide such documentation, tools, personnel, access equipment etc. as necessary to enable the Authority to perform the inspections.

AMC No. 1 to 21.A.129(c) Obligations of the manufacturer – Conformity of proto-type models and test specimens

SIM-To-Lt-035 21.A.33 requires determination of conformity of prototype models and test specimens to the applicable design data. For a complete aircraft a 'conformity document', that has to be validated by the Authority, should be provided as part of the assistance to the design approval applicant. For products other than a complete aircraft, and for parts and appliances, an EMAR Form 1 (SVY901) validated by the Authority may be used as a conformity document as part of the assistance to the design approval applicant.

AMC No. 2 to 21.A.129(c) Obligations of the manufacturer – Conformity with Applicable Design Data

Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type certificate holder. There are also likely to be unintentional divergences (concessions or non-conformances) during the manufacturing process. All these changes are required to have been approved by the design approval applicant/holder, or when necessary by the Authority.

AMC No. 3 to 21.A.129(c) Obligations of the manufacturer – Condition for safe operation

Before issue of the Statement of Conformity to the Authority the manufacturer under this Subpart should make an investigation so as to be satisfied in respect to each of the items listed below. The documented results of this investigation should be kept on file by the manufacturer. Certain of these items may be required to be provided (or made available) to the operator or owner of the aircraft, and, for validation of the statement of conformity, to the Authority.

- a) Equipment or modifications which do not meet the requirements of the state of manufacture but have been accepted by the Authority of the importing country.
- b) Identification of products, parts or appliances which:
 - i. Are not new;
 - ii. Are furnished by the buyer or future operator (including those identified in SIM-To-Lt-035 21.A.801 and SIM-To-Lt-035 21.A.805).

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- c) Technical records which identify the location and serial numbers of components that have traceability requirements for continued airworthiness purposes including those identified in SIM-To-Lt-035 21.A.801 and SIM-To-Lt-035 21.A.805.
- d) Log book and a modification record book for the aircraft as required by the Authority.
- e) Log books for products identified in SIM-To-Lt-035 21.A.801 installed as part of the type design as required by the Authority.
- f) A weight and balance report for the completed aircraft.
- g) A record of missing items or defects which do not affect airworthiness. These, for example, could be furnishings or GFE (Items may be recorded in a technical log or other suitable arrangement such that the operator and Authority are formally aware).
- h) Product support information required by Certification Basis, such as a Maintenance Manual, a Parts Catalogue, or MMEL all of which are to reflect the actual build standard of the particular aircraft. Also an Electrical load analysis and a wiring diagram.
- i) Records which demonstrate completion of maintenance tasks appropriate to the test flight flying hours recorded by the aircraft. These records should show the relationship of the maintenance status of the particular aircraft to the manufacturers recommended maintenance task list and the Maintenance Review Board (MRB) document/report.
- j) Details of the serviceability state of the aircraft in respect of, a) the fuel and oil contents, b) provision of operationally required emergency equipment such as life rafts, etc.
- k) Details of the approved interior configuration if different from that approved as part of the type design.
- l) An approved Flight Manual which conforms to the build standard and modification state of the particular aircraft should be available.
- m) Show that inspections for foreign objects at all appropriate stages of manufacture have been satisfactorily performed.
- n) The registration has been marked on the exterior of the aircraft as required by national legislation. Where required by national legislation fix a fireproof owners nameplate.
- o) Where applicable, there should be a certificate for noise and, for the aircraft radio station.
- p) The installed compass and or compass systems have been adjusted and compensated and a deviation card displayed in the aircraft.
- q) Software criticality list.
- r) A record of rigging and control surface movement measurements.
- s) Details of installations which will be removed before starting regular operations (e.g. ferry kits for fuel, radio or navigation).
- t) List of all applicable Service Bulletins and airworthiness directives that have been implemented.

AMC No. 1 to 21.A.130(b) Statement of Conformity for Complete Aircraft

1. PURPOSE AND SCOPE

The description for this AMC refers only to the use of the aircraft Statement of Conformity issued under SIM-To-Lt-035 Section A Subpart F. Statement of Conformity under SIM-To-Lt-035 Section A Subpart F for products other than complete aircraft, and for parts and appliances is described in AMC No. 2 to 21.A.130(b).

Use of the aircraft Statement of Conformity issued by an approved production organisation is described in SIM-To-Lt-035 Section A Subpart G 21.A.163(b) and the completion instructions are to be found together with SVY952 (EMAR Form 52).

The purpose of the aircraft Statement of Conformity SVY952 (EMAR Form 52) issued under SIM-To-Lt-035 Section A Subpart F is to present to the Authority a complete aircraft. The Authority only validates the Statement of Conformity if it finds, as described in SIM-To-Lt-035 21.A.130 and its associated GM, that the aircraft conforms with the type design and is in condition for safe operation.

2. GENERAL

The Statement of Conformity must comply with the format provided with SVY952 (EMAR Form 52) including block numbers and the location of each Block. The size of each Block may however be varied to suit the individual application, but not to the extent that would make the Statement of Conformity unrecognisable. If in doubt consult the Authority.

The Statement of Conformity must either be pre-printed or computer generated but in either case the printing of lines and characters must be clear and legible. Pre-printed wording is permitted in accordance with the attached model but no other certification statements are permitted.

Statements of Conformity must be issued in one or more of the official language(s) of the issuing Authority with translations in English shown below, if required. Completion may be either machine/computer printed or handwritten using block letters to permit easy reading.

A copy of the Statement of Conformity and all referenced attachments are to be retained by the manufacturer. A copy of the validated Statement of Conformity is to be retained by the competent authority.

3. COMPLETION OF THE AIRCRAFT STATEMENT OF CONFORMITY BY THE ORIGINATOR

There must be an entry in all Blocks to make the document a valid Statement.

A Statement of Conformity must not be issued for validation by the competent authority, unless the design of the aircraft and its installed products are approved.

The information required in Blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the manufacturer, unless the competent authority agrees otherwise.

This Statement of Conformity is not intended to provide for the complete equipment fit required by the applicable operational rules. However, some of these individual items may be included in Block 10 or in

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the approved type design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operation.

Block 1

Enter name of the State of manufacture.

Block 2

The Authority under which authority the Statement of Conformity is issued.

Block 3

A unique serial number should be pre-printed in this Block for Statement control and traceability purposes. Except that in the case of a computer generated document the number need not be pre-printed where the computer is programmed to produce and print a unique number.

Block 4

The full name and location address of the manufacturer issuing the statement. This Block may be pre-printed. Logos, etc., are permitted if the logo can be contained within the Block.

Block 5

The aircraft type in full as defined in the type-certificate and its associated data sheet.

Block 6

The type-certificate reference numbers and issue for the subject aircraft.

Block 7

If the aircraft is registered then this mark will be the registration mark. If the aircraft is not registered then this will be such a mark that is accepted by the Authority of the Member State and, if applicable, by the Authority of a third country.

Block 8

The identification number assigned by the manufacturer for control and traceability and product support. This is sometimes referred to as a Manufacturers Serial No or Constructors No.

Block 9

The engine and propeller type(s) in full as defined in the relevant type-certificate and its associated data sheet. Their manufacturer identification No and associated location should also be shown.

Block 10

Approved design changes to the Aircraft Definition.

Block 11

A listing of all applicable airworthiness directives (or equivalent) and a declaration of compliance, together with a description of the method of compliance on the subject individual aircraft including products and installed parts, appliances and equipment. Any future compliance requirement time should be shown.

Block 12

Approved unintentional deviation to the approved type design sometimes referred to as concessions, divergences, or non-conformances.

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Block 13

Only agreed exemptions, waivers or derogations may be included here.

Block 14

Remarks: Any statement, information, particular data or limitation which may affect the airworthiness of the aircraft. If there is no such information or data, state: 'NONE'. If the Authority has endorsed a CO2 emissions production cut-off exemption, make the following record: 'Aeroplane exempted from the applicability of paragraph 2.1.1 [x] as referenced in the 1st Edition of Annex 16, Volume III, Part II, Chapter 2 (July 2017).'

Block 15

Enter 'Certificate of Airworthiness' or 'Restricted Certificate of Airworthiness' for the Certificate of Airworthiness requested.

Block 16

Additional requirements such as those notified by an importing country should be noted in this Block.

Block 17

Validity of the Statement of Conformity is dependent on full completion of all Blocks on the form. A copy of the flight test report together with any recorded defects and rectification details should be kept on file by the manufacturer. The report should be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g., test pilot or flight test engineer. The flight tests performed are those required by EMAR 21.A.127 and GM 21.A.127, to ensure that the aircraft conforms to the applicable design data and is in condition for safe operation.

The listing of items provided (or made available) to satisfy the safe operation aspects of this statement should be kept on file by the manufacturer.

Block 18

The Statement of Conformity may be signed by the person authorised to do so by the manufacturer in accordance with 21.A.130(a). A rubber stamp signature should not be used.

Block 19

The name of the person signing the certificate should be typed or printed in a legible form.

Block 20

The date the Statement of Conformity is signed must be given.

Block 21

For production under EMAR 21 Subpart F, state 'NOT APPLICABLE'

Additionally, for production under EMAR 21 Section A Subpart F, the Statement of Conformity should include validation by the Authority. For this purpose, the validation statement below should be included in the Block 21 itself, and not referred in a separate document. The statement can be pre-printed, computer generated or stamped, and should be followed by the signature of the representative of the Authority validating the certificate, the name and the position/identification of such representative of the Authority, and the date of such validation by the Authority.

VALIDATION STATEMENT:

“After due inspection the [identify the issuing Authority] is satisfied that this document constitutes an accurate and valid Statement of Conformity in accordance with [EMAR 21 Section A Subpart F (to be replaced by the reference to the applicable national regulation)].”.

AMC No. 2 to 21.A.130(b) Statement of Conformity for Products (other than complete aircraft), parts, appliances and materials - The Authorised Release Certificate (EMAR Form 1 (SVY901) – See EMAR Forms Document (<https://ilmavoimat.fi/svy/lomakkeet>))

A. INTRODUCTION

This AMC relates specifically to the use of the EASA Form 1 for manufacturing purposes under SIM-To-Lt-035 Subpart F. It can be used as a supplement to the completion instructions provided with EMAR Form 1 (SVY901).

1. PURPOSE AND USE

The EMAR Form 1 (SVY901) is prepared and signed by the manufacturer. For production under SIM-To-Lt-035 Subpart F it is presented for validation by the Authority.

Under Subpart F the certificate may only be issued by the Authority.

A mixture of items released under Subpart G and under Subpart F of Part 21 is not permitted on the same certificate.

2. GENERAL FORMAT

Refer to the specimen of EMAR Form 1 (SVY901).

3. COPIES

Refer to the instructions for the use of EMAR Form 1 (SVY901).

The SIM-To-Lt-035 Subpart F originator must retain a copy of the certificate in a form that allows verification of original data.

4. ERROR(S) ON THE CERTIFICATE

If an end user finds an error(s) on a certificate, they must identify it/them in writing to the originator. The originator may prepare and sign a new certificate for validation by the Authority if they can verify and correct the error(s).

The new certificate must have a new tracking number, signature and date.

The request for a new certificate may be honoured without re-verification of the item(s) condition. The new certificate is not a statement of current condition and should refer to the previous certificate in Block 12 by the following statement: ‘This certificate corrects the error(s) in block(s) [enter block(s) corrected] of the certificate [enter original tracking number] dated [enter original issuance date] and does

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not cover conformity/condition/release to service.’ Both certificates should be retained according to the retention period associated with the first.

5. COMPLETION OF THE CERTIFICATE BY THE ORIGINATOR

Refer to the instructions for the use of EMAR Form 1 (SVY901) for completion of the certificate. Specific instructions that differ from these instructions are provided below.

Block 1 – Approving Authority/Country

State the name and country of the Authority under whose jurisdiction this certificate is issued.

Block 12 – Remarks (see also point 4)

Examples of conditions which would necessitate statements in Block 12 are:

- a) When the certificate is used for prototype purposes, the following statement must be entered at the beginning of Block 12:

‘NOT ELIGIBLE FOR INSTALLATION ON IN-SERVICE TYPE-CERTIFICATED AIRCRAFT’.

- b) Re-certification of items from ‘prototype’ (conformity only to non-approved data) to ‘new’ (conformity to approved data and in a condition for safe operation) once the applicable design data is approved.

The following statement must be entered in Block 12:

RE-CERTIFICATION OF ITEMS FROM ‘PROTOTYPE’ TO ‘NEW’:

THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA [insert TC/STC number, revision level], DATED [insert date if necessary for identification of revision status], TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.

- c) When a new certificate is issued to correct error(s), the following statement must be entered in Block 12:

‘THIS CERTIFICATE CORRECTS THE ERROR(S) IN BLOCK(S) [enter block(s) corrected] OF THE CERTIFICATE [enter original tracking number] DATED [enter original issuance date] AND DOES NOT COVER CONFORMITY/CONDITION/RELEASE TO SERVICE’.

Additionally, for production under Subpart F, this block must include the Statement of Conformity by the manufacturer under SIM-To-Lt-035 21.A.130. For this purpose, the appropriate Block 13a statement must be included in the Block 12 and not referenced in a separate document. The statement may be pre-printed, computer generated or stamped, and must be followed by the signature of the manufacturer’s authorised person under SIM-To-Lt-035 21.A.130(a), the name and the position/identification of such person and the date of the signature.

- d) In case of an engine, when the Authority has granted an emissions production cut-off exemption the following statement must be entered in Block 12:

['‘NEW” OR “SPARE”] ENGINE EXEMPTED FROM NO_x EMISSIONS PRODUCTION CUT-OFF REQUIREMENT’.

Block 13b – Authorised Signature

This space shall be completed with the signature of the Authority representative validating the Block 12 manufacturer Statement of Conformity, under 21.A.130(d). To aid recognition, a unique number identifying the representative may be added.

Block 13c – Approval/Authorisation Number

Enter the authorisation number reference. This number or reference is given by the Authority to the manufacturer working under SIM-To-Lt-035 Subpart F.

GM 21.A.130(b)(4) considerations for determining environmental requirements, if required

Military aviation is not within the scope of the environmental requirements of the Chicago Convention. However, in case that compliance to these requirements is required by national law or the Authority, the following guidance should be used to determine compliance with SIM-To-Lt-035 21.A.130(b)(4).

1. Definitions of engine type certification date and production date:

Volume II of Annex 16 to the Chicago Convention contains two different references to applicability dates:

- a) 'Date of manufacture for the first individual production model' which refers to the engine type certification date; and
- b) 'Date of manufacture for the individual engine' which refers to the production date of a specific engine serial number (date of EMAR Form 1 (SVY901)).

The second reference is used in the application of the engine NO_x emissions production cut-off requirement, which specifies a date after which all in-production engine models must meet a certain NO_x emissions standard.

SIM-To-Lt-035 21.A.130(b)(4) includes the production requirements and refers to paragraphs (b) and (d) of Volume II, Part III, Chapter 2, paragraph 2.3 of Annex 16 to the Chicago Convention.

2. Applicable engine exhaust emissions requirements

If not otherwise specified by the Authority, EASA AMC 21.A.130(b)(4)(i) as per ED Decision 2019/018/R could be used to determine compliance to SIM-To-Lt-035 21.A.130(b)(4)(i).

3. Applicable aeroplane CO₂ emissions requirements

If not otherwise specified by the Authority, EASA AMC 21.A.130(b)(4)(ii) as per ED Decision 2019/018/R could be used to determine compliance to SIM-To-Lt-035 21.A.130(b)(4)(ii).

AMC 21.A.130(c) Validation of the Statement of Conformity

It is the responsibility of the applicant to ensure that each and every product, part and appliance conforms to the applicable design data and is in condition for safe operation before issuing and signing the relevant Statement of Conformity. During manufacture, the applicant is expected to use such facilities, systems, processes and procedures as described in the Manual and have been previously agreed with the Authority.

The Authority should then make such inspection and investigation of records and product, part or appliance as are necessary to determine that the agreed facilities, systems, processes and procedures have been used, and that the Statement of Conformity may be regarded as a valid document.

To enable timely inspection and investigation by the Authority, the Statement of Conformity should be prepared and submitted to the Authority immediately upon satisfactory completion of final production inspection and text.

AMC 21.A.130(c)(1) Initial transfer of ownership

Upon transfer of ownership:

- a) For a complete aircraft, whether or not an application for a Certificate of Airworthiness is to be made, an SVY952 (EMAR Form 52) should be completed and submitted to the Authority for validation.
- b) For anything other than a complete aircraft an SVY952 (EMAR Form 52) is inappropriate, and an EMAR Form 1 (SVY901) should be completed and submitted to the Authority for validation.

NOTE: If there is significant delay between the last production task and presentation of SVY952 (EMAR Form 52) or EMAR Form 1 (SVY901) to the Authority, then additional evidence relating to the storage, preservation and maintenance of the item since its production should be presented to the Authority.

SUBPART G - MILITARY PRODUCTION ORGANISATION APPROVAL FOR PRODUCTS, PARTS AND APPLIANCES

GM 21.A.131 Scope – Applicable design data

Applicable design data is defined as all necessary drawings, specifications and other technical information provided by the applicant for, or holder of a design organisation approval, TC, STC, approval of repair or minor change design, or TSO authorisation and released in a controlled manner to a production organisation approval holder. This is to be sufficient for the development of production data to enable repeatable manufacture to take place in conformity with the design data.

Prior to issue of the TC, STC, approval of repair or minor change design or TSO authorisation, or equivalent, design data is defined as 'not approved' but parts and appliances may be released with an EMAR Form 1 (SVY901) as a certificate of conformity.

After issue of the TC, STC, approval of repair or minor change or TSO authorisation, or equivalent, this design data is defined as 'approved' and items manufactured in conformity are eligible for release on an EMAR Form 1 (SVY901) for airworthiness purposes.

For the purpose of Subpart G of SIM-To-Lt-035, the term 'applicable design data' includes the information related to the applicable engine exhaust emissions and aeroplane CO₂ emissions production cut-off requirements.

GM 21.A.133(a) Eligibility – Approval appropriate for showing conformity

'Appropriate' is to be understood as follows:

- a) The applicant produces or intends to produce aeronautical products, parts and/or appliances intended for airborne use as part of a type certificated product (this excludes simulators, ground equipment and tools).
- b) The applicant will be required to show a need for an approval, normally based on one or more of the following criteria:
 - i. Production of aircraft, engines or propellers (except if the Authority considers a POA inappropriate);
 - ii. Production of TSO articles and parts marked MPA;

- iii. Direct delivery to users such as owners or operators maintenance organisations with the need for exercising the privileges of issuing Authorised Release Certificates – EMAR Form 1 (SVY901);
 - iv. Participation in an international co-operation programme where working under an approval is considered necessary by the Authority;
 - v. Criticality and technology involved in the part or appliance being manufactured. Approval in this case may be found by the Authority as the best tool to exercise its duty in relation to airworthiness control;
 - vi. Where an approval is otherwise determined by the Authority.
- c) It is not the intent of the Authority to issue approvals to manufacturing firms that perform only sub-contract work for main manufacturers of products and are consequently placed under their direct surveillance.
- d) Where standard parts, materials, processes or services are included in the applicable design data (see guidance on applicable design data in GM 21.A.131) their standards are to be controlled by the POA holder in a manner which is satisfactory for the final use of the item on the product, part or appliance. Accordingly, the manufacturer or provider of the following will not at present be considered for production organisation approval:
- i. consumable materials;
 - ii. raw materials;
 - iii. standard parts;
 - iv. parts identified in the product support documentation as ‘industry supply’ or ‘no hazard’;
 - v. non-destructive testing or inspection;
 - vi. processes (heat treatment, surface finishing, shot peening, etc.).

AMC No. 1 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations

An arrangement is considered appropriate if it is documented and satisfies the Authority that co-ordination is satisfactory.

To achieve satisfactory coordination the documented arrangements should at least define the following aspects irrespective of whether the two organisations are separate legal entities or not:

- a) The responsibilities of a design organisation which assure correct and timely transfer of up-to-date airworthiness data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);

- b) The responsibilities and procedures of a POA holder/applicant for developing, where applicable, its own manufacturing data in compliance with the airworthiness data package;
- c) The responsibilities of a POA holder/applicant to assist the design organisation in dealing with continuing airworthiness matters and for required actions (e.g., traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.);
- d) The scope of the arrangements should cover SIM-To-Lt-035 Section A Subpart G requirements and associated AMC and GM, in particular: SIM-To-Lt-035 21.A.145(b), SIM-To-Lt-035 21.A.165(c), (f) and (g);
- e) The responsibilities of a POA holder/applicant, in case of products prior to type certification to assist a design organisation in demonstrating compliance with airworthiness requirements (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);
- f) The procedures to deal adequately with production deviations and non-conforming parts;
- g) The procedures and associated responsibilities to achieve adequate configuration control of manufactured parts, to enable the production organisation to make the final determination and identification for conformity or airworthiness release and eligibility status;
- h) The identification of the responsible persons/offices who control the above;
- i) The acknowledgment by the holder of the TC/STC/repair or change approval / MTSO authorisation that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved.

In many cases the production organisation may receive the approved design data through an intermediate production organisation. This is acceptable provided an effective link between the design approval holder and the production organisation can be maintained to satisfy the intent of SIM-To-Lt-035 21.A.133.

When the design and production organisations are two separate legal entities a Direct Delivery Authorisation should be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

Where there is no general agreement for Direct Delivery Authorisation, specific permissions may be granted (refer to AMC 21.A.4).

AMC No. 2 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations

In accordance with AMC No.1 to 21.A.133(b) and (c) the POA holder should demonstrate to the Authority that it has entered into an arrangement with the design organisation. The arrangement should be documented irrespective of whether the two organisations are separate legal entities or not.

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The documented arrangement should facilitate the POA holder to demonstrate compliance with the requirement of SIM-To-Lt-035 21.A.133(b) and (c) by means of written documents agreed.

In the case where the design organisation and POA holder are part of the same legal entity these interfaces may be demonstrated by company procedures accepted by the Authority.

In all other cases to define such a design/production interface the following sample format is offered:

Arrangement Sample Form

ARRANGEMENT in accordance with SIM-To-Lt-035 21.A.133(b) and (c)	
The undersigned agree on the following commitments:	Relevant interface procedures
<p>The design organisation <i>[NAME]</i> takes responsibility to</p> <ul style="list-style-type: none"> – assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the production organisation approval holder <i>[NAME]</i> – provide visible statement(s) of approved design data. 	
<p>The production organisation approval holder <i>[NAME]</i> takes responsibility to</p> <ul style="list-style-type: none"> – assist the design organisation <i>[NAME]</i> in dealing with continuing airworthiness matter and for required actions – assist the design organisation <i>[NAME]</i> in case of products prior to type certification in demonstrating compliance with certification specifications – develop, where applicable, its own manufacturing data in compliance with the airworthiness data package. 	
<p>The design organisation <i>[NAME]</i> and the POA holder <i>[NAME]</i> take joint responsibility to</p> <ul style="list-style-type: none"> – deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the production organisation approval holder – achieve adequate configuration control of manufactured parts, to enable the POA holder to make the final determination and identification for conformity. 	
<p>The scope of production covered by this arrangement is detailed in <i>[DOCUMENT REFERENCE/ATTACHED LIST]</i></p>	
<p><i>[When the design organisation is not the same legal entity as the production organisation approval holder]</i></p> <p>Transfer of approved design data: The TC/STC/MTSOA holder <i>[NAME]</i> acknowledges that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved by the Authority and therefore the parts and appliances manufactured in accordance with these data and found in a condition for safe operation may be released certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation.</p>	

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[When the design organisation is not the same legal entity as the production organisation approval holder]

Direct Delivery Authorisation:

This acknowledgment includes also [OR does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

For the *[NAME of the design organisation/DOA holder]*

For the *[NAME of the POA holder]*

Date:

Signature:

Date:

Signature:

xx.xx.xxxx

xx.xx.xxxx

[NAME

[NAME in block letters]

in block letters]

GM 21.A.134 Application – Application form and manner

SVY950 (EMAR Form 50) or the equivalent national form as required by the Authority, should be obtained from the Authority, and completed by the Accountable Manager of the organisation.

The completed form, an outline of the production organisation exposition, and details of the proposed terms of approval are to be forwarded to the Authority.

GM to 21.A.135 Issue of Military Production Organisation Approval

- a) Where a production organisation has an extant EASA Part 21 production organisation approval, and when the military production activity is within the scope of the EASA term of approval, the organisation may be accepted by the Authority to satisfy the SIM-To-Lt-035 requirements for that scope of work with any further investigation limited only to the delta between the two approvals. The Authority is to be kept informed by the production organisation of significant changes to the organisation and of any EASA findings that may impact the military production activity.
- b) Where a production organisation has an extant EASA Part 21 production organisation approval, and when the scope of the EASA term of approval does not entirely cover the military production activity, those parts of the organisation's EASA Part 21 exposition that are equally applicable to satisfy the SIM-To-Lt-035 may be accepted by the Authority as equivalent in respect of the SIM-To-Lt-035 requirements. It is permissible that only those parts of the organisation that are specific to the military activity or requirements are addressed in the SIM-To-Lt-035 exposition. Those requirements covered by read-across of the sections of the EASA exposition document are to be identified and the EASA document clause reference quoted.
- c) The civil airworthiness release certificates signed under the civil POA authority can be recognised and accepted. Authorised signatures may be accepted by the FIMAA for the common civil-military parts manufactured and delivered to a military organisation. Appropriate procedures are to be established to demonstrate that validation of the military applicability of civil parts

installed is performed. Suitable consideration must be given to the impact on continued airworthiness especially with regard to the implementation of applicable civil and military Airworthiness Directives.

GM No. 1 to 21.A.139(a) Quality System

The quality system is an organisational structure with responsibilities, procedures, processes, and resources which implement a management function to determine and enforce quality principles.

The quality system is to be documented in such a way that the documentation can be made easily available to personnel who need to use the material for performing their normal duties, in particular:

- a) procedures, instructions, data to cover the issues of SIM-To-Lt-035 21.A.139(b)(1) are available in a written form,
- b) distribution of relevant procedures to offices/persons is made in a controlled manner,
- c) procedures which identify persons responsible for the prescribed actions are established,
- d) the updating process is clearly described.

The manager responsible for ensuring that the quality system is implemented and maintained is to be identified.

The Authority will verify on the basis of the exposition and by appropriate investigations that the production organisation has established and can maintain their documented quality system.

GM No. 2 to 21.A.139(a) Quality System – Conformity of supplied parts or appliances

The POA holder is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of supplied products, parts or appliances, whether to be used in production or delivered to customers as spare parts. This responsibility also includes GFE (Government Furnished Equipment) items.

To discharge this responsibility the quality system needs an organisational structure and procedures to adequately control suppliers. Elements of the quality system for the control of suppliers may be performed by other parties provided that the conditions of AMC No. 1 or No. 2 to SIM-To-Lt-035 21.A.139(b)(1)(ii) are met.

Control can be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity):

- qualification and auditing of supplier's quality system,

- evaluation of supplier capability in performing all manufacturing activities, inspections and tests necessary to establish conformity of parts or appliances to type design,
- first article inspection, including destruction if necessary, to verify that the article conforms to the applicable data for new production line or new supplier,
- incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt,
- identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents,
- a vendor rating system which gives confidence in the performance and reliability of this supplier,
- any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subjected to the checks normally provided by subsequent production or inspection stages.

The POA holder may rely on inspection/tests performed by supplier if it can establish that:

- personnel responsible in charge of these tasks satisfy the competency standards of the POA quality system,
- quality measurements are clearly identified,
- the records or reports showing evidence of conformity are available for review and audit.

The control of suppliers holding a POA for the parts or appliances to be supplied can be reduced, to a level at which a satisfactory interface between the two quality systems can be demonstrated. Thus, for the purpose of showing conformity, a POA holder can rely upon documentation for parts or appliances released under a supplier's SIM-To-Lt-035 21.A.163 privileges.

A supplier who does not hold a POA is considered as a sub-contractor under the direct control of the POA quality system.

The POA holder retains direct responsibility for inspections/tests carried out either at its own facilities or at supplier's facilities.

GM 21.A.139(b)(1) Quality System – Elements of the quality system

- a) The control procedures covering the elements of SIM-To-Lt-035 21.A.139(b)(1) should document the standards to which the production organisation intends to work.
- b) An organisation having a Quality system designed to meet a recognised Standard such as AS/EN 9100 (relevant to the scope of approval being requested) should expand it to include at least the following additional topics, as appropriate, in order to demonstrate compliance with the requirements of SIM-To-Lt-035 Section A Subpart G:

- i. Mandatory Occurrence Reporting and continued airworthiness as required by SIM-To-Lt-035 21.A.165(e);
 - ii. Control of work occasionally performed (outside the POA facility by POA personnel);
 - iii. Co-ordination with the applicant for, or holder of, an approved design as required by SIM-To-Lt-035 21.A.133(b) and (c) and SIM-To-Lt-035 21.A.165(g);
 - iv. Issue of certifications within the scope of approval for the privileges of SIM-To-Lt-035 21.A.163;
 - v. Incorporation of airworthiness data in production and inspection data as required in SIM-To-Lt-035 21.A.133(b) and (c) and SIM-To-Lt-035 21.A.145(b);
 - vi. When applicable, ground test and/or production flight test of products in accordance with procedures defined by the applicant for, or holder of, the design approval;
 - vii. Procedures for traceability including a definition of clear criteria of which items need such traceability. Traceability is defined as a means of establishing the origin of an article by reference to historical records for the purpose of providing evidence of conformity;
 - viii. Personnel training and qualification procedures especially for certifying staff as required in SIM-To-Lt-035 21.A.145(d).
- c) An organisation having a quality system designed to meet a recognised aerospace quality standard will still need to ensure compliance with all the requirements of SIM-To-Lt-035 Section A Subpart G. In all cases, the Authority will still need to be satisfied that compliance with SIM-To-Lt-035 Section A Subpart G is established.

AMC No. 1 to 21.A.139(b)(1)(ii) Vendor and sub-contractor assessment, audit and control –Production Organisation Approval (POA) holder using documented arrangements with other parties for assessment and surveillance of a supplier

1. General

Note:

For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as 'suppliers', regardless of whether or not they hold a POA and audit and control is hereafter referred to as 'surveillance'.

The production organisation is required by SIM-To-Lt-035 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The use of Other Parties (OP), such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the POA holder from its obligations under SIM-To-Lt-035 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA Holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of OP to perform supplier assessments and surveillance should be part of the production organisation quality system and fulfil the conditions of this AMC.

This AMC is applicable to a method whereby a POA holder has a documented arrangement with OP for the purpose of assessing and/or surveying a POA's supplier.

2. Approval by the Authority

Implementing or changing procedures for using OP for supplier assessment and surveillance is a significant change to the quality system and requires approval in accordance with SIM-To-Lt-035 21.A.147.

3. Conditions and criteria for the use of OP to perform supplier assessment and surveillance

- a) The POA holder should include the use of OP for supplier assessment and surveillance in the POA holders' quality system to demonstrate compliance with the applicable requirements of SIM-To-Lt-035.
- b) Procedures required for using OP for supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.
- c) Procedures of the POA holder that uses OP to perform supplier assessment and surveillance should include the following:
 - 1) Identification of the OP that will conduct supplier assessment and surveillance.
 - 2) A listing of suppliers under surveillance by the OP. This listing should be maintained by the POA holder and made available to the Authority upon request.
 - 3) The method used by the POA holder to evaluate and monitor the OP. The method should include the following as a minimum:
 - i. Verification that standards and checklists used by the OP are acceptable for the applicable scope.
 - ii. Verification that the OP is appropriately qualified and have sufficient knowledge, experience and training to perform their allocated tasks.
 - iii. Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.

- iv. Verification that the suppliers' assessment and surveillance is conducted on-site by the OP.
- v. Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited and working in accordance with an aviation standard (e.g. AS/EN 9104 series of requirements) that describes requirements for the other party assessment and surveillance, the items (ii) and (iv) shall be deemed to be complied with.

- 4) A definition to what scope the OP will conduct suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
 - 5) The procedures used by the OP to notify the POA holder of non-conformities discovered at the supplier's facility, corrective action and follow-up.
- d) The POA should make arrangements that allow the Authority to make investigation in accordance with SIM-To-Lt-035 21.A.157 to include OP activities.

AMC No. 2 to 21.A.139(b)(1)(ii) Vendor and sub-contractor assessment, audit and control - Production Organisation Approval (POA) holder using other party supplier certification

1. General

Note:

For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as 'suppliers', regardless of whether or not they hold a POA and audit and control is hereafter referred to as 'surveillance'.

Other party supplier certification is a method whereby a supplier contracts with an appropriately recognised or accredited Other Party (OP) for the purpose of obtaining a certification from that OP. Certification indicates that the supplier has satisfactorily demonstrated to meet the applicable standard on a continuing basis. OP certification results in placing the supplier on the OP list of certified organisations, or in the supplier receiving a certificate identifying the requirements that have been met. Periodic follow-up evaluations are conducted by the OP to verify continued compliance with the requirements of the applicable standard.

The production organisation is required by SIM-To-Lt-035 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The assessment and surveillance of suppliers by an OP should be deemed to satisfy the requirements of SIM-To-Lt-035 21.A.139(b)(1)(ii) when the conditions of this AMC are satisfied. The assessment and surveillance of suppliers by OP as part of supplier certification does not exempt the POA holder from its obligations under SIM-To-Lt-035 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA Holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of suppliers that are certified by OP in accordance with this AMC should be part of a production organisation quality system.

2. Approval by the Authority

Implementing or changing procedures for using suppliers that are certified by an OP is a significant change to the quality system and requires approval in accordance with SIM-To-Lt-035 21.A.147.

3. Conditions and criteria for using supplier certification for the supplier assessment and surveillance.

- a) The POA holder should include the use of supplier certification for the supplier assessment and surveillance in the POA holder's quality system to demonstrate compliance with the applicable requirements of SIM-To-Lt-035.
- b) Procedures required for use of supplier certification for the supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.
- c) Procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:
 - 1) Listing of the OP that has certified or will certify suppliers and will conduct supplier assessment and surveillance or the scheme under which the accreditation of the OP is controlled. This listing should be maintained by the POA holder and made available to the Authority upon request.
 - 2) A listing of the certified suppliers under surveillance by the OP and used by the POA holder. This listing should be maintained by the POA holder and made available to the Authority upon request.
 - 3) The method used by the POA holder to evaluate and monitor the certification process of any OP certification body or OP certification scheme used. This applies not only to new suppliers, but also to any decision by the POA holder to rely on OP certification of current suppliers. The method should include the following as a minimum:
 - i. Verification that certification standards and checklists are acceptable and applied to the applicable scope.
 - ii. Verification that the OP is appropriately qualified and has sufficient knowledge, experience and training to perform its allocated tasks.

- iii. Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.
- iv. Verification that the suppliers' surveillance is conducted on-site by the OP.
- v. Verification that the surveillance report will be made available to the competent authority upon request.
- vi. Verification that the OP continues to be recognised or accredited.
- vii. Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited and working in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the OP certification, the items (ii), (iv) and (v) shall be deemed to be complied with:

- 4) A definition to what scope the OP will conduct suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
 - 5) Procedures that ensure that the POA is aware of the loss of an existing certification.
 - 6) Procedures that ensure that the POA holder is aware of non-conformities and has access to detailed information of these non-conformities.
 - 7) Procedures to evaluate the consequences of non-conformities and take appropriate actions.
- d) The POA should make arrangements that allow the Authority to make investigation in accordance with SIM-To-Lt-035 21.A.157 to include OP activities.

GM No. 1 to 21.A.139(b)(2) Quality System – Independent quality assurance function

The quality assurance function which is part of the organisation is required to be independent from the functions being monitored. This required independence relates to the lines of reporting, authority and access within the organisation and assumes an ability to work without technical reliance on the monitored functions.

GM No. 2 to 21.A.139(b)(2) Quality System – Adequacy of procedures and monitoring function

Adequacy of procedures means that the quality system, through the use of the procedures as set forth, is capable of meeting the conformity objectives identified in SIM-To-Lt-035 21.A.139(a).

The quality assurance function to ensure the above should perform planned continuing and systematic evaluations or audits of factors that affect the conformity (and, where required, safe operation) of the products, parts or appliances to the applicable design. This evaluation should include all elements of the quality system in order to demonstrate compliance with SIM-To-Lt-035 Section A Subpart G.

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

1. General

- a) Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

- b) Format

The FTOM may:

- be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (ADOA)¹ documents, or
- be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

- c) Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

- a) Exposition (not applicable in the case of ADOA)¹:

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of

¹ Also referred to as APDOA by EASA

flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b) Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c) Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d) Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e) Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f) Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

i. documents associated with a Flight Test Programme:

– Flight Order for a given flight, which should include:

- a list of the tests to be performed and associated conditions;
- safety considerations relevant to the flight;
- category of the flight (e.g. Category 1);
- composition of the crew;

- names of persons other than crew members;
 - aircraft configuration items relevant to the test to be highlighted to the crew;
 - loading of the aircraft;
 - reference to approved flight conditions; and
 - restrictions relevant to the flight to be highlighted to the crew.
- Flight crew report.
- ii. documentation and information to be carried on the aircraft during flight test;
 - iii. record-keeping: the FTOM should describe the policy relative to record-keeping.
- g) Permit to fly:
- The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.
- h) Currency and training:
- The FTOM should describe how training for flight test is organised.
- Currency of the flight test crew may be ensured either through recent experience or refresher training.
- The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.
- A system should be established to record the currency of the flight test crew's training.

GM 21.A.143 Exposition – Production Organisation Exposition

The purpose of the POE is to set forth in a concise document format the organisational relationships, responsibilities, terms of reference, and associated authority, procedures, means and methods of the organisation.

The information to be provided is specified in SIM-To-Lt-035 21.A.143(a). Where this information is documented and integrated in manuals, procedures and instruction, the POE is to provide a summary of the information and an appropriate cross reference.

The Authority requires the POE to be an accurate definition and description of the production organisation. The document does not require approval in itself, but it will be considered as such by virtue of the approval of the organisation.

When changes to the organisation occur, the POE is required to be kept up to date per a procedure, laid down in the POE. Significant changes to the organisation (as defined in GM 21.A.147(a)) is to be approved by the Authority prior to update of the POE.

When an organisation is approved against any other implementing rule containing a requirement for an exposition, a supplement covering the differences may suffice to meet the requirements of SIM-To-Lt-035 Section A Subpart G except that the supplement is to have an index identifying where those parts missing from the supplement are covered. Those items then formally become part of the POE. In any combined documents the POE is to be easily identifiable.

GM 21.A.145(a) Approval Requirements

A facility is a working area where the working conditions and the environment are controlled as appropriate in respect of: cleanliness, temperature, humidity, ventilation, lighting, space/access, noise, air pollution.

Equipment and tools should be such as to enable all specified tasks to be accomplished in a repeatable manner without detrimental effect. Calibration control of equipment and tools which affect critical dimensions and values are to demonstrate compliance with, and be traceable to, national or international standards.

Sufficient personnel means that the organisation has for each function according to the nature of the work and the production rate, a sufficient quantity of qualified personnel to accomplish all specified manufacturing tasks and to attest the conformity. Their number should be such that airworthiness consideration may be applied in all areas without undue pressure.

An evaluation of the competence of personnel is performed as part of the quality system. This should include, where appropriate, verification that specific qualification standards have been implemented, for example NDT, welding, etc. Training should be organised to establish and maintain the personal competence levels determined by the organisation to be necessary.

GM 21.A.145(b)(2) Approval Requirements – Airworthiness and environmental protection, production/quality data procedures

- a) When a POA holder/applicant is developing its own manufacturing data, such as computer-based data, from the design data package delivered by a design organisation, procedures are required to demonstrate the right transcription of the original design data.
- b) Procedures are required to define the manner in which airworthiness and environmental data is used to issue and update the production/quality data, which determines the conformity of products, parts and appliances. The procedure must also define the traceability of such data to each individual product, part or appliance for the purpose of certifying condition for safe operation and issuing a Statement of Conformity or EMAR Form 1 (SVY901).

GM 21.A.145(c)(1) Approval Requirements – Accountable Manager

Accountable Manager means the manager who is responsible, and has corporate authority for ensuring that all production work is carried out to the required standard. This function may be carried out by the Chief Executive or by another person in the organisation, nominated by him or her to fulfil the function provided his or her position and authority in the organisation permits to discharge the attached responsibilities.

The manager is responsible for ensuring that all necessary resources are available and properly used in order to produce under the production approval in accordance with SIM-To-Lt-035 Section A Subpart G.

The manager needs to have sufficient knowledge and authority to enable him or her to respond to the Authority regarding major issues of the production approval and implement necessary improvements.

The manager needs to be able to demonstrate that he or she is fully aware of and supports the quality policy and maintains adequate links with the quality manager.

GM 21.A.145(c)(2) Approval Requirements – Responsible managers

The person or persons nominated should represent the management structure of the organisation and be responsible for all functions as specified in SIM-To-Lt-035 Section A Subpart G. It therefore follows that, depending on the size of the SIM-To-Lt-035 Section A Subpart G organisation, the functions may be subdivided under individual managers (and in fact may be further subdivided) or combined in a variety of ways.

The Authority requires the nominated managers to be identified and their credentials submitted on an SVY904 (EMAR Form 4) to the Authority in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the production activities as performed by the SIM-To-Lt-035 Section A Subpart G organisation.

The responsibilities and the tasks of each individual manager are required to be clearly defined, in order to prevent uncertainties about the relations, within the organisation. In the case of organisation structures where staff-members are responsible to more than one person, as for instance in matrix and project organisations, responsibilities of the managers should be defined in such a way that all responsibilities are covered.

Where a SIM-To-Lt-035 Section A Subpart G organisation chooses to appoint managers for all or any combination of the identified SIM-To-Lt-035 functions because of the size of the undertaking, it is necessary that these managers report ultimately to the Accountable Manager. In cases where a manager does not directly report to the Accountable Manager, he or she should have a formally established direct access to the Accountable Manager.

One such manager, normally known as the quality manager is responsible for monitoring the organisation's compliance with SIM-To-Lt-035 Section A Subpart G and requesting remedial action as necessary by the other managers or the Accountable Manager as appropriate. He or she should have a direct access to the Accountable Manager.

AMC 21.A.145(d)(1) Approval Requirements – Certifying staff

- a) Certifying Staff are nominated by the production organisation to ensure that products, parts and/or appliances qualify for Statements of Conformity or Release Certificates. Certifying Staff positions and numbers are to be appropriate to the complexity of the product and the production rate.
- b) The qualification of certifying staff is based on their knowledge, background and experience and a specific training (or testing) established by the organisation to ensure that it is appropriate to the product, part, or appliance to be released.
- c) Training must be given to develop a satisfactory level of knowledge of organisation procedures, aviation legislation, and associated regulations, airworthiness codes or standards, and associated GM, relevant to the particular role.
- d) For that purpose, in addition to general training policy, the organisation should define its own standards for training, including pre-qualification standards, for personnel to be identified as certifying staff.
- e) Training policy is part of the Quality System and its appropriateness forms part of investigation by the Authority within the organisation approval process and subsequent surveillance of persons proposed by managers.
- f) The training must be updated in response to experience gained and changes in technology.
- g) A feedback system to ascertain that the required standards are being maintained must be put in place to ensure the continuing compliance of personnel to authorisation requirements.
- h) For release of products, parts or appliances, the responsibilities to issue statements of conformity/release certificates (EMAR Form 1 (SVY901)) or military permit to fly including approval of flight conditions are allocated to the certifying staff identified in SIM-To-Lt-035 21.A.145(d)(2).
- i) The Authority holds the right to reject those personnel, appointed by the organisation, if found to have inappropriate experience or not to otherwise comply with its requirements.

AMC 21.A.145(d)(2) Approval Requirements – Record of certifying staff

- a) The following is the minimum information to be recorded in respect of each certifying person:
 - i. Name;
 - ii. Date of Birth;
 - iii. Basic Training and standard attained;

- iv. Specific Training and standard attained;
 - v. If appropriate – Continuation Training;
 - vi. Experience;
 - vii. Scope of the authorisation;
 - viii. Date of first issue of the authorisation;
 - ix. If appropriate – expiry date of the authorisation;
 - x. Identification Number of the authorisation.
- b) The record may be kept in any format and must be controlled by an internal procedure of the organisation. This procedure forms part of the quality system.
 - c) Persons authorised to access the system must be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner and that confidential records cannot become accessible to unauthorised persons.
 - d) The certifying person must be given reasonable access on request to his or her own records.
 - e) Under the provision of SIM-To-Lt-035 21.A.157 the Authority has a right of access to the data held in such a system.
 - f) The organisation must keep the record for at least two years after the certifying person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

AMC 21.A.145(d)(3) Approval requirements – Evidence of authorisation

- a) The authorisation document must be in a style that makes its scope clear to the certifying staff 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.
- b) Certifying staff 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 Authority.

GM 21.A.147(a) Changes to the approved production organisation – Significant changes

- a) Changes to be approved by the Authority include:
 - i. Significant changes to production capacity or methods;

- ii. Changes in the organisation structure especially those parts of the organisation in charge of quality;
 - iii. A change of the Accountable Manager or of any other person nominated under SIM-To-Lt-035 21.A.145(c)(2);
 - iv. Changes in the production or quality systems that may have an important impact on the conformity/airworthiness of each product, part or appliance;
 - v. Changes in the placement or control of significant sub-contracted work or supplied parts.
- b) To ensure that changes do not result in non-compliance with SIM-To-Lt-035 Section A Subpart G it is in the interest of both the Authority and the approval holder to establish a relationship and exchange information that will permit the necessary evaluation work to be conducted before the implementation of a change. This relationship should also permit agreement on the need for variation of the terms of approval (ref. SIM-To-Lt-035 21.A.143(a)(9)).
- c) Where a change of name or ownership results in the issue of a new approval the investigation will normally take account of the Authority's knowledge and information from the preceding approval.
- d) Changes of location are addressed in SIM-To-Lt-035 21.A.148 and changes of ownership in SIM-To-Lt-035 21.A.149, change of scope of approval in SIM-To-Lt-035 21.A.153.

AMC 21.A.148 Changes of location – Management during change of location

- a) The relocation of any work, to an unapproved location, or a location with inappropriate scope of approval, constitutes a change of significance to the organisation and requires approval by the Authority as prescribed in SIM-To-Lt-035 21.A.147. An unapproved relocation will invalidate the production organisation approval, and may necessitate re-application for any similar approval required at the new location. However, suitable transitional arrangements may be agreed with the Authority, in advance of the relocation, which can allow continuation of the approval.
- b) When an organisation expands its facility to include a new production location or moves parts of its production to a new location the production organisation approval may continue in force, but the approval does not include the new location until the Authority has indicated its satisfaction with the arrangements.
- c) For a change in location, taking an extended period of time, suitable transitional arrangements would require preparation of a co-ordination plan for the removal. The plan must, at least, identify the following:
- i. A clearly identified person, or group of persons, responsible for co-ordinating the removal and acting as focal point for communication with all parties, including the Authority;
 - ii. The basis of the co-ordination plan, e.g., whether by product or area;
 - iii. Planned timing of each phase of relocation;

- iv. Arrangements for maintaining the standards of the approval up to the point where the production area is closed down;
 - v. Arrangements for verifying continued production quality upon resumption of work at the new location;
 - vi. Arrangements for check and/or re-calibration of inspection aids or production tools and jigs before resuming production;
 - vii. Procedures which ensure that goods are not released from the new location until their associated production and quality systems have been verified;
 - viii. Arrangements for keeping the Authority informed of progress with the relocation.
- d) From the co-ordination plan, the Authority can determine the points at which it wishes to conduct investigation.
- e) If an agreed co-ordination plan is in operation, the Authority will normally allow the existing approval to remain in force and will, where appropriate, grant an additional approval to cover the new address for the duration of the move.

GM 21.A.149 Transferability

Transfer of approval would normally only be agreed in cases where the ownership changes but the organisation itself remains effectively unchanged. For example:

An acceptable transfer situation could be a change of company name (supported by the appropriate certificate from the National Companies Registration Office or equivalent) but with no changes to site address, facilities, type of work, staff, Accountable Manager or person nominated under SIM-To-Lt-035 21.A.145.

Alternatively, in the event of receivership (bankruptcy, insolvency or other equivalent legal process) there may be good technical justification for continuation of the approval provided that the company continues to function in a satisfactory manner in accordance with their POE. It is likely that at a later stage the approval might be voluntarily surrendered or the organisation transferred to new owners in which case the former paragraphs apply. If it does not continue to operate satisfactorily then the Authority could suspend or revoke the approval.

In order for the Authority to agree to a transfer of approval, it will normally prescribe it as a condition in accordance with SIM-To-Lt-035 21.A.147(b) that the obligations and responsibilities of the former organisation should be transferred to the new organisation, otherwise transfer is not possible and application for a new approval will be required.

GM 21.A.151 Terms of approval – Scope and categories

Terms of approval document(s) will be issued by the Authority under SIM-To-Lt-035 21.A.135 to identify the scope of work, the products, and/or categories for which the holder is entitled to exercise the privileges defined in SIM-To-Lt-035 21.A.163.

The codes shown against each scope of work item are intended for use by the Authority for purposes such as managing, administering and filing details of approvals. It may also assist in the production and publication of a list of approval holders.

The scope of work, the Products, Parts, or Appliances for which the POA holder is entitled to exercise the privileges defined in SIM-To-Lt-035 21.A.163 will be described by the Authority as follows.

FOR PRODUCTS:

1. General area, similar to the titles of the corresponding certification codes.
2. Type of Product, in accordance with the type-certificate.

FOR PARTS AND APPLIANCES:

1. General area, showing the expertise, e.g., mechanical, metallic structure.
2. Generic type, e.g., wing, landing gear, tyres.

SCOPE OF WORK		PRODUCTS/CATEGORIES
A1	Large Aeroplanes	State types
A2	Small Aeroplanes	'
A3	Large Helicopters	'
A4	Small Helicopters	'
A5	Gyroplanes	'
A6	Sailplanes	'
A7	Motor Gliders	'
A8	Manned Balloons	'
A9	Airships	'
A10	Light Sport Aeroplanes	'
A11	Very Light Aeroplanes	'
A12	Other	'
M1	Military Aeroplanes	'
M2	Military Helicopters	'
U1	Fixed Wing UAV	'
U2	Rotary wing UAV	'
B1	Turbine Engines	'
B2	Piston Engines	'
B3	APU's	'
B4	Propellers	'
C1	Appliances:	State appliance generic types (e.g., Tyres, Altimeter, etc.) Examples include: Avionic, Com/Nav/Pulse Computer System,

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SCOPE OF WORK		PRODUCTS/CATEGORIES
C2	Parts:	Aircraft/Engine/Avionic Instruments, Mechanical/Electrical/Gyroscopic/Electronic Mechanical/Hydraulic/Pneumatic State part generic types (e.g., Wing, Landing Gear, etc.) Examples include: Structural, Metallic/non-metallic Mechanical/Hydraulic/Pneumatic Electrical Electronic
D1	Maintenance	State aircraft types
D2	Issue of permit to fly	State aircraft types

AMC 21.A.153 Changes to the terms of approval – Application for a change to the terms of approval

SVY951 (EMAR Form 51) must be obtained from the Authority and completed in accordance with the procedures of the production organisation exposition (POE).

The information entered on the form is the minimum required by the Authority to assess the need for change of the production organisation approval.

The completed form and an outline of the changed POE, and details of the proposed change to POA terms of approval must be forwarded to the Authority.

GM 21.A.157 Investigations – Arrangements

The arrangements made by the applicant for, or holder of an approval under SIM-To-Lt-035 Section A Subpart G should allow the Authority to make investigations that include the complete production organisation including partners, sub-contractors and suppliers, whether they are in the State of the applicant or not.

The investigation may include; audits, enquiries, questions, discussions and explanations, monitoring, witnessing, inspections, checks, flight and ground tests and inspection of completed products, parts or appliances produced under the POA.

In order to maintain its confidence in the standards achieved by a POA holder or applicant the Authority may make an investigation of a sample product part or appliance and its associated records, reports and certifications.

The arrangements should enable the organisation to give positive assistance to the Authority and co-operate in performing the investigation during both initial assessment and for the subsequent surveillance to maintain the POA.

Co-operation in performing investigation means that the Authority has been given full and free access to the facilities and to any information relevant to demonstrate compliance to SIM-To-Lt-035 Section A Subpart G requirements, and assistance (personnel support, records, reports, computer data, etc., as necessary).

Assistance to the Authority includes all appropriate means associated with the facilities of the production organisation to allow the Authority to perform these investigations, such as the availability of a meeting room, office and personnel support, documentation and data, and communication facilities, all properly and promptly available as necessary.

The Authority seeks to have an open relationship with the organisation and suitable liaison personnel are to be nominated to facilitate this, including suitable representative(s) to accompany Authority staff during visits not only at the organisations own facilities but also at sub-contractors, partners or suppliers.

GM No. 1 to 21.A.158(a) Uncontrolled non-compliance with applicable design data

An uncontrolled non-compliance with applicable design data is a non-compliance:

- a) that cannot be discovered through systematic analysis; or
- b) that prevents identification of affected products, parts, appliances, or material.

GM No. 2 to 21.A.158(a) Examples of level one findings

Examples of level one findings are non-compliances with any of the following SIM-To-Lt-035 paragraphs, that could affect the safety of the aircraft:

21.A.139, 21.A.145, 21.A.147, 21.A.148, 21.A.151, 21.A.163, 21.A.165(b), (c), (d), (e), (f) and (g).

It should be anticipated that a non-compliance with these paragraphs is only considered a level one finding when objective evidence has been found that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.

In addition, the failure to arrange for investigations under SIM-To-Lt-035 21.A.157, in particular to obtain access to facilities, after denial of one written request should be classified as a level one finding.

GM 21.A.159(a)(3) Evidence of a lack of satisfactory control

A positive finding by the Authority of:

- a) an uncontrolled non-compliance with type design data affecting the airworthiness of product part or appliance;
- b) an incident/accident identified as caused by POA holder;
- c) non-compliance with the POE and its associated procedures which could affect conformity of manufactured items to design data;
- d) insufficient competence of certifying staff;
- e) insufficient resources in respect of facilities, tools and equipment;
- f) insufficient means to ensure good production work standards;
- g) a lack of effective and timely response to prevent a recurrence of any of paragraph a) to f).

GM 21.A.163 Privileges

SIM-To-Lt-035 21.A.163 lists the privileges an applicant for a production organisation approval may be granted by the authority within the terms of approval, depending on the result of the demonstration of compliance with the associated requirements of SIM-To-Lt-035 Subpart G. Some privileges may be subject to national legal restrictions. Therefore, only those privileges explicitly listed in the terms of approval apply.

AMC 21.A.163(c) Computer generated signature and electronic exchange of the EMAR Form 1 (SVY901)

1. Submission to the Authority

Any POA holder/applicant intending to implement an electronic signature procedure to issue EMAR Form 1 (SVY901) and/or to exchange electronically such data contained on the EMAR Form 1 (SVY901), should document it and submit it to the competent authority as part of the documents attached with its exposition.

2. Characteristics of the electronic system generating the EMAR Form 1 (SVY901).

The electronic system should:

- guarantee secure access for each certifying staff;
- ensure integrity and accuracy of the data certified by the signature of the Form and be able to show evidence of the authenticity of the EMAR Form 1 (SVY901) (recording and record keeping) with suitable security, safeguards and backups;
- be active only at the location where the part is being released with an EMAR Form 1 (SVY901);

- not permit to sign a blank form;
- provide a high degree of assurance that the data has not been modified after signature (if modification is necessary after issuance, i.e., re-certification of a part, a new form with a new number and reference to the initial issuance should be made);
- provide for a "personal" electronic signature identifying the signatory. The signature should be generated only in the presence of the signatory.

An electronic signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication and should meet the following criteria:

- it is uniquely linked to the signatory;
- it is capable of identifying the signatory;
- it is created using means that the signatory can maintain under their sole control.

The electronic signature is defined as an electronically generated value based on a cryptographic algorithm and appended to data in a way to enable the verification of the data's source and integrity.

POA holders/applicants are reminded that additional national and/or European requirements may need to be satisfied when operating electronic systems.

The electronic system should be based on a policy and management structure (confidentiality, integrity and availability), such as:

- administrators, signatories;
- scope of authorisation, rights;
- password and secure access, authentication, protections, confidentiality;
- track changes;
- minimum blocks to be completed, completeness of information;
- archives;
- etc.

The electronic system generating the EMAR Form 1 (SVY901) may contain additional data such as:

- manufacturer code;
- customer identification code;
- workshop report;
- inspection results;
- etc.

3. Characteristics of the EMAR Form 1 (SVY901) generated from the electronic system

To facilitate understanding and acceptance of the EMAR Form 1 (SVY901) released with an electronic signature, the following statement should be in Block 13b: 'Electronic Signature on File'.

In addition to this statement, it is accepted to print or display a signature in any form such as a representation of the hand-written signature of the person signing (i.e. scanned signature) or their name.

When printing the electronic form, it should meet the general format of EMAR Form 1 (SVY901). A watermark-type 'PRINTED FROM ELECTRONIC FILE' should be printed on the document.

When the electronic file contains a hyperlink to data, required to determine the airworthiness of the item(s), the data associated to the hyperlink, when printed, should be in a legible format and be identified as a reference from the EMAR Form 1 (SVY901).

Additional information not required by the EMAR Form 1 (SVY901) completion instructions may be added to the printed copies of EMAR Form 1 (SVY901) as long as the additional data do not prevent a person from filling out, issuing, printing, or reading any portion of the EMAR Form 1 (SVY901). This additional data should be provided only in block 12 unless it is necessary to include it in another block to clarify the content of that block.

4. Electronic exchange of the electronic EMAR Form 1 (SVY901)

The electronic exchange of the electronic EMAR Form 1 (SVY901) should be accomplished on a voluntary basis. Both parties (issuer and receiver) should agree on electronic transfer of the EMAR Form 1 (SVY901).

For that purpose, the exchange needs to include:

- all data of the EMAR Form 1 (SVY901), including data referenced from the EMAR Form 1 (SVY901);
- all data required for authentication of the EMAR Form 1 (SVY901).

In addition, the exchange may include:

- data necessary for the electronic format;
- additional data not required by the EMAR Form 1 (SVY901) completion instructions, such as manufacturer code, customer identification code.

The system used for the exchange of the electronic EMAR Form 1 (SVY901) should provide:

- a high level of digital security; the data should be protected, unaltered or uncorrupted;
- traceability of data back to its source should be possible.

Trading partners wishing to exchange EMAR Form 1 (SVY901) electronically should do so in accordance with these means of compliance stated in this document. It is recommended that they use an established, common, industry method such as Air Transport Association (ATA) Spec 2000 Chapter 16.

The applicant(s) is/are reminded that additional national and/or European requirements may need to be satisfied when operating the electronic exchange of the electronic EMAR Form 1 (SVY901).

The receiver should be capable of regenerating the EMAR Form 1 (SVY901) from the received data without alteration; if not the system should revert back to the paper system.

When the receiver needs to print the electronic form, refer to the subparagraph 3 above.

AMC No 2 to 21.A.163(c) Completion of EMAR Form 1 (SVY901)

EMAR Form 1 (SVY901) Block 8 'Part Number'

The part number as it appears on the item, is usually defined in the design data; however in the case of a kit of parts, media containing software or any other specific condition of supply may be defined in production data developed from design data. Information about the contents of the kit or media may be given in block 12 or in a separate document cross-referenced from block 12.

EMAR Form 1 (SVY901) Block 12 'Remarks'

Examples of conditions which would necessitate statements in Block 12 are:

- When the certificate is used for prototype purposes the following statement must be entered at the beginning of block 12:

'NOT ELIGIBLE FOR INSTALLATION ON IN-SERVICE TYPE-CERTIFICATED AIRCRAFT'.

- Re-certification of items from 'prototype' (conformity only to non-approved data) to 'new' (conformity to approved data and in a condition for safe operation) once the applicable design data is approved.

The following statement must be entered in block 12:

RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW':

THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA [insert TC/STC number, revision level], DATED [insert date if necessary for identification of revision status], TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.

- When a new certificate is issued to correct error(s) the following statement must be entered in block 12:

'THIS CERTIFICATE CORRECTS THE ERROR(S) IN BLOCK(S) [enter block(s) corrected] OF THE CERTIFICATE [enter original tracking number] DATED [enter original issuance date] AND DOES NOT COVER CONFORMITY/ CONDITION/RELEASE TO SERVICE'.

Examples of data to be entered in this block as appropriate:

- For complete engines, a statement of compliance with the applicable emissions requirements current on the date of manufacture of the engine.
- For MTSO articles, state the applicable MTSO number.
- Modification standard.

- Compliance or non-compliance with airworthiness directives or service bulletins.
- Details of repair work carried out, or reference to a document where this is stated.
- Shelf-life data, manufacture date, cure date, etc.
- Information needed to support shipment with shortages or reassembly after delivery.
- References to aid traceability, such as batch numbers.

In the case of an engine, if the Authority has granted an engine exhaust emissions production cut-off exemption, the record: '[New or Spare] engine exempted from NOx emissions production cut-off requirements'.

AMC 21.A.163(d) Privileges – Maintenance

The applicant may apply for terms of approval, which cover maintenance of a new aircraft that it has manufactured, as necessary to keep it in an airworthy condition, but not beyond the point at which the applicable operational rules require maintenance to be performed by an approved maintenance organisation. If the production organisation intends to maintain the aircraft beyond that point, it would have to apply for and obtain an appropriate maintenance approval.

When the Authority is satisfied that the procedures required by SIM-To-Lt-035.A.139 are satisfactory to control maintenance activities so as to ensure that the aircraft is airworthy, this capability will be stated in the terms of approval.

MAINTENANCE OF AIRCRAFT

Examples of such maintenance activities are:

- Preservation, periodic inspection visits, etc.
- Embodiment of a Service Bulletin.
- Application of airworthiness directives.
- Repairs.
- Maintenance tasks resulting from special flights.
- Maintenance tasks to maintain airworthiness during flight training, demo flights and other non-revenue flights.

Any maintenance activities must be recorded in the Aircraft Log Book. It must be signed by certifying staff for attesting the conformity of the work to the applicable airworthiness data.

In some cases the Aircraft Log Book is not available, or the production organisation prefers to use a separate form (for instance for a large work package or for delivery of the aircraft to the customer). In these cases, production organisations must use SVY953 (EMAR Form 53) which must subsequently become part of the aircraft maintenance records.

MAINTENANCE OF COMPONENTS OUTSIDE THE POA CAPABILITY

Such a maintenance activity outside the capability of the aircraft POA holder may still be accomplished under the production approval of the original release organisation. In such circumstances, the engine(s), propeller(s), parts and appliances will require re-release in accordance with SIM-To-Lt-035.A.163(c) (EMAR Form 1 (SVY901)).

Records relevant to continued airworthiness or retirement lives, such as engine runs, flight hours, landings, etc., which affect part retirement of maintenance schedules must be specified on any re-release.

As an alternative the engine, propeller, part or appliance may be maintained by the holder of an approval in accordance with SIM-To-Lt-031, classified and released as 'used'.

AMC 21.A.163(e) Procedure for the issue of a military permit to fly including approval of the flight conditions

1. Intent

This acceptable means of compliance provides means to develop a procedure for the issue of a military permit to fly including approval of the flight conditions.

Each POA applicant or holder must develop its own internal procedure following this AMC, in order to obtain the privilege of SIM-To-Lt-035 21.A.163(e) to issue permits to fly for an aircraft under procedures agreed with its Authority for production, when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight.

2. Procedure for the issue of a military permit to fly

2.1. Content

The procedure must address the following points:

- a) as relevant, in accordance with SIM-To-Lt-035 21.A.710(b), the approval of flight conditions;
- b) conformity with approved conditions;
- c) issue of the military permit to fly under the POA privilege;
- d) authorised signatories;
- e) interface with the local Authority for the flight.

2.2. Approval of the flight conditions (when relevant)

The procedure must include the process to establish and justify the flight conditions, in accordance with SIM-To-Lt-035 21.A.708 and how compliance with SIM-To-Lt-035 21.A.710(c) is established, and include the SVY918b (EMAR Form 18b) as defined in AMC 21.A.709(b) for the approval under the POA privilege.

2.3. Conformity with approved conditions

The procedure must indicate how conformity with approved conditions is made, documented and attested by an authorised person.

2.4. Issue of the military permit to fly under the MPOA privilege

The procedure must describe the process to prepare the SVY920b (EMAR Form 20b) and how compliance with SIM-To-Lt-035 21.A.711(c) and (e) is established before signature of the military permit to fly.

2.5. Authorised signatories

The person(s) authorised to sign the military permit to fly under the privilege of SIM-To-Lt-035 21.A.163(e) must be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the Production Organisation Exposition.

2.6. Interface with the local Authority for the flight

The procedure must include provisions describing the communication with the local Authority for compliance with the local requirements which are outside the scope of the conditions of SIM-To-Lt-035 21.A.708(b) (see SIM-To-Lt-035 21.A.711(e)).

GM 21.A.165(a) Obligations of the holder – Basic working document

Compliance with the production organisation exposition (POE) is a prerequisite for obtaining and retaining a production organisation approval.

The organisation should make the POE available to its personnel where necessary for the performance of their duties. A distribution list is to therefore be established. Where the POE mainly refers to separate manuals or procedures, the distribution of the POE could be limited.

The organisation should ensure that personnel have access to and are familiar with that part of the content of the POE or the referenced documents, which covers their activities.

Monitoring of compliance with the POE is normally the responsibility of the quality assurance function.

GM No. 1 to 21.A.165(c) Obligations of the holder – Conformity of prototype models and test specimens

SIM-To-Lt-035 21.A.33 requires determination of conformity of prototype models and test specimens to the applicable design data. The EMAR Form 1 (SVY901) may be used as a conformity certificate as part of the assistance a POA holder provides to a design approval holder/applicant.

GM No. 2 to 21.A.165(c) Obligations of holder – Conformity with type design

Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type certificate holder. There are also likely to be unintentional divergences (concessions or non-conformances) during the manufacturing process. All these changes should have been approved by the design approval holder, or when necessary by the Authority.

GM No. 3 to 21.A.165(c) Obligations of the holder – Condition for safe operation

Before issue of the Statement of Conformity to the Authority of the State of registry, the holder of a production organisation approval should make an investigation so as to be satisfied in respect of each of the items listed below. The documented results of this investigation are to be kept on file by the POA holder. Certain of these items may be required to be provided (or made available) to the operator or owner of the aircraft (and in some cases the Authority of the State of registry):

- a) Equipment or modifications which do not meet the requirements of the State of manufacture but have been accepted by the Authority of the importing country;
- b) Identification of products, parts or appliances which:
 - i. are not new;
 - ii. are furnished by the buyer or future operator (including those identified in SIM-To-Lt-035 21.A.801 and SIM-To-Lt-035 21.A.805).
- c) Technical records which identify the location and serial numbers of significant components that have special traceability requirements for continued airworthiness purposes including those identified in SIM-To-Lt-035 21.A.801 and SIM-To-Lt-035 21.A.805;
- d) Log book and a modification record book for the aircraft as required by the Authority;
- e) Log books for products identified in SIM-To-Lt-035 21.A.801 installed as part of the type design as required by the Authority;
- f) A weight and balance report for the completed aircraft;
- g) A record of missing items or defects which do not affect airworthiness these for example could be furnishing or GFE (Items may be recorded in a technical log or other suitable arrangement such that the operator and Authority are formally aware);
- h) Product support information required by other rules and associated airworthiness requirements or GM, such as a Maintenance Manual, a Parts Catalogue, or MMEL all of which are to reflect

the actual build standard of the particular aircraft. Also, an Electrical load analysis and a wiring diagram;

- i) Records which demonstrate completion of maintenance tasks appropriate to the test flight flying hours recorded by the aircraft. These records should show the relationship of the maintenance status of the particular aircraft to the manufacturers recommended maintenance task list and the MRB document/report;
- j) Details of the serviceability state of the aircraft in respect of a) the fuel and oil contents, b) provision of operationally required emergency equipment such as life rafts, etc.;
- k) Details of the approved interior configuration if different from that approved as part of the type design;
- l) An approved Flight Manual which conforms to the build standard and modification state of the particular aircraft shall be available;
- m) Show that inspections for foreign objects at all appropriate stages of manufacture have been satisfactorily performed;
- n) The registration has been marked on the exterior of the aircraft as required by national legislation. Where required by national legislation fix a fireproof owners nameplate;
- o) Where applicable there should be a certificate for noise and for the aircraft radio station;
- p) The installed compass and or compass systems have been adjusted and compensated and a deviation card displayed in the aircraft;
- q) Software criticality list;
- r) A record of rigging and control surface movement measurements;
- s) Details of installations which will be removed before starting operations (e.g., ferry kits for fuel, radio or navigation);
- t) Where maintenance work has been performed under the privilege of SIM-To-Lt-035 21.A.163(d) issue a release to service that includes a statement that the aircraft is in a condition for safe operation;
- u) List of all applicable Service Bulletins and airworthiness directives that have been implemented.

GM No. 4 to 21.165(c) Airworthiness Release or Conformity Certificate

The EMAR Form 1 (SVY901), when used as a release certificate as addressed in SIM-To-Lt-035 21.A.165(c)(2) and (3), may be issued in two ways:

- a) As an airworthiness release, only when by virtue of the arrangement described in SIM-To-Lt-035 21.A.133(b) and (c), it can be determined that the part conforms to the approved design data and is in condition for safe operation.

- b) As a conformity certificate, only when by virtue of the arrangement described in SIM-To-Lt-035 21.A.133(b) and (c), it can be determined that the part conforms to applicable design data which is not (yet) approved, for a reason that is indicated in Block 12. Parts released with an EMAR Form 1 (SVY901) as a conformity Certificate are not eligible for installation in a type certificated aircraft.

The EMAR Form 1 (SVY901) should only be used for conformity release purposes when it is possible to indicate the reason that prevents its issue as for airworthiness release purposes.

GM 21.A.165(c)(3) Definitions of engine type certification date and production date

In case the Authority requires compliance with civil environmental requirements, Volume II of Annex 16 to the Chicago Convention contains two different references to applicability dates:

1. 'Date of manufacture for the first individual production model' which refers to the engine type certification date; and
2. 'Date of manufacture for the individual engine' which refers to the production date of a specific engine serial number (date of Form 1).

The second reference is used in the application of engine NO_x emissions production cut-off requirement which specifies a date after which all in-production engine models must meet a certain NO_x emissions standard.

AMC 21.A.165(c)(4) Applicable aircraft CO₂ emissions requirements

This determination is made according to the data provided by the aircraft type certificate holder. This data should allow the determination of whether the aircraft complies with the CO₂ emissions requirements established by the Authority.

GM 21.A.165(d) and (h) Obligations of the holder – Recording and archiving system

Records within a production environment satisfy two purposes. Firstly, they are required, during the production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.

Therefore, the approved production organisation should implement a system for the compilation and retention of records during all stages of manufacture, covering short-term and long-term records appropriate to the nature of the product and its production processes.

The management of such information should be subject to appropriate procedures in the Quality System required by SIM-To-Lt-035 21.A.139.

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

The related organisation procedures should:

- a) Identify records to be kept;
- b) Describe the organisation of and responsibility for the archiving system (location, compilation, format) and conditions for access to the information (e.g., by product, subject);
- c) Control access and provide effective protection from deterioration or accidental damage;
- d) Ensure continued readability of the records;
- e) Demonstrate to the Authority proper functioning of the records system;
- f) Clearly identify the persons involved in conformity determination;
- g) Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:
 - i. Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate;
 - ii. Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.
- h) Ensure that the recording and record-keeping system used by the partners, supplier and sub-contractors meet the objective of conformity of the product, part or appliance with the same level of confidence as for their own manufacture. They should define in each case who is to retain the record data (organisation or partner, supplier or sub-contractor). They should also define method for surveillance of the recording/record keeping system of the partners, suppliers or sub-contractors.

SUBPART J - MILITARY DESIGN ORGANISATION APPROVAL

GM to 21.A.235 Issue of a Design Organisation Approval

- a) Where a design organisation has an extant EASA Part 21 design organisation approval, and when the military design activity is in the scope of the EASA terms of approval, the organisation may be accepted by the Authority to satisfy the SIM-To-Lt-035 requirements for that scope of work with any further investigation limited only to the delta between the two approvals. The Authority is to be kept informed by the design organisation of significant changes to the organisation and of any EASA findings that may impact the military design activity.
- b) Where a design organisation has an extant EASA Part 21 design organisation approval, and when the scope of the EASA terms of approval does not entirely cover the military design activity, those parts of the organisation's EASA Part 21 handbook that are equally applicable to satisfy SIM-To-Lt-035 may be accepted by the Authority as equivalent in respect of the SIM-To-Lt-035 requirements. It is permissible that only those parts of the organisation that are specific to the military activity or requirements are addressed in the SIM-To-Lt-035 handbook (Design Organisation Exposition). Those requirements covered by read-across of the sections of the EASA handbook are to be identified with a reference to the applicable procedures or other basic working documents as referred to in the EASA handbook.

GM No. 1 to 21.A.239(a) Design assurance system

1. Purpose

This GM outlines some basic principles and objectives of SIM-To-Lt-035 21.A.239(a).

2. Definitions

2.1. The design assurance system is the organisational structure, responsibilities, procedures and resources to ensure the proper functioning of the design organisation.

2.2. The design assurance means all those planned and systematic actions necessary to provide adequate confidence that the organisation has the capability:

- to design products, or parts in accordance with the applicable airworthiness requirements and environmental protection requirements;
- to demonstrate and verify the compliance with these requirements; and
- to demonstrate this compliance to the Authority.

2.3. The “Type Investigation” means the tasks of the organisation in support of the type certificate, supplemental type certificate or other design approval processes necessary to demonstrate and verify and to maintain compliance with the applicable airworthiness codes and standards and environmental protection requirements.

3. Design Assurance

The complete process, starting with the airworthiness codes and standards and 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.

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 codes and standards and environmental protection requirements and will continue to comply after any change.

Two main aspects should therefore be considered:

- How the planned and systematic actions are defined and implemented, from the very beginning of design activities up to and including the continued airworthiness activities;
- How these actions are regularly evaluated and corrective actions implemented as necessary.

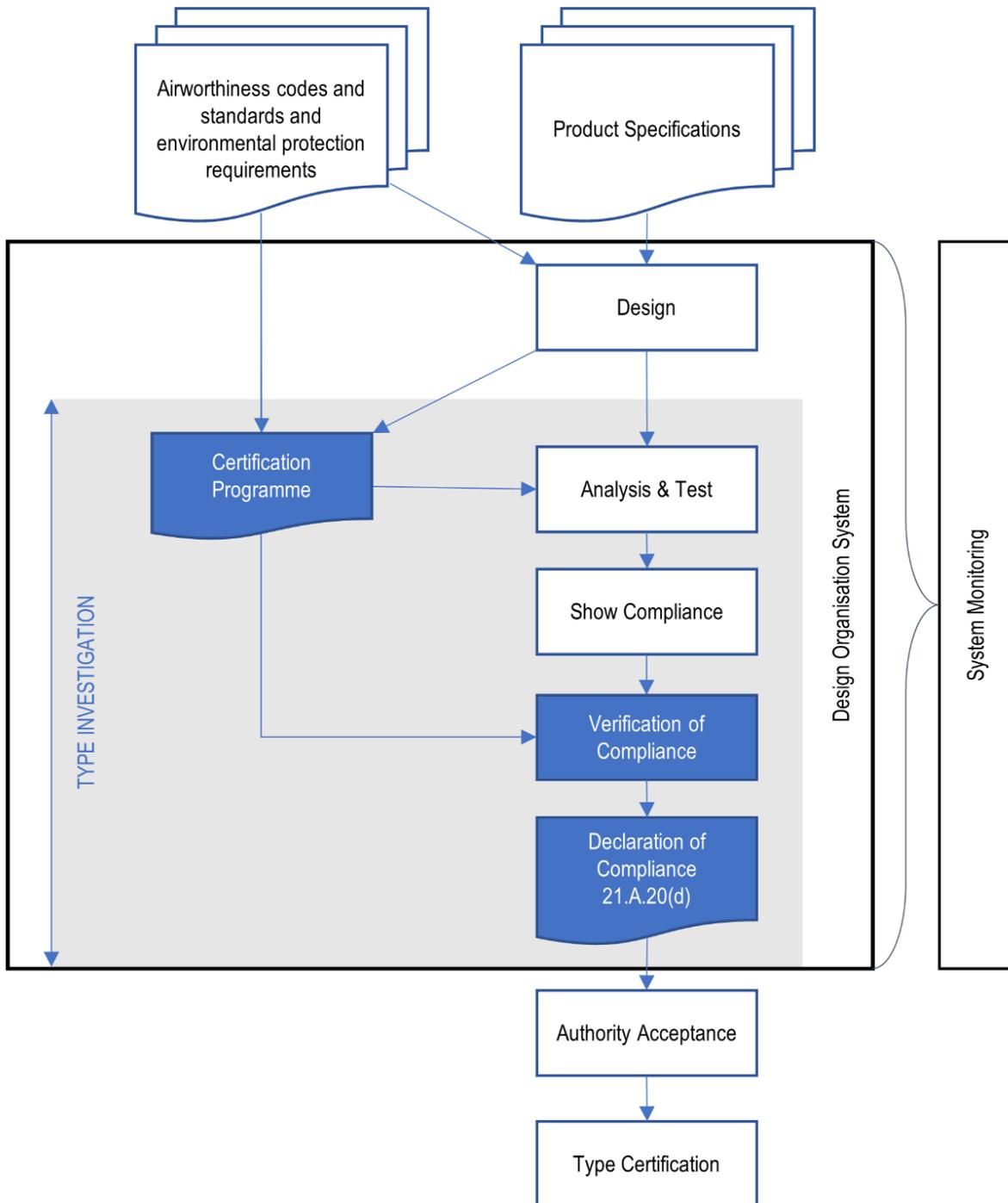


Figure 1 - Relationships between design, design assurance and type investigation

3.1. 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:

3.1.1. General

- a) To issue or, where applicable, supplement or amend the design organisation handbook in accordance with SIM-To-Lt-035 21.A.243, in particular to indicate the initiation of design activities on a product.
- b) To assure that all instructions of the handbook is adhered to.
- c) To conduct Type Investigation.
- d) To nominate staff as 'compliance verification engineers' responsible to approve compliance documents as defined in paragraph 3.1.3.
- e) To nominate personnel belonging to the Office of Airworthiness responsible as defined in paragraph 3.1.4.
- f) In the case of an applicant for a supplemental type-certificate, to obtain the agreement of the type-certificate holder for the proposed supplemental type-certificate to the extent defined in SIM-To-Lt-035 21.A.115.
- g) To ensure full and complete liaison between the type design organisation and related organisations having responsibility for products manufactured to the type-certificate.
- h) To provide the assurance to the Authority that prototype models and test specimens adequately conform to the type design (see SIM-To-Lt-035 21.A.33(b)(1)).

3.1.2. Chief Executive and Head of design organisation (or his or her Deputy)

- a) The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.
- b) The Head of the design organisation, or an authorised representative, should sign a declaration of compliance (see SIM-To-Lt-035 21.A.20(d) and SIM-To-Lt-035 21.A.97(a)(3)) with the applicable airworthiness codes and standards and environmental protection requirements after verification of satisfactory completion of the Type Investigation. In accordance with SIM-To-Lt-035 21.A.20(e) and SIM-To-Lt-035 21.A.97(a)(4), his or her signature on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM A.265(b)).
- c) The functions of Chief Executive and Head of the design organisation may be performed by the same person.

3.1.3. Compliance Verification

- a) Approval by signing of all compliance documents, including test programmes and data, necessary for the verification of compliance with the applicable airworthiness codes and standards and environmental protection requirements as defined in the certification programme.
- b) Approval of the technical content (completeness, technical accuracy...), including any subsequent revisions, of the manuals approved by the Authority (Aircraft Flight Manual, the Airworthiness Limitations section of the Instructions for Continuing Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable).

3.1.4. Office of Airworthiness

- a) Liaison between the design organisation and the Authority with respect to all aspects of the certification programme.
- b) Ensuring that a handbook is prepared and updated as required in SIM-To-Lt-035 21.A.243.
- c) Co-operation with the Authority in developing procedures to be used for the type certification process.
- d) Issuing of guidelines for documenting compliance.
- e) Co-operation in issuing guidelines for the preparation of the manuals required by the applicable regulations, Service Bulletins, drawings, specifications, and standards.
- f) Ensuring procurement and distribution of applicable airworthiness codes or standards, environmental protection requirements and other specifications.
- g) Co-operating with the Authority in proposing the type-certification basis
- h) Interpretation of airworthiness codes or standards and environmental protection requirements and requesting decisions of the Authority in case of doubt.
- i) Advising of all departments of the design organisation in all questions regarding airworthiness, operational suitability, environmental protection approvals and certification.
- j) Preparation of the certification programme and co-ordination of all tasks related to Type Investigation in concurrence with the Authority.
- k) Regular reporting to the Authority about Type Investigation progress and announcement of scheduled tests in due time.
- l) Ensuring co-operation in preparing inspection and test programmes needed for demonstration of compliance.
- m) Establishing the compliance checklist and updating for changes.
- n) Checking that all compliance documents are prepared as necessary to demonstrate compliance with all airworthiness codes and standards and environmental protection requirements, as well as for completeness, and signing for release of the documents.
- o) Checking the required type design definition documents described in SIM-To-Lt-035 21.A.31 and ensuring that they are provided to the Authority for approval when required.

- p) Preparation, if necessary, of a draft for a type-certificate data sheet and/or type-certificate data sheet modification.
- q) Providing verification to the head of the design organisation that all activities required for Type Investigation have been properly completed.
- r) Approving the classification of changes in accordance with SIM-To-Lt-035 21.A.91 and granting the approval for minor changes in accordance with SIM-To-Lt-035 21.A.95(b).
- s) Monitoring of significant events on other aeronautical products as far as relevant to determine their effect on airworthiness or operational suitability of products being designed by the design organisation.
- t) Ensuring co-operation in preparing Service Bulletins and the Structural Repair Manual, and subsequent revisions, with special attention being given to the manner in which the contents affect airworthiness and environmental protection and granting the approval on behalf of the Authority.
- u) Ensuring the initiation of activities as a response to a failure (accident/incident/in-service occurrence) evaluation and complaints from the operation and providing of information to the Authority in case of airworthiness or operational suitability impairment (continuing airworthiness and continued operational suitability).
- v) Advising the Authority with regard to the issue of airworthiness directives in general based on Service Bulletins.
- w) Ensuring that the manuals approved by the Authority, including any subsequent revisions (the Aircraft Flight Manual, MMEL, the Airworthiness Limitations section of the Instructions for Continuing Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable) are checked to determine that they meet the respective requirements, and that they are provided to the Authority for approval.

3.1.5. Maintenance and Operating Instructions

- a) Ensuring the preparation and updating of all maintenance and operating instructions (including instructions for continuing airworthiness and services bulletins) needed to maintain airworthiness (continuing airworthiness) in accordance with the relevant airworthiness codes and standards. For that purpose, the applicant should:
 - establish the list of all documents it is producing and that are to be delivered to the operator, such as Flight Manual, ICA, engine configuration and interface documentation (e.g as required to comply with EASA CS 2X.1581, EASA CS 2X.1529, EASA CS-E 20/25 or EASA CS-P 40);
 - establish a system to collect in-service experience to be used for the improvement of the instructions;
 - define procedures and organisation to produce and issue these documents, under the obligation of SIM-To-Lt-035 21.A.265(h); the procedures should cover:

- preparation, including the format and language (available industrial standards can be referred to and used);
- proofreading (checking for clarity, readability, typos, etc.);
- checking of technical consistency with the corresponding approved change(s), repair(s) or approved data, including the effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;
- checking of feasibility in practical applications; and
- responsibilities and authorised signatories.

b) In accordance with SIM-To-Lt-035 21.A.57, 21.A.62, 21.A.108, 21.A.119 and SIM-To-Lt-035 21.A.120B, ensuring that these documents are provided to all affected operators and training organisations and all involved authorities.

3.2. 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.

GM No. 2 to 21.A.239(a) Design assurance system for minor changes to type design or minor repairs to products

1. Purpose

This GM outlines some basic principles and objectives in order to comply with SIM-To-Lt-035 21.A.239(a) for organisations designing only minor changes to type design or minor repairs to products.

2. Design assurance system

- a) an organisational structure to:
 - i. control the design;
 - ii. demonstrate compliance with applicable airworthiness codes and standards and environmental protection requirements;
 - iii. independently check demonstrations of compliance;
 - iv. liaise with the Authority;
 - v. continuously evaluate the design organisation;
 - vi. control sub-contractors.

- b) procedures and responsibilities associated with the functions listed above, taking due account of SIM-To-Lt-035 requirements applicable to design and approval of minor changes to type design or minor repairs to products.

AMC 21.A.239(a)(3) Design assurance system - Independent system monitoring

The system monitoring function required by SIM-To-Lt-035 21.A.239(a)(3) may be undertaken by the existing quality assurance organisation when the design organisation is part of a larger organisation.

AMC 21.A.239(b) Design assurance system - Independent checking function of the demonstration of compliance

1. The independent checking function of the demonstration of compliance 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.
2. The verification should be shown by signing compliance documents, including test programmes and data.
3. For a product, there is normally only one compliance verification engineer nominated for each relevant subject. A procedure should cover the non-availability of nominated persons and their replacement when necessary.
4. For STC cases, when compliance statement and associated documentation are produced by the TC holder, and when these data are approved under the system of the authority of TC holder, then the STC applicant does not need to provide, within its own DOA, the independent checking function required in SIM-To-Lt-035 21.A.239(b) for these data.

GM 21.A.239(c) Design assurance system

In meeting the requirements of SIM-To-Lt-035 21.A.239(c) the applicant for a design organisation approval under SIM-To-Lt-035 Section A Subpart J may adopt the following policy:

1. The satisfactory integration of the Partner/Sub-contractor and applicant's design assurance systems should be demonstrated for the activities covered under the applicant's terms of approval.
2. In the event that a Partner/Sub-contractor holds a design organisation approval (DOA), then in accordance with SIM-To-Lt-035 21.A.239(c), the applicant may take this into account in demonstrating the effectiveness of this integrated system.

3. When any Partner/Sub-contractor does not hold a DOA then the applicant will need to establish to its own satisfaction and the satisfaction of the Authority, the adequacy of that partner's/sub-contractor's design assurance system in accordance with SIM-To-Lt-035 21.A.243(b).

**AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b)
Flight Test Operations Manual (FTOM)**

1. General

- a) Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

- b) Format

The FTOM may:

- be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (ADOA)¹ documents, or
- be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

- c) Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

- a) Exposition (not applicable in the case of ADOA)¹:

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

- b) Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

¹ Also referred to as APDOA by EASA

c) Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d) Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e) Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f) Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

i. documents associated with a Flight Test Programme:

– Flight Order for a given flight, which should include:

- a list of the tests to be performed and associated conditions;
- safety considerations relevant to the flight;
- category of the flight (e.g. Category 1);
- composition of the crew;
- names of persons other than crew members;
- aircraft configuration items relevant to the test to be highlighted to the crew;
- loading of the aircraft;
- reference to approved flight conditions; and

- restrictions relevant to the flight to be highlighted to the crew.
 - Flight crew report.
 - ii. documentation and information to be carried on the aircraft during flight test;
 - iii. record-keeping: the FTOM should describe the policy relative to record-keeping.
- g) Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.
- h) Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

AMC No. 1 to 21.A.243(a) Handbook (Design Organisation Exposition) requirements

The handbook (design organisation exposition) should provide the following information for each product covered by the design organisation approval.

1. A description of the tasks which can be performed under the approval, according to the following classification:
 - a) General areas, like turbojet and turbo-propeller aircraft, small aircraft, UAVs, 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.

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2. 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.
3. 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.
4. A general description of the way in which the organisation performs all the design functions in relation to airworthiness, operational suitability and environmental protection approvals including:
 - 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 codes and standards 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.
5. A general description of the way in which the organisation performs its functions in relation to the continued airworthiness and continued operational suitability of the product it designs, including co-operation with the production organisation when dealing with any continued airworthiness actions that are related to production of the product, part or appliance, as applicable.
6. A description of the human resources, facilities and equipment, which constitutes the means for design, and where appropriate, for ground and flight testing.
7. 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.
8. 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...).
9. A description of the record keeping system to comply with SIM-To-Lt-035 21.A.55 and SIM-To-Lt-035 21.A.105.
10. A description of the means by which the organisation monitors and responds to problems affecting the airworthiness or operational suitability of its product during design, production and in service in

particular to comply with SIM-To-Lt-035 21.A.3A (see also GM No. 1 to SIM-To-Lt-035 21.A.239(a), paragraphs 3.1.4(s) and (u)).

11. The names of the design organisation authorised signatories. Nominated persons with specific responsibilities such as mentioned in SIM-To-Lt-035 21.A.33 and SIM-To-Lt-035 21.A.35 should be listed.
12. (Reserved).
13. A clear definition of the tasks, competence and areas of responsibility of the Office of Airworthiness.
14. A description of the procedures for the establishment and the control of the maintenance and operating instructions (see SIM-To-Lt-035 21.A.57, SIM-To-Lt-035 21.A.61, SIM-To-Lt-035 21.A.107, SIM-To-Lt-035 21.A.119, SIM-To-Lt-035 21.A.120A and SIM-To-Lt-035 21.A.449).
15. 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.
16. A description of the procedures for the establishment and the control of the operational suitability data (see SIM-To-Lt-035 21.A.57, SIM-To-Lt-035 21.A.62, SIM-To-Lt-035 21.A.108, SIM-To-Lt-035 21.A.119 and SIM-To-Lt-035 21.A.120B).

AMC No. 2 to 21.A.243(a) Handbook (Design Organisation Exposition) requirements - Model content for organisations designing minor changes to type design or minor repairs to products

Part 1. Organisation

- 1.1 Objective of the handbook and binding statement
- 1.2 Responsible person for administration of the 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 GM No. 2 to 21.A.243(d), paragraph 2)
- 1.12 Independent system monitoring

Part 2. Procedures

- 2.1 Management of changes to type design and design of repairs
 - configuration control
 - classification
 - 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
 - in relations with the changes and repairs
 - in relation with failures/malfunctions and defects (i.e. Services - Bulletins)
- 2.6 Record keeping.

GM No. 1 to 21.A.243(d) Statement of qualifications and experience

1. Purpose

This GM provides guidelines on the following points:

- Who are the persons covered by SIM-To-Lt-035 21.A.243(d)?
- What is requested from the applicant for these persons?

2. Who are the persons?

Three different types of functions are named or implicitly identified in the requirements of SIM-To-Lt-035 Section A Subpart J or in associated AMC and GM, using qualified and experienced personnel:

- the Chief Executive [see GM No. 1 to 21.A.239(a), para. 3.1.2, GM 21.A.249, GM 21.A.265(b)].
- the other management staff:
 - the Head of the design organisation [see GM No. 1 to 21.A.239(a), para.3.1.2, GM No. 1 21.A.245, para. 4.1, GM 21.A.265(b)];
 - the Chief of the Office of Airworthiness, or [see GM No. 1 to 21.A.245, para. 4.2];
 - the Chief of the independent monitoring function of the design assurance system [see SIM-To-Lt-035 21.A.239(a)(3) and AMC No. 1 to 21.A.243(a), para.2].

- the personnel making decisions affecting airworthiness, operational suitability and environmental protection:
 - compliance verification engineers [see GM No. 1 to 21.A.239(a), para. 3.1.3; AMC 21.A.239(b)];
 - personnel of the Office of Airworthiness making decisions affecting airworthiness, operational suitability and environmental protection, especially those linked with the SIM-To-Lt-035 21.A.263 privileges (signing documents for release, approving classification of changes and repairs, and granting the approval of minor changes and minor repairs, granting the approval of SBs, and minor revisions to the aircraft flight manual) [see GM No. 1 to 21.A.239(a), para. 3.1.4].

3. Kind of statement

3.1. Chief Executive

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

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

3.2. Other management staff

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 SIM-To-Lt-035 Section A Subpart J. Depending on the size of the organisation, the functions may be subdivided under individual managers.

The nominated managers should be identified and their credentials furnished to the Authority on SVY904 (EMAR Form 4) 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.

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.

3.3. Personnel making decisions affecting airworthiness, operational suitability and environmental protection

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

The following guidelines for such a system are proposed:

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

- The needs, in terms of quantity of these personnel to sustain the design activities, should be identified by the organisation.
- These personnel should be chosen on the basis of their knowledge, background and experience.
- When necessary, complementary training should be established, to ensure sufficient background and knowledge in the scope of their authorization. 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.
- Training policy forms part of the design assurance system and its appropriateness forms part of investigation by the Authority within the organisation approval process and subsequent surveillance of persons proposed by the organisation.
- This training should be adapted in response to experience gained within the organisation.
- 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.
- The following minimum information should be kept on record:
 - a) Name;
 - b) Date of birth;
 - c) Experience and training;
 - d) Position in organisation;
 - e) Scope of the authorisation;
 - f) Date of first issue of the authorisation;
 - g) If appropriate, date of expiry of the authorisation;
 - h) Identification number of the authorisation.

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

- 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.
- Personnel should be given access to their own record.
- Under the provision of SIM-To-Lt-035 21.A.257 the Authority has a right of access (subject to contract) to the data held in such a system.

- The organisation should keep the record for at least 2 years after a person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

GM No. 2 to 21.A.243(d) Data requirements - Statement of the qualification and experience- Organisations designing minor changes to type design or minor repairs to products

For organisations designing minor changes to type design or minor repairs to products, the statement of the qualifications and experience required by SIM-To-Lt-035 21.A.243(d) should be addressed as follows:

1. The nominated managers should be identified and their credentials submitted to the Authority on SVY904 (EMAR Form 4) 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.
2. The persons responsible for
 - classifying changes to type design or repairs,
 - verifying compliance (SIM-To-Lt-035 21.A.239(b)),
 - approving minor changes to type design and minor repairs (SIM-To-Lt-035 21.A.263(c)(2)),
 - issue information or instructions (SIM-To-Lt-035 21.A.265(h)),

should be selected by the organisation in accordance with a procedure and criteria agreed with the Authority.

GM No. 1 to 21.A.245 Requirements for approval

See SIM-To-Lt-035 21.A.245

1. General.

The data submitted in accordance with SIM-To-Lt-035 21.A.243 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 GM No. 1 to 21.A.239(a), paragraph 2.3.

2. Personnel.

The applicant should show that the personnel available to comply with SIM-To-Lt-035 21.A.245(a) 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 codes and standards and environmental protection requirements while taking into account the present state of the art and new experience.

3. Technical.

The applicant should have access to:

- a) Workshops and production facilities which are suitable for manufacturing prototype models and test specimens;
- b) Accommodation and test facilities which are suitable for carrying out tests and measurements needed to demonstrate compliance with the airworthiness codes and standards and environmental protection requirements. The test facilities may be subjected to additional technical conditions related to the nature of tests performed.

4. Organisation.

The data submitted in accordance with SIM-To-Lt-035 21.A.243 should show that:

- 4.1. 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 SIM-To-Lt-035 Section A Subpart J.
- 4.2. 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, operational suitability and environmental protection matters (see GM No. 1 to 21.A.239(a) paragraph 3.1.4); 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.
- 4.3. [Reserved]
- 4.4. Responsibilities for all tasks related to Type Investigations are assigned in such a way that gaps in authority are excluded.
- 4.5. The responsibility for a number of tasks as in paragraph 4.4 may be assigned to one person especially in the case of simple projects.
- 4.6. Co-ordination between technical departments and the persons in charge of the system monitoring required by SIM-To-Lt-035 21.A.239(a)(3) has been established:
 - a) to ensure quick and efficient reporting and resolution of difficulties encountered using the handbook and associated procedures;
 - b) to maintain the design assurance system;
 - c) to optimise auditing activities.

GM No. 2 to 21.A.245 Requirements for approval - Organisations designing minor changes to type design or minor repairs to products

The data submitted in accordance with SIM-To-Lt-035 21.A.243 should show that:

1. 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.
2. Person(s) have been nominated to liaise with the Authority and to co-ordinate airworthiness, operational suitability and environmental protection matters. Their position in the organisation should allow direct report to the manager responsible for design.
3. 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
4. The responsibility for a number of tasks as in paragraph 3 may be assigned to one person especially in the case of simple projects.

GM 21.A.247 Significant changes in the design assurance system

In addition to a change in ownership (see SIM-To-Lt-035 21.A.249), the following changes to the design assurance system should be considered to be “significant” to the demonstration of compliance or to the airworthiness, operational suitability or environmental protection of the products:

1. Organisation
 - Relocation to new premises (see also GM 21.A.249).
 - Change in the industrial organisation (partnership, suppliers, design work sharing) unless it can be shown that the independent checking function of the demonstration of compliance is not affected.
 - Change in the parts of the organisation that contribute directly to the airworthiness, operational suitability or environmental protection (independent checking function, office of airworthiness (or equivalent)).
 - Change to the independent monitoring principles (see SIM-To-Lt-035 21.A.239(a)(3)).
2. Responsibilities
 - Change of the management staff
 - the Head of the design organisation (GM No. 1 to 21.A.239(a), para. 3.1.2, GM No. 1 to 21.A.245, para. 4.1, GM 21.A.265(b));
 - the Chief of the Office of Airworthiness (GM No. 1 to 21.A.245, para. 4.2);

- the Chief of the independent monitoring function of the design assurance system (SIM-To-Lt-035 21.A.239(a)(3) and AMC No. 1 to 21.A.243(a), para.2).
- New distribution of responsibilities affecting airworthiness, operational suitability or environmental protection.
- For organisations designing minor changes to type design or minor repairs to products, change of the persons identified in GM No. 2 to 21.A.243(d).

3. Procedures

Change to the principles of procedures related to:

- the type certification;
- the classification of changes and repairs as " major " or " minor " (SIM-To-Lt-035 21.A.263(c)(1));
- the treatment of major changes and major repairs;
- the approval of the design of minor changes and minor repairs (SIM-To-Lt-035 21.A.263(c)(2));
- the approval of the design of certain major repairs (SIM-To-Lt-035 21.A.435(b) or SIM-To-Lt-035 21.A.263(c)(5));
- the approval of the conditions under which a permit to fly can be issued (SIM-To-Lt-035 21.A.263(c)(6));
- the issue of a permit to fly (SIM-To-Lt-035 21.A.263(c)(7));
- the approval of certain major changes to a type certificate (SIM-To-Lt-035 21.A.263(c)(8));
- the approval of certain supplemental type certificates (SIM-To-Lt-035 21.A.263(c)(9));
- the approval of certain major changes to certain supplemental type certificates; (SIM-To-Lt-035 21.A.263(c)(9));
- continued airworthiness or continued operational suitability (see SIM-To-Lt-035 21.A.3A);
- the configuration control, when airworthiness, operational suitability or environmental protection is affected;
- the acceptability of design tasks undertaken by partners or subcontractors (SIM-To-Lt-035 21.A.239(c));
- the issue of data and information under the obligation of 21.A.265(h).

4. Resources

- Substantial reduction in number and/or experience of staff (see SIM-To-Lt-035 21.A.245(a)).

GM 21.A.249 Transferability

1. Transfer of the approval would normally only be agreed in cases where the organisation itself remains substantially unchanged.
2. An acceptable transfer situation could be for example a change of company name (supported by the appropriate certificate from the National Companies Registration Office or equivalent) but with no changes to site address or Chief Executive. However, if the same legal entity were to relocate to new premises with a new Chief Executive and/or new departmental heads, then a substantial investigation by the Authority would be necessary such that the change would be classified as a re-approval.
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 organisation in which case the former paragraphs apply.

GM No. 1 to 21.A.251 Terms of approval

1. The terms of approval are stated on the certificate of approval issued by the Authority. 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 MTSO authorisation for APU, the list of product types covered by the design assurance system should be included.
2. Approval of a change in the terms of approval in accordance with SIM-To-Lt-035 21.A.253 will be confirmed by an appropriate amendment of the certificate of approval.
3. The certificate references the handbook of the approved design organisation, provided in accordance with SIM-To-Lt-035 21.A.243. This handbook defines the tasks which may be performed under the approval.
4. Scopes of work are, for example, “subsonic turbojet aircraft”, “turbo-propeller aircraft”, “small aircraft”, “rotorcraft”. Technologies are quoted in the scope of work when it is considered by the Authority as a limitation for the design organisation approval.
5. For repair design activities, the certificate states the scope of work with the appropriate limitations for which the approval has been granted.

GM No. 2 to 21.A.251 Terms of approval - Organisations designing minor changes to type design or minor repairs to products

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

1. Scope of work

This design organisation approval has been granted for:

- designing minor changes to type design or minor repairs to [aircraft, engine, propeller] in accordance with the applicable airworthiness codes and standards and environmental protection requirements,
- demonstrating and verifying the compliance with these airworthiness codes and standards and environmental protection requirements.

2. Category of products

Any other indication if the Authority has found a limitation related to aircraft systems or technologies and reducing the scope as defined in paragraph 1.

3. Privileges

The holder of this approval is entitled to list the privileges granted with the approval, pursuant to SIM-To-Lt-035 21.A.263(c)(1) and (2).

GM 21.A.257(a) Investigations

Arrangements that allow the Authority 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-operating with the Authority in performing inspections and audits conducted during initial assessment and subsequent surveillance.

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

AMC No. 1 to 21.A.263(c)(1) Procedure for the classification of changes to a type certificate (TC) or a supplemental type certificate (STC) and of repair designs as minor and major

1. INTENT

This AMC provides means to develop a procedure for the classification of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs.

Each design organisation approval (DOA) applicant should develop its own internal classification procedure following this AMC, in order to obtain the associated privilege under SIM-To-Lt-035 21.A.263(c)(1).

2. PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TC, APU MTSO, OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND REPAIR DESIGNS

2.1. Content

The procedure should address the following points:

- a) the identification of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs,
- b) classification;
- c) justification of the classification;
- d) authorised signatories, and
- e) supervision of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs initiated by subcontractors.

For changes to a TC, APU MTSO or to that part of the product covered by an STC, the criteria used for classification should be in compliance with SIM-To-Lt-035 21.A.91 and GM 21.A.91.

For repairs, criteria used for classification should be in compliance with SIM-To-Lt-035 21.A.435 and GM 21.A.435.

2.2. Identification of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs

The procedure should indicate how the following are identified:

- major changes to a TC, APU MTSO or to that part of the product covered by an STC or major repairs;
- those minor changes to a TC, APU MTSO or to that part of the product covered by an STC or minor repairs where additional work is necessary to demonstrate compliance with the applicable airworthiness codes and standards and environmental protection requirements; and
- other minor changes to a TC, APU MTSO or to that part of the product covered by an STC or minor repairs requiring no further demonstration of compliance.

2.3. Classification

The procedure should show how the effects on airworthiness as well as operational suitability and environmental protection are analysed, from the very beginning, by reference to the applicable requirements.

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

2.4. Justification of the classification

All decisions on the classification of changes to a TC, APU MTSO or that part of the product covered by an STC, and repair designs as “major” or “minor” should be recorded and, for those which are not straightforward, also documented. These records should be easily accessible to the Authority for sample checking.

2.5. Authorised signatories

All classifications of changes to a TC, APU MTSO or that part of the product covered by an STC, and repair designs should be accepted by an appropriate authorised signatory, belonging to or tasked by the Office of Airworthiness, as explained in GM No 1 to 21.A.239(a)(3.1.4)(r).

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

For those changes or repairs that are handled by subcontractors, as described under paragraph 2.6, it should be described how the DOA holder manages its classification responsibility.

2.6. Supervision of changes to a TC, APU MTSO or that part of the product covered by an STC, and repair designs initiated by subcontractors

The procedure should indicate, directly or by cross-reference to written procedures, how changes to that part of the product covered by an STC, and repair designs may be initiated and classified by subcontractors and are controlled and supervised by the DOA holder.

AMC No 2 to 21.A.263(c)(1) Privileges – Organisations that design minor changes to a type certificate (TC) or a supplemental type certificate (STC) and minor repairs to products: classification procedure

1. Content

The procedure should address the following points:

- configuration control rules, especially the identification of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs;

- classification, in compliance with SIM-To-Lt-035 21.A.91 and GM 21.A.91 for changes and GM 21.A.435 for repairs;
- justification of the classification;
- authorised signatories.

2. Identification of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs

The procedure should indicate how the following minor changes to a TC or minor repairs are identified:

- those minor design changes to a TC or minor repairs where additional substantiation data is necessary to demonstrate compliance with the airworthiness codes, standards or environmental protection requirements;
- other minor design changes to a TC or minor repairs requiring no further demonstration of compliance.

3. Classification

The procedure should show how the effects on airworthiness as well as on operational suitability and environmental protection are analysed, from the very beginning, by reference to the applicable requirements.

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

For repair, see also GM 21.A.435.

4. Justification of the classification

All decisions of the classification of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs as "minor" should be recorded and, for those which are not straightforward, also documented.

These records should be easily accessible to the Authority for sample checking.

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

5. Authorised signatories

All classifications of changes to a TC, APU MTSO or to that part of the product covered by an STC, and repair designs should be accepted by an appropriate authorised signatory.

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

AMC No. 1 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (TC), APU MTSO or a supplemental type certificate (STC), and minor repairs

1. INTENT

This AMC provides means to develop a procedure for the approval of minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs.

Each design organisation approval (DOA) applicant should develop its own internal procedures following this AMC, in order to obtain the associated privilege under SIM-To-Lt-035 21.A.263(c)(2).

2. PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A TC, APU MTSO OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND MINOR REPAIRS

2.1. Content

The procedure should address the following points:

- compliance documentation;
- approval under the DOA privilege;
- authorised signatories;
- supervision of minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs handled by subcontractors.

2.2. Compliance documentation

For those minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable airworthiness codes and standards and environmental protection requirements is necessary, compliance documentation should be established and independently checked as required by SIM-To-Lt-035 21.A.239(b).

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

2.3. Approval under the DOA privilege

2.3.1. For those minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable airworthiness codes and standards and environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

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

- applicable airworthiness codes or standards or environmental protection requirements and methods of compliance;
- reference to the compliance documents;
- effects, if any, on limitations and on the approved documentation;
- evidence of the independent checking function of the demonstration of compliance;
- evidence of the approval under the privilege of SIM-To-Lt-035 21.A.263(c)(2) by an authorised signatory;
- date of the approval.

For repairs, see AMC 21.A.433(b) and AMC 21.A.447.

2.3.2. For the other minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs, the procedure should 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 should be controlled by the Office of Airworthiness, either directly or through appropriate procedures of the DOA holder's design assurance system.

2.4. Authorised signatories

The persons authorised to sign for the approval under the privilege of SIM-To-Lt-035 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that maybe linked to the design organisation handbook.

2.5. Supervision of minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs handled by subcontractors

For the minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs described in 2.3.2, that are handled by subcontractors, the procedure should indicate, directly or by cross-reference to written procedures how these minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs are approved at the subcontractor level and the arrangements made for supervision by the DOA holder.

AMC No. 2 to 21.A.263(c)(2) Privileges - Organisations designing minor changes to a type certificate (TC), APU MTSO or a supplemental type certificate (STC) and minor repairs to products: procedure for the approval of minor changes to a TC, APU MTSO or minor repairs

1. Content

The procedure should address the following points:

- compliance documentation;
- approval under the DOA privilege;
- authorised signatories.

2. Compliance documentation

For those minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable airworthiness codes and standards and environmental protection requirements is necessary, compliance documentation should be established and independently checked as required by SIM-To-Lt-035 21.A.239(b).

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

3. Approval under the DOA privilege

3.1. For those minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable airworthiness codes or standards or environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

- a) the identification and brief description of the change or the repair and reason for change or repair;
- b) the applicable airworthiness codes or standards 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 demonstration of compliance;
- f) evidence of the approval under the privilege of SIM-To-Lt-035 21.A.263(c)(2) by an authorised signatory; and
- g) the date of the approval.

For repairs, see also AMC 21.A.433(b) and SIM-To-Lt-035 21.A.447.

3.2. For the other minor changes to a TC, APU MTSO or to that part of the product covered by an STC, and minor repairs, the procedure should 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 should 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 SIM-To-Lt-035 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

AMC No 3 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (TC) which affect the aircraft flight manual (AFM)

1. Intent

This AMC provides additional guidance for developing a procedure for the approval of minor changes to a TC which affect the aircraft flight manual (AFM).

Each design organisation approval (DOA) applicant/holder should develop its own internal procedure, based on these guidelines. For guidance on the classification of changes to a TC which affect the AFM, see GM 21.A.91.

2. Procedure for the approval of minor changes to a TC which affect the AFM

2.1. Content

The procedure should address the following points:

- assessment of any change to a TC for the impact of the change on the AFM;
- preparation of revisions or supplements to the AFM;
- classification of the change to a TC, taking into account the impact on the AFM;
- classification of stand-alone revisions or supplements to the AFM;
- control of the configuration of the AFM;
- approval of the revisions or supplements to the AFM; and
- the approval statement.

2.2. Preparation

The procedure should indicate how revisions or supplements to the AFM are prepared and how the coordination among the persons in charge of design changes is performed.

2.3. Classification

The procedure should indicate how changes to a TC which affect the AFM are classified, in accordance with the criteria of GM 21.A.91 Section 3.4.

The procedure should indicate how classification decisions are recorded, documented and signed.

Easy accessibility of these records to the Authority for sample checking should be ensured. All classifications should be accepted by an appropriately authorised signatory. The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

2.4. Configuration control of the AFM

The procedure should explain the traceability of changes in order to understand who has approved what. Especially if a given page or data module has been revised several times, it should be traceable which part(s) of the page or data module has (have) been approved directly by the Authority under which approval, and which part(s) has (have) been approved under the privilege of a DOA holder.

2.5. Approval

The procedure should indicate how the approval under the privilege of SIM-To-Lt-035 21.A.263(c)(2) is formalised.

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

2.6. Approval statement

The amended AFM, or the supplement to the AFM, approved under the privilege of SIM-To-Lt-035 21.A.263(c)(2) should be issued under the obligation of SIM-To-Lt-035 21.A.265(h) (see SIM-To-Lt-035 21.A.265(h) and the related GM) with a respective statement in the log of revisions.

AMC 21.A.263(c)(6) Procedure for the approval of the conditions for issue of a military permit to fly

1. INTENT

This AMC provides means to develop a procedure to determine that an aircraft can fly, under the appropriate restrictions compensating for non-compliance with the airworthiness requirements applicable to the aircraft category.

Each DOA applicant or holder should develop its own internal procedure following this AMC, in order to obtain the privilege to make this determination and approve associated conditions without Authority involvement, under SIM-To-Lt-035 21.A.263(c)(6). When the privilege does not apply, the DOA holder will prepare all necessary data required for the determination in accordance with the same procedure required for the privilege, and will apply for Authority approval.

The establishment of flight conditions may include conditions related to engines/propellers without a type certificate or with unapproved changes that are fitted to the aircraft, for which a permit to fly (PtF) is requested. These conditions (i.e. the installation, operating, maintenance conditions or limitations) should be defined by the organisation responsible for the design of the engine/propeller and provided to the organisation responsible for the design of the aircraft. In this context, the organisation responsible for the design of the engine/propeller acts as a supplier of the organisation responsible for the design of the aircraft.

These conditions should be established and substantiated under an arrangement between the organisation responsible for the design of the aircraft and the organisation responsible for the design of the engine/propeller. However, the establishment and substantiation of the flight conditions for the aircraft, including its engine(s), is ultimately the responsibility of the organisation responsible for the design of the aircraft.

2. PROCEDURE FOR THE APPROVAL OF THE CONDITIONS FOR ISSUE OF A MILITARY PERMIT TO FLY

2.1. Content

The procedure should address the following points:

- decision to use the privilege;
- management of the aircraft configuration;
- determination of the conditions that should be complied with to perform safely a flight;
- documentation of flight conditions substantiations;
- approval under the DOA privilege, when applicable;
- authorised signatories.

2.2. Decision to use the privilege of SIM-To-Lt-035 21.A.263(c)(6)

The procedure should include a decision to determine:

- flights for which the privilege of SIM-To-Lt-035 21.A.263(c)(6) will be exercised.

2.3. Management of the aircraft configuration

The procedure should indicate:

- how the aircraft, for which an application for military permit to fly is made, is identified;
- how changes to the aircraft will be managed.

2.4. Determination of the conditions that should be complied with to perform safely a flight

The procedure should describe the process used by the DOA holder to justify that an aircraft can perform the intended flight(s) safely. This process should include:

- identification of deviations from applicable airworthiness requirements or non-compliance with SIM-To-Lt-035 conditions for the issue of a certificate of airworthiness;
- analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can perform safely a flight;
- the establishment of specific maintenance instructions and conditions to perform these instructions;

- independent technical verification of the analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can perform the intended flight(s) safely;
- statement by the office of airworthiness (or equivalent), that the determination has been made in accordance with the procedure and that the aircraft has no features and characteristics making it unsafe for the intended operation under the identified conditions and restrictions;
- approval by an authorised signatory.

2.5. Documentation of flight conditions substantiation

1. The analysis, calculations, tests, or other means used to determine under which conditions or restrictions the aircraft can perform safely a flight, should be compiled in compliance documents. These documents should be signed by the author and by the person performing the independent technical verification.
2. Each compliance document should have a number and issue date. The various issues of a document should be controlled.
3. The data submitted and approved by the type certificate holder can be used as substantiations. In that case, the independent technical verification referred to in 2.4 is not required.

2.6. Approval under the DOA privilege

2.6.1. Initial approval

The procedure should include SVY918A (EMAR Form 18A) to support the approval under the DOA privilege.

When the privilege of SIM-To-Lt-035 21.A.263(c)(6) is not applicable, the signed form should be presented by the office of airworthiness (or equivalent) to the Authority.

2.6.2. Approval of changes

2.7. Authorised signatories

The person(s) authorised to sign the approval form should be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the DOA handbook.

AMC 21.A.263(c)(7) Procedure for the issue of a military permit to fly

1. INTENT

This acceptable means of compliance provides means to develop a procedure for the issue of a military permit to fly.

Each DOA applicant or holder should develop its own internal procedure following this AMC, in order to obtain the privilege of SIM-To-Lt-035 21.A.263(c)(7) to issue military permits to fly for aircraft it has designed or modified, or for which it has approved under SIM-To-Lt-035 21.A.263(c)(6) the conditions under which the military permit to fly can be issued, and when the design organisation itself is controlling under its DOA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight.

2. PROCEDURE FOR THE ISSUE OF A MILITARY PERMIT TO FLY

2.1. Content

The procedure should address the following points:

- conformity with approved conditions;
- issue of the military permit to fly under the DOA privilege;
- authorised signatories;
- interface with the local Authority for the flight.

2.2. Conformity with approved conditions

The procedure should indicate how conformity with approved conditions is made, documented and attested by an authorised person.

2.3. Issue of the military permit to fly under the DOA privilege

The procedure should describe the process to prepare the SVY920b (EMAR Form 20b) and how compliance with SIM-To-Lt-035 21.A.711(b) and (e) is established before signature of the military permit to fly.

2.4. Authorised signatories

The person(s) authorised to sign the military permit to fly under the privilege of SIM-To-Lt-035 21.A.263(c)(7) should be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the DOA handbook.

2.5. Interface with the local Authority for the flight

The procedure should include provisions describing the communication with the local Authority for compliance with the local requirements which are outside the scope of the conditions of SIM-To-Lt-035 21.A.708(b) (see SIM-To-Lt-035 21.A.711(e)).

AMC No 1 to 21.A.263(c)(5), (8) and (9) Scope and criteria

1. Definition of 'certain major repairs'

'Certain major repairs' for which privileges may be granted as per SIM-To-Lt-035 21.A.263(c)(5) are:

- a) major repairs to products or auxiliary power units (APUs) for which the design organisation approval (DOA) holder holds the type certificate (TC) or the supplemental type certificate (STC) or the Military technical standard order authorisation (MTSOA); or
- b) major repairs to products or APUs for which the DOA holder does not hold the TC or the STC or MTSOA and that meet the criteria of 3(a), (b) and (c) below.

1.1. Criteria for limitations on eligibility

An Authority approval may be required in cases of major repairs proposed by DOA holders who are the TC, STC or APU MTSOA holders if the major repair is:

- a) related to a new interpretation of any item of the certification basis as used for the type certification (such as the airworthiness requirements, certification review items for special conditions, equivalent safety findings, deviations or 'elect to comply'); and
- b) related to the application of an airworthiness code or standard that is different from the one used for type certification.

Note: This should be established at the time of granting the privilege to the DOA holder, or later through an Authority-agreed procedure.

2. Definition of 'certain major changes' and 'certain supplemental type certificates'

'Certain major changes' and 'certain supplemental type certificates' for which privileges may be granted as per SIM-To-Lt-035 21.A.263(c)(8) and (9) are changes similar to those that have been previously approved by the Authority for the same DOA holder.

The similarity of the changes is to be seen in terms of the design, the installation, and the operational characteristics, whereas their repetitiveness is seen in terms of the applicable requirements and the compliance demonstration.

In this context, a 'requirement' means any element of the type-certification basis as specified in SIM-To-Lt-035 21.B.80, or the operational suitability data (OSD) certification basis as specified in SIM-To-Lt-035 21.B.82, or the environmental protection requirements as specified in SIM-To-Lt-035 21.B.85.

2.1. Criteria for limitations on eligibility

The following types of changes are not eligible:

- a) changes that require a revision to a type certificate data sheet (TCDS) (e.g. the introduction of a derivative model or variant) or a type certificate data sheet for noise (TCDSN);
- b) changes that require an amendment to the existing certification basis by a special condition, equivalent safety finding, deviation or 'elect to comply';
- c) changes that revise airworthiness limitations or operating limitations, unless otherwise agreed with the Authority;
- d) changes that are intended to be used as alternative method of compliance (AMOC) to an airworthiness directive (AD);
- e) changes that are made mandatory by an AD or that are the terminating action of an AD;

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- f) changes that are classified as 'significant' in accordance with SIM-To-Lt-035 21.A.101;
 - g) changes for which, in the affected area and for the operations for which the design is to be certified, more conservative airworthiness requirements are applicable which were not used in the description of the Authority-approved procedure of the DOA holder, e.g. in the case of a type, model or modification with a later, more stringent certification basis;
 - h) changes that affect the noise and/or emissions characteristics of the changed product, unless otherwise agreed with the Authority;
 - i) changes that affect a part or system, a single failure of which may have a catastrophic effect upon the product, and for which critical characteristics have been identified, which should be controlled to ensure the required level of integrity;
 - j) changes to engines or propellers, a single failure of which may have a hazardous effect upon the product, and for which critical characteristics have been identified, which should be controlled to ensure the required level of integrity; and
 - k) changes for which a non-compliance has been found in the referenced change during the continued-airworthiness process.
3. Criteria for major repairs, major changes and STCs for which the privileges of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9) may be granted

The following criteria need to be met:

a) Similarity

The installation on the product, the design, the operation, and the equipment qualification are basically the same as in projects for which the Authority has already been involved and issued an approval for the same DOA holder.

b) Repetitiveness of the certification process

The whole certification process is repetitive, i.e. identical to, or part of, an already approved referenced process. For a change or repair that is a part of the referenced 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates', the certification process is still identical to the one for the affected change. This is the case when each compliance demonstration is performed to the same extent in accordance with the same requirements, GM, and content of the interpretative material, as well as with the same means and method of compliance (not only the same means-of-compliance (MoC) code).

Note: In this AMC, a 'requirement' means any element of the type-certification basis as specified in SIM-To-Lt-035 21.B.80, or OSD certification basis as specified in SIM-To-Lt-035 21.B.82, or an environmental protection requirement as specified in SIM-To-Lt-035 21.B.85.

c) Performance and experience in previous projects

To demonstrate 'similarity' and 'repetitiveness', the Authority should have classified the level of performance of the organisation as 'medium' or 'high' during at least the latest project referenced.

In addition, the Authority should have classified the likelihood of an unidentified non-compliance as 'low' or 'very low' for all the included compliance demonstration items (CDIs) identified in at least the latest project referenced, to demonstrate 'similarity' and 'repetitiveness' (applying the criteria for the determination of the Authority's level of involvement (LoI) in product certification, see AMC 21.B.100(a) and 21.A.15(b)(6)).

The process to obtain and to use the privileges of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9) is described in AMC No 2 to 21.A.263(c)(5), (8) and (9).

AMC No 2 to 21.A.263(c)(5), (8) and (9) Procedure for the approval of a major repair, a major change to a type certificate (TC), or a supplemental type certificate (STC) by a design organisation approval (DOA) holder under their privileges

This AMC describes the process to be followed in order to obtain and use the privilege to approve 'certain major repairs' and 'certain major changes' to a TC, and 'certain supplemental type certificates' as defined in points 1(b) and 2 of AMC No 1 to 21.A.263(c)(5), (8) and (9).

1. PROCESS FOR OBTAINING A PRIVILEGE

A DOA holder that applies for the privileges referred to in SIM-To-Lt-035 21.A.263(c)(5), (8) or (9) should do the following:

- a) Submit to the Authority an application for a significant change in the design assurance system (see SIM-To-Lt-035 21.A.247 and 21.A.253).
- b) Establish internal procedures for the application of the privilege covering the following elements, and add them to the application:
 - 1) The definition of the 'list associated with the privilege' of certain major repairs/changes/STCs. The 'list associated with the privilege' is a list of all 'certain major changes', 'certain STCs' and 'certain major repairs' (or families thereof) plus the associated 'justification document' references for which the privileges as per SIM-To-Lt-035 21.A.263(c)(5), (8) and (9) have been granted.
 - 2) A 'justification document' for a 'certain major repair', 'certain major change' or a 'certain STC', as applicable. The 'justification document' should contain:
 - i. The reference(s) to the Authority-approved major change(s), STC(s) and major repair(s), which is (are) used to demonstrate the DOA holder's experience and performance.

Note: The number of already Authority-approved major change(s), STC(s) or major repair(s) used to demonstrate the DOA holder's experience and performance is based on an assessment of the scope of the

‘certain major repairs’, ‘certain major changes’ or ‘certain supplemental type certificates’ which is requested to be added to the ‘list associated with the privilege’, as well as on the performance of the DOA holder during previous projects.

- ii. The certification programme(s) of the major change(s), STC(s), or major repair(s), accepted by the Authority, used to demonstrate the applicant’s experience and performance.
- iii. The applicable product configuration(s).

The applicant should list the type(s) and model(s) to which the major change(s)/STC(s)/repair(s) applies (apply) or may apply. Exceptionally, this may be done for a dedicated product, system or equipment if the type or model has no technical influence on the major change(s)/STC(s)/repair(s), i.e. when the installation issues are negligible (e.g. the TCAS 7.1 software change for a certain equipment), such a listing is not mandatory, but it needs to be justified.

- iv. The list of ‘requirements’ for the demonstration of compliance, if not identical to the ones referenced in the certification programme.
- v. The certification process, if not identical to the one referenced in the certification programme.
- vi. A detailed description with all the technical data relevant to the installation of the product, the design, the operation and the qualification which ensures the proper use of the privilege for future major changes, major repairs or STCs. This description should include the criteria defining the conditions that should be met in order to apply the privileges.
- vii. Any other limits on the use of the privilege.

- 3) The assessment of the acceptability of using the privilege for major repairs, major changes or STCs against the ‘list associated with the privilege’ and the ‘justification document’ of ‘certain major repairs’, ‘certain major changes’ or ‘certain STCs’.
- 4) The approval process, including the templates to be used, the authorised signatories, records management and the provision of a ‘summary list’ of major changes, major repairs and STCs approved under the privilege of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9). This process should clarify that the approval is issued under the DOA holder’s privilege.

The persons authorised under the privilege of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9) should be identified by their names, signatures and scopes of authority in the appropriate documents and referenced in the procedure.

A ‘summary list’ of all the major changes, STCs and major repairs approved under a privilege should be provided to the Authority on a regular basis, as agreed with the Authority.

- 5) Extension of the ‘list associated with the privilege’ after the privilege is granted.

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SIM-To-Lt-035 (FIN EMAR 21)

After the granting of the privilege, the initial list of 'certain major repairs', 'certain major changes' and 'certain STCs' under the privilege may be further extended by an agreement with the Authority, as shown in Section 2 as well as in Figures 2 and 3 below.

- c) Identify in the 'list associated with the privilege' the eligible major changes, major repairs or STCs proposed for inclusion in the scope of the privilege (see also AMC No 1 to 21.A.263(c)(5), (8) and (9)).
- d) Provide a 'justification document' for each proposed certain major change, certain major repair or certain STC identified under (c) above.

Note: The 'list associated to the privilege' identifying all certain major repairs, certain major changes and certain STCs and the associated 'justification document(s)' are to be referenced in the DOA holder procedure mentioned under (b) above.

The process for obtaining the privilege, referred to in SIM-To-Lt-035 21.A.263(c)(5), (8) and (9), is summarised in Figure 1 below:

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SIM-To-Lt-035 (FIN EMAR 21)

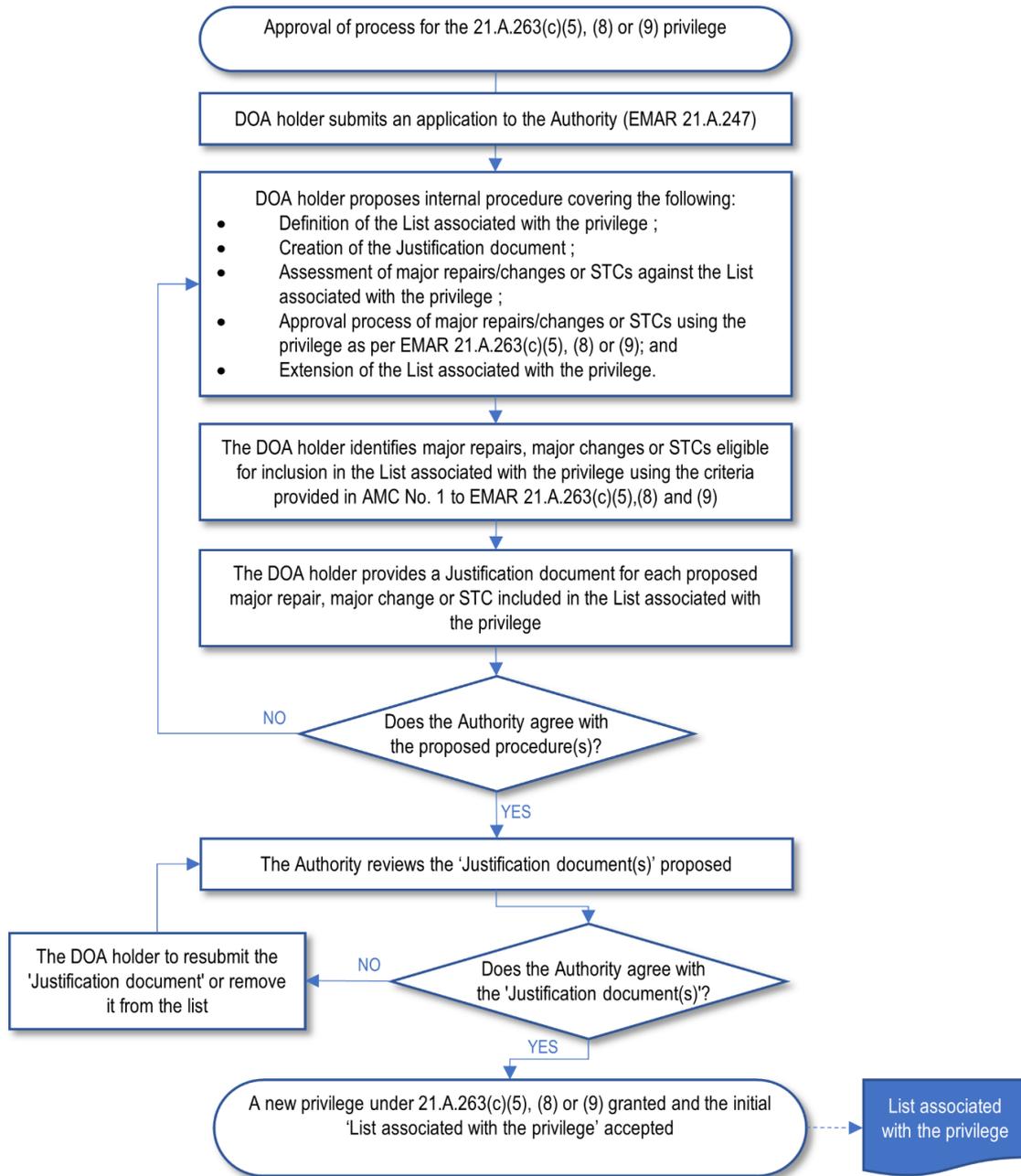


Figure 1

The privilege referred to in SIM-To-Lt-035 21.A.263(c)(5), (8) and (9) may be used by a DOA holder for the approval of major repairs, major changes or STCs, as applicable, under the following conditions:

- a) the privilege has already been granted by the Authority;
- b) the major repair/change/STC to be approved falls under the ‘List associated with the privilege’ agreed by the Authority; and

- c) the criteria established in the relevant 'Justification document' are met and the relevant assessment is recorded.

If all the above conditions are met, the privilege may be used and the approval of major repairs, major changes or STCs, as applicable, can be obtained by the DOA holder without the Authority's involvement.

Note: If a DOA holder applies for a third-country validation after having approved a modification under its DOA holder privilege, the Authority may review some of the compliance demonstration data in order to support the validation activity.

2. EXTENSION OF THE 'PRIVILEGE LIST' OF 'CERTAIN MAJOR REPAIRS', 'CERTAIN MAJOR CHANGES' OR 'CERTAIN STCs' AFTER THE PRIVILEGE IS GRANTED

When the DOA holder intends to update the 'List associated with the privilege', a 'Justification document' needs to be provided to the Authority, as described in Section 1(b)(2) above. After the Authority agrees with the updated 'privilege list' as part of the DOA holder's procedure, the DOA holder may proceed as per Section 4 below.

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ACCEPTABLE MEANS OF COMPLIANCE AND GUIDANCE MATERIAL TO
SIM-To-Lt-035 (FIN EMAR 21)

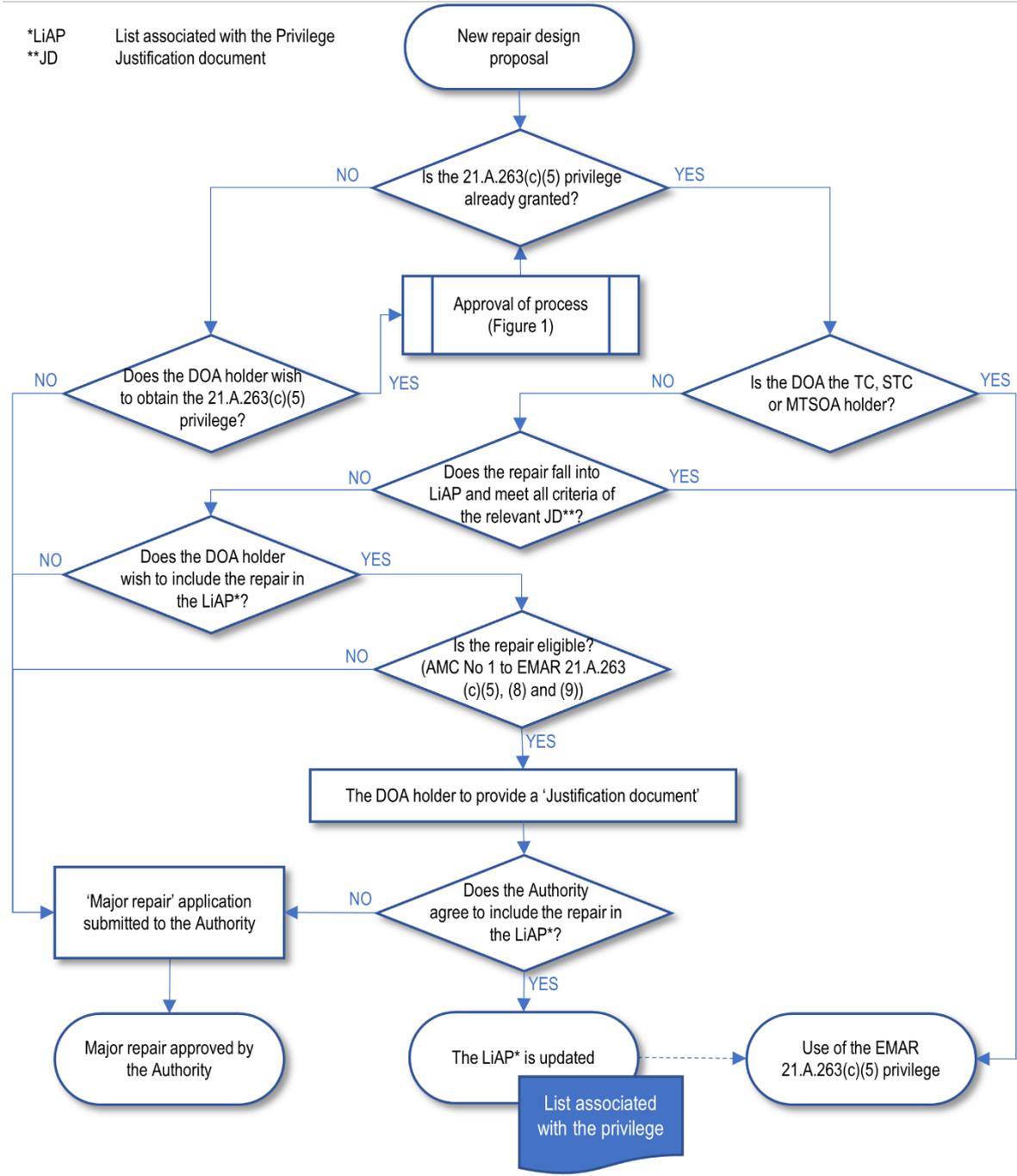


Figure 2

AMC&GM
ACCEPTABLE MEANS OF COMPLIANCE AND GUIDANCE MATERIAL TO
SIM-To-Lt-035 (FIN EMAR 21)

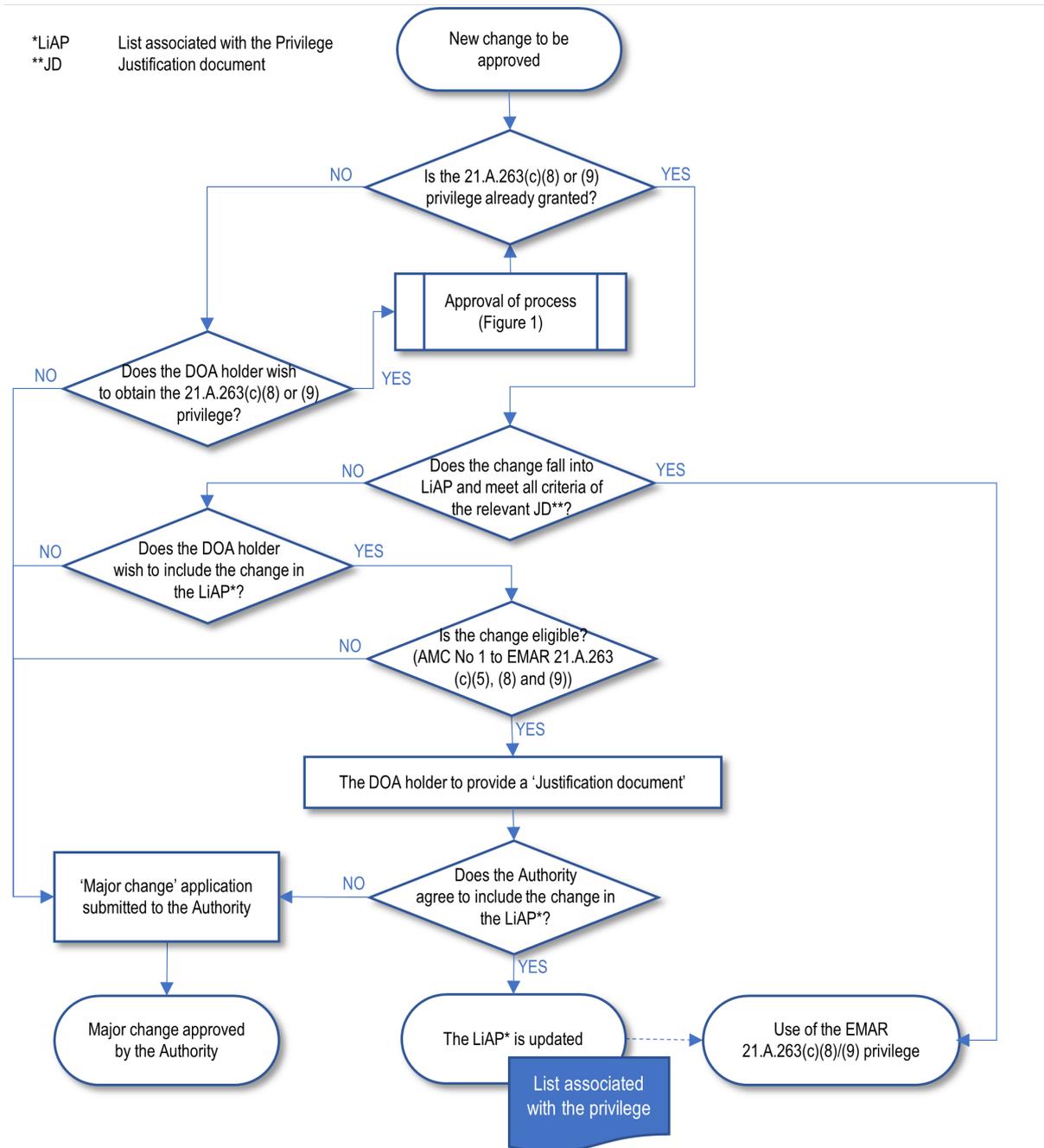


Figure 3

3. TC, STC OR APU ETSOA HOLDER APPROVAL OF A MAJOR REPAIR UNDER A MAJOR REPAIR PRIVILEGE — SPECIFIC CONSIDERATIONS

TC, STC or APU ETSOA DOA holders that intend to approve a major repair design under the privilege of SIM-To-Lt-035 21.A.263(c)(5) should ensure that:

- a) the type-certification basis for the product, part or appliance to be repaired is identified, together with all the other relevant requirements;
- b) all the records and substantiation data, including the documents that demonstrate compliance with all the relevant requirements, are provided to the Authority for review; and
- c) for repair designs created for a specific product serial number, an assessment is made as to whether or not the repair design is affected by the presence of any embodied STC, change or repair.

4. DOA HOLDER'S APPROVAL BASED ON THE PRIVILEGE FOR A MAJOR REPAIR, MAJOR CHANGE OR STC — SPECIFIC CONSIDERATIONS

For the approval of:

- major repairs by DOA holders that are not the TC, STC or APU MTSO authorisation holders;
- major changes; and
- STCs

by a DOA holder under the privilege of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9), the following should be considered.

4.1. Eligibility of the proposed major repair, major change or STC

The DOA holder should assess the proposed major repair, major change or STC against the 'list associated with the privilege' and the 'justification document' of 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates' in order to determine whether the criteria of AMC No 1 to 21.A.263(c)(5), (8) and (9), Section 2.2, are met.

4.2. Forms for approval certificates

For the issuance of an approval under their privilege the DOA holder should use forms provided by the Authority.

If such forms are not available or if the DOA holder chooses to use their own forms, it must be ensured that at least the information as requested by the Authority is presented.

4.3. Approval under the DOA holder's privilege

When the DOA holder makes use of the privilege of SIM-To-Lt-035 21.A.263(c)(5), (8) or (9), they should include the following in the certification data package:

- a record of the assessment as described in 4.1 above;
- the reference to the 'justification document';
- the applicable product configuration;
- the applicable airworthiness codes and standards or environmental protection requirements and methods of compliance;

- the compliance documents;
- the effects, if any, on limitations and on the approved documentation;
- the evidence of the independent checking of the compliance demonstration;
- the approval document containing the statement of the approval under the privilege of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9) by an authorised signatory; and
- the date of approval.

In any case, before the major change, STC or major repair is approved under the DOA privilege, the DOA holder should ensure that the Part 21 requirements, in particular SIM-To-Lt-035 21.A.97, 21.A.115 and 21.A.433, are met.

4.4. Authorised signatories

An authorised person that is identified and authorised as described in Section 1(b)(4) above should sign the approval under the privilege of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9).

4.5. Summary list

The DOA holder should add to the 'summary list' as described in Section 1(b)(4) above the major change, STC or major repair approved under the privilege of SIM-To-Lt-035 21.A.263(c)(5), (8) and (9).

AMC 21.A.263(d)(1) Declaration of applicability

1. Intent

This acceptable means of compliance provides means for a DOA applicant to obtain the associated privileges under SIM-To-Lt-035 21.A.263(d)(1) to declare the applicability of a modification, or of an instruction for continuing airworthiness, or of a modification to the flight manual or of a modification to the maintenance manual, as relevant, when it is already approved by a recognized civil airworthiness authority, to a product derivative from a civil type certified product.

2. Procedure for declaring the applicability

In order to obtain the associated SIM-To-Lt-035 21.A.263(d)(1) privilege for a scope of derivative product, a DOA applicant should respect the following conditions:

- a) Agree with the authority the procedures to evaluate within the scope of its SIM-To-Lt-035 DOA a modification, or an instruction for continuing airworthiness, or a modification to the flight manual or a modification to the maintenance manual being already approved by a recognized civil airworthiness authority. Such procedures shall include necessary arrangements with the civil DOA to ensure access to the data related to the type design.
- b) Develop its own internal procedure addressing the following points as agreed with the Authority:

- i. Identification of the derivative delta to be assessed:
 - type design definition including modifications
 - operational characteristics
 - performances
 - limitation
 - certification requirements
 - means of demonstration of compliance
- c) Assessment results should be documented and recorded. These records should be easily accessible to the Authority for sample check.
- d) The declaration of applicability should be signed by an appropriate authorised signatory.

In case further investigation is needed for analysis of impact due to STC or because the specific configuration is not known by the applicant, the applicant will provide the data requested by the Authority for complementary analysis.

AMC 21.A.263(d)(2) Approval

1. INTENT

This acceptable means of compliance provides means for a DOA applicant to obtain the associated privileges under SIM-To-Lt-035 21.A.263(d)(2) to approve a major modification, or the approved parts of the maintenance manual, or of the flight manual, and their evolutions, when it is already approved by a recognized civil airworthiness authority and when it has been declared applicable to the product derivative from the civil type certified product.

Applying this privilege implies that no additional work to show compliance to the (military) airworthiness requirements is needed.

In case the applicability to the specific definition of the derivative needs further demonstration of compliance (i.e. the assessment of “no impact” is not confirmed) the applicant will apply the relevant procedures of its military design assurance system for getting approval of the change.

Approval of minor changes is to be considered under relevant privileges SIM-To-Lt-035 21.A.263(c)(2).

2. PROCEDURE FOR APPROVING

In order to obtain the associated SIM-To-Lt-035 21A.263(d)(2) privilege, a DOA applicant should comply with the following:

- a) The conditions related to privileges SIM-To-Lt-035 21.A.263(d)(1)
- b) Its own internal approval procedure as agreed by the Authority

In addition, the applicant should:

- c) Define how the approval under the DOA privilege will be formalized and how the link with the civil approval is made visible.
- d) Provide records and substantiation data including documents showing compliance with the airworthiness requirements required for the civil approval, to the Authority when requested.
- e) Maintain a summary list of approvals under this privilege to the Authority on a regular basis as agreed with the Authority.

AMC 21.A. 265(a) Administration of the Handbook (Design Organisation Exposition)

1. The handbook (Design Organisation Exposition) 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. The applicant may be requested to provide an English translation of the handbook and other supporting documents as necessary for the investigation.
2. The handbook must be produced in a concise form with sufficient information to meet SIM-To-Lt-035 21.A.243 relevant to the scope of approval sought by the applicant. The handbook must include the following:
 - a) Organisation name, address, telephone, telex and facsimile numbers.
 - b) Document title, and company document reference No (if any).
 - c) Amendment or revision standard identification for the document.
 - d) Amendment or revision record sheet.
 - e) List of effective pages with revision/date/amendment identification for each page.
 - f) Contents list or index.
 - g) A distribution list for the handbook.
 - h) 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 Authority.
 - i) The certificate of approval must be reproduced in the document.
 - j) Identification of the department responsible for administration of the handbook.

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

3. An updating system must be clearly laid down for carrying out required amendments and modifications to the handbook.
4. The handbook may be completely or partially integrated into the company organisation manual. In this case, identification of the information required by SIM-To-Lt-035 21.A.243 must be provided by giving appropriate cross references, and these documents must be made available, on request, to the Authority.

GM 21.A.265(b) Use of the Handbook (Design Organisation Exposition)

1. The handbook 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.
2. All procedures referenced in the handbook are considered as parts of the handbook and therefore as basic working documents.

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

1. INTENT

This GM provides guidance for complying with the obligation of SIM-To-Lt-035 21.A.265(h), and addresses the various aspects that the DOA holder should cover in order to have a comprehensive procedure for the designation of data and information.

2. SCOPE

The term 'data and information' as used in SIM-To-Lt-035 21.A.265(h) also includes instructions.

Data and information referred to in SIM-To-Lt-035 21.A.265(h) are issued by a DOA holder and cover the following:

- embodiment instructions for design changes or repairs (usually in the form of a service bulletin, a modification bulletin, repair instructions or engineering order, etc.);
- manuals required by SIM-To-Lt-035 or the applicable airworthiness codes and standards (such as the aircraft flight manual (AFM), rotorcraft flight manual, instructions for continued airworthiness (ICAs), etc.);

- operation suitability data (OSD);
- continued-airworthiness instructions (usually in the form of service bulletins) which may be covered by airworthiness directives (ADs);
- additional data to be defined by the DOA holder (e.g. alternative maintenance instructions that are not, per se, ICAs).

Note: This data and information may be issued in a digital or paper format.

The obligation does not apply to, and the statement provided with the data and information should not be used on, the following documents:

- certification documents (e.g. the certification programme, compliance checklist, etc.);
- compliance documents;
- design data transferred to production organisations; and
- production deviations (also referred to as ‘unintended deviations’ or ‘concessions’).

3. RATIONALE

The purpose of this obligation is to give certainty to the end users about the approval status of the data and information issued by the DOA holder.

4. STATEMENT

The statement provided with the data and information should also cover those items prepared by sub-contractors or vendors that the DOA holder has declared as applicable to their products. The technical content of the statement is related to the type certificate data and information.

The approval included in the statement means that:

- the type certificate data has been appropriately approved; and
- the information contains practical and well-defined installation or inspection methods, and, when those methods are implemented, the product is in conformity with the approved type certificate data.

Note: Data and information related to the measures required by SIM-To-Lt-035 21.A.3B(b) (airworthiness directives (ADs)) are submitted to the Authority to ensure their compatibility with the content of an AD (see SIM-To-Lt-035 21.A.265(e)), and contain a statement that they are, or will be, subject to an AD issued by the Authority.

SUBPART K - PARTS AND APPLIANCES

GM 21.A.301 Scope

Parts and appliances can include Government Furnished Equipment.

GM to 21.A.303 Showing of compliance of parts and appliances

SIM-To-Lt-035 21.A.303 requires the showing of compliance of parts and appliances to be installed in a type-certificated aircraft to be made in conjunction with the type-certification procedures of SIM-To-Lt-035. This is to identify all risks associated with such parts and appliances and define appropriate mitigation means (design, operational procedures) in order to ensure that all equipment on board of a type-certified product does not have a negative impact on its airworthiness. In the military context, the role of aircraft may change in urgent response to changes in operational scenarios, and flexibility is required regarding mission specific equipment. Typical examples are the integration of tactical radios and Medical Evacuation (MEDEVAC) equipment, containing parts and appliances sourced from non-aviation suppliers.

Parts and appliances with functions relevant for the safe operation of the aircraft are always to be considered as 'installed' and therefore part of the approved design of the aircraft. Other items, such as those carried by crew or passengers, are considered 'loose items' and not in the scope of SIM-To-Lt-035 21.A.303 and hence, usually not certified under the procedures of SIM-To-Lt-035. To use such items on board of certified aircraft, the safe integration into the aircraft environment has to be ensured, e.g. by verification that the aircraft design, as approved under the processes outlined in 21.A.303 (a) to (c), has sufficient safety margins to cope with any hazard originating from these items as well as appropriate storage for critical flight phases.

Examples for such equipment are personal electronic devices (PED) which can be understood as 'any kind of electronic device, typically but not limited to consumer electronics, brought on board the aircraft by crew members, passengers, or as part of the cargo and that are not included in the approved aircraft configuration'. This includes all equipment that is able to consume electrical energy, rechargeable, non-rechargeable or connected to specific aircraft power sources.

Specific equipment like Patient Transport Units (PTU) for intensive care can be separated into a certified 'provision' being an approved configuration of the aircraft, and 'loose items / PED' under the responsibility of the operating organisation. The same principles could be similarly applied for military mission equipment.

Certified provisions act as the interface between non-certified equipment and the aircraft. They are designed to ensure the airworthiness, providing all safety relevant function, such as (crew/passenger/ patient) restraint, emergency oxygen supply, evacuation means, safe storage and power supply. The provision can also be used to mitigate the increased fire risk of batteries from consumer devices by providing appropriate detection and extinguishing capacity.

For non-certified equipment, including PED's, the safe integration into the aircraft environment can be determined based on compliance to adequate industry standards, acceptable to the authority, or dedicated technical assessments and tests conducted by an appropriate test facility.

GM 21.A.303(c) Officially Recognised Standards

In this context "officially recognised Standards" means:

- a) Those standards established or published by an official body whether having legal personality or not, which are widely recognised by the aerospace sector as constituting good practice.
- b) The standard used by the manufacturer of the equipment as mentioned in paragraph 2 of AMC 21.A.303(c).

AMC 21.A.307(d) Installation without EMAR Form 1 (SVY901)

Parts and appliances that are required by applicable airworthiness codes used for the certification of airworthiness, certification of intended operations or declaration of performance equivalence thereto (e.g. EASA CS-25, EASA CS-ANCS), or where improper functioning would reduce the safety of the certified product, are to be released with an EMAR Form 1 (SVY901). For other equipment (parts or appliances), the Authority may accept a statement of conformity or equivalent release documentation, if it has been appropriately shown for these items

- 1) by test or compliance with appropriate industry consensus standards, that they are not a source of danger in themselves;
- 2) as a result of investigations referred to in SIM-To-Lt-035 21.A.303, that they are properly identified for installation and that the items will not otherwise adversely affect the airworthiness of the product on which they are to be installed; and
- 3) appropriate tests can be conducted upon installation to confirm they are safe to operate.

The assessments shall adequately address potential safety relevant failures and provide sufficient justification that they would only have negligible safety effect on aircraft operation'. The safety of third parties should be taken into account, where relevant.

SUBPART M REPAIRS

GM 21.A.431A(a) Scope

Manuals and other instructions for continuing airworthiness (such as the Manufacturers Structural Repair Manual, Maintenance Manuals and Engine Manuals provided by the holder of the type certificate, supplemental type certificate, design approval or APU MTSO authorisation as applicable) for operators, contain useful information for the development and approval of repairs.

When these data are explicitly identified as approved, they may be used by operators without further approval to cope with anticipated in-service problems arising from normal usage provided that they are used strictly for the purpose for which they have been developed.

Approved data is data which is approved either by the Authority, or by an appropriately approved design organisation.

When specific repair data is approved in another State in accordance with this SIM-To-Lt-035 or under an equivalent regulatory system, such data may be accepted under the conditions defined in the applicable arrangement (e.g. recognition agreement) between the Authority and the Authority of the other State.

In the absence of such arrangement, the repair data should follow the approval route as if it was designed for the certified product where it will be embodied.

GM 21.A.431A(d) Repairs to MTSO articles other than an APU

A repair to an MTSO article other than an APU can either be seen:

- a) Under SIM-To-Lt-035 21.A.611 in the context of an MTSO authorisation, i.e., when an article as such is specifically approved under SIM-To-Lt-035 Section A Subpart O, with dedicated rules that give specific rights and obligations to the designer of the article, irrespective of any product type design or change to the type design. For a repair to such an article, irrespective of installation on any aircraft, SIM-To-Lt-035 Section A Subpart O, and SIM-To-Lt-035 21.A.611 in particular, should be followed; or
- b) When an SIM-To-Lt-031 / SIM-To-Lt-036) organisation is designing a new repair (based on data not published in the TC holder or Original Equipment Manufacturer documentation) on an article installed on an aircraft, such a repair can be considered as a repair to the product in which the article is installed, not to the article taken in isolation. Therefore Subpart M can be used for the approval of this repair, that will be identified as 'repair to product x affecting article y', but not 'repair to article y'.

GM 21.A.431B Standard repairs – airworthiness codes

The Authority will decide on the applicability of airworthiness codes (e.g. certification specifications contained in EASA CS-STAN) referred to in SIM-To-Lt-035 21.A.431B(a)(2). Guidance on the implementation of Standard Changes and Standard Repairs is to be provided by the Authority.

GM 21.A.432B(b) Alternative procedures

See AMC 21.A.14(b) for the details of the alternative procedures.

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

1. General

- a) Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

- b) Format

The FTOM may:

- be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (ADOA)¹ documents, or
- be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

- c) Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

- a) Exposition (not applicable in the case of ADOA)¹

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of

¹ Also referred to as APDOA by EASA

flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b) Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c) Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d) Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e) Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f) Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

i. documents associated with a Flight Test Programme:

– Flight Order for a given flight, which should include:

- a list of the tests to be performed and associated conditions;
- safety considerations relevant to the flight;
- category of the flight (e.g. Category 1);
- composition of the crew;

- names of persons other than crew members;
 - aircraft configuration items relevant to the test to be highlighted to the crew;
 - loading of the aircraft;
 - reference to approved flight conditions; and
 - restrictions relevant to the flight to be highlighted to the crew.
- Flight crew report.
- ii. documentation and information to be carried on the aircraft during flight test;
 - iii. record-keeping: the FTOM should describe the policy relative to record-keeping.
- g) Permit to fly:
- The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.
- h) Currency and training:
- The FTOM should describe how training for flight test is organised.
- Currency of the flight test crew may be ensured either through recent experience or refresher training.
- The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.
- A system should be established to record the currency of the flight test crew's training.

AMC 21.A.432B(d) Alternative Demonstration

In some countries a government organisation is approved by the Authority to execute the Repair Approval Holder responsibilities. This government organisation may apply for a repair approval from its Authority, without being the original design organisation. In this case the government organisation should, in accordance with SIM-To-Lt-035 21.A.2, enter an agreement with a design organisation to ensure the undertaking of specific actions and obligations. Alternative procedures (refer to SIM-To-Lt-035 21.A.14(b)) for establishing a Design Assurance System to fulfil the obligations required under SIM-To-Lt-035 21.A.451 must be acceptable to the Authority.

AMC 21.A.15(a), 21.A.93(a), 21.A.113(a), 21.A.432C(a) Form and manner

The applicant should file an application using the forms or tools specified by the Authority. In doubt, the applicant should consult with the Authority to get informed about the relevant forms, tools, and procedure.

The application should be completed in accordance with the instructions given in the forms or tools or as received from the authority and sent to the addressee nominated by the Authority by fax, email, or regular mail.

AMC 21.A.432C(b) Certification programme for a repair design approval

Clarification of SIM-To-Lt-035 21.A.432C(b)(1): the description of the repair should consist of:

1. the pre- and post-repair configuration;
2. a drawing or outline of the repair;
3. a list of the detailed features;
4. a description of the type and extent of the inspection; and
5. an outline of the damage.

Clarification of SIM-To-Lt-035 21.A.432C(b)(3): the identification of reinvestigations does not refer to the demonstration of compliance itself, but to the list of the affected airworthiness codes or standards (e.g. EASA CSs), together with the means of compliance.

AMC 21.A.433(b) and 21.A.447 Repair design and Record Keeping

- a) Relevant substantiation data associated with a new major repair design and record keeping should include:
 - i. the identification of the damage and the reporting source;
 - ii. the major repair design approval sheet identifying the applicable specifications and references of justifications;
 - iii. the repair drawing and/or instructions and scheme identifier;
 - iv. the correspondence with the holder of the type-certificate (TC), supplemental type-certificate (STC), or auxiliary power unit military technical standard order (APU MTSO) authorisation, if its advice on the design has been sought;
 - v. the structural justification (static strength, fatigue, damage tolerance, flutter etc.) or references to this data;

- vi. the effect on the aircraft, engines and/or systems, (performance, flight handling, etc. as appropriate);
 - vii. the effect on the maintenance programme,
 - viii. the effect on airworthiness limitations, the flight manual and the operating manual;
 - ix. any weight and moment changes; and
 - x. special test requirements.
- b) Relevant minor repair documentation includes paragraphs (a)(i) and (a)(iii). Other points of paragraph (a) may be included where necessary. If the repair is outside the approved data, justification for classification is required.
- c) Special consideration should be given to repairs that impose subsequent limitations on the part, product or appliance, (e.g., engine turbine segments that may only be repaired a finite number of times, number of repaired turbine blades per set, oversizing of fastener holes, etc.).
- d) Special consideration should also be given to Life Limited parts and Critical Parts, notably with the involvement of the TC or STC holder, when deemed necessary under SIM-To-Lt-035 21.A.433(b).
- e) Repairs to engine or APU critical parts would normally only be accepted with the involvement of the TC holder.

GM 21.A.435(a) Classification of repairs

1. Clarification of the terms Major/Minor

In line with the definitions given in SIM-To-Lt-035 21.A.91, a new repair is classified as 'major' if the result on the approved type design has an appreciable effect on structural performance, weight, balance, systems, operational characteristics or other characteristics affecting the airworthiness of the product, part or appliance. In particular, a repair is classified as major if it needs extensive static, fatigue and damage tolerance strength justification and/or testing in its own right, or if it needs methods, techniques or practices that are unusual (i.e., unusual material selection, heat treatment, material processes, jiggling diagrams, etc.)

Repairs that require a re-assessment and re-evaluation of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements, are to be considered as major repairs.

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

It is understood that not all the certification substantiation data will be available to those persons/organisations classifying repairs. A qualitative judgement of the effects of the repair will therefore be

acceptable for the initial classification. The subsequent review of the design of the repair may lead to it being re-classified, owing to early judgements being no longer valid.

2. Airworthiness concerns for Major/Minor classification

The following should be considered for the significance of their effect when classifying repairs. Should the effect be considered to be significant then the repair should be classified 'Major'. The repair may be classified as 'Minor' where the effect is known to be without appreciable consequence.

a) Structural performance

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

b) Weight and balance

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

c) Systems

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

d) Operational characteristics

Changes may include:

- i. stall characteristics;
- ii. handling;
- iii. performance and drag;
- iv. vibration.

e) Other characteristics

- i. changes to load path and load sharing;
- ii. fire protection / resistance.

Note: Considerations for classifying repairs 'Major/Minor' should not be limited to those listed above.

3. Examples of 'Major' repairs

- a) A repair that requires a permanent additional inspection to the approved maintenance programme, necessary to ensure the continued airworthiness of the product. Temporary repairs for which specific inspections are required prior to installation of a permanent repair do not necessarily need to be classified as 'Major'. Also, inspections and changes to inspection frequencies not required as part of the approval to ensure continued airworthiness do not cause classification as 'Major' of the associated repair.
- b) A repair to life limited or critical parts.
- c) A repair that introduces a change to the Aircraft Flight Manual.

GM 21.A.435(b) Repair design approval

a) Repair Design Approval by the Authority

1) Products first type-certified by the Authority

Approval by the Authority is required in cases of major repair designs proposed by design organisation approval (DOA) holders that do not hold the necessary privilege as per SIM-To-Lt-035 21.A.263(c)(5) to approve certain major repair designs, as well as in cases of minor repair designs proposed by persons or organisations that do not hold a DOA.

2) Products first type-certified by an Authority of another state

Approval by the Authority is always required for major repairs on products first type-certified by an Authority of another state. For repairs approved by an Authority of another state, the conditions for acceptance may be defined in applicable arrangements between the Authority and the Authority of that state. In the absence of such an arrangement, the repair data should follow the approval route of SIM-To-Lt-035.

b) Repair Design Approval by the DOA Holder

1) Approval by the DOA holder

Approval of repairs through the use of procedures agreed with the Authority implies that the DOA holder issues the approval without the Authority's involvement. The Authority will monitor the application of this procedure within the surveillance plan for the relevant organisation. When the organisation exercises this privilege, the repair release documentation should clearly show that the approval is issued on the basis of its privilege.

2) Previously approved data for other applications

When it is intended to use previously approved data for other applications, it is expected that an appropriately approved design organisation has checked the applicability and effectiveness of this data. After damage identification, if a repair solution exists in the available approved data, and if the application of this solution to the identified damage remains justified by the previously approved repair design (structural justifications still

valid, possible airworthiness limitations unchanged), the solution may be considered to be approved and may be used again.

3) Temporary repairs

These are life-limited repairs to be removed and replaced by permanent repairs after a limited service period. These repairs should be classified under SIM-To-Lt-035 21.A.435, and the service period should be defined when the temporary repair is approved.

4) Fatigue and damage tolerance

An approved design issued before the fatigue- and damage-tolerance evaluation has been completed should specify the limited service period.

GM 21.A.439 Production of repair parts

A maintenance body, (organisation or person), may manufacture parts for repair purposes when approved under SIM-To-Lt-035 Section A Subpart G. In addition, a maintenance organisation may manufacture parts for its own repair purposes when expressly authorised by the Authority.

GM 21.A.441 Repair Embodiment

Repairs should be accomplished by an organisation or person in accordance with the relevant airworthiness requirements.

The holder of a production organisation approval under SIM-To-Lt-035 Section A Subpart G may accomplish repairs to new aircraft, within its terms of approval, under the privilege of SIM-To-Lt-035 21.A.163(d).

GM 21.A.443 Limitations

Instructions and limitations associated with repairs should be specified and controlled by those procedures required by the applicable requirements (e.g. operations rules).

GM 21.A.445 Unrepaired damage

This is not intended to supersede the normal maintenance practices defined by the type certificate holder, (e.g., blending out corrosion and re-protection, stop drilling cracks, etc.), but addresses specific cases not covered in the manufacturer's documentation.

AMC 21.A.433(b) and 21.A.447 Repair design and Record Keeping

- a) Relevant substantiation data associated with a new major repair design and record keeping should include:
- i. the identification of the damage and the reporting source;
 - ii. the major repair design approval sheet identifying the applicable specifications and references of justifications;
 - iii. the repair drawing and/or instructions and scheme identifier;
 - iv. the correspondence with the holder of the type-certificate (TC), supplemental type-certificate (STC), or auxiliary power unit military technical standard order (APU MTSO) authorisation, if its advice on the design has been sought;
 - v. the structural justification (static strength, fatigue, damage tolerance, flutter etc.) or references to this data;
 - vi. the effect on the aircraft, engines and/or systems, (performance, flight handling, etc. as appropriate);
 - vii. the effect on the maintenance programme,
 - viii. the effect on airworthiness limitations, the flight manual and the operating manual;
 - ix. any weight and moment changes; and
 - x. special test requirements.
- b) Relevant minor repair documentation includes paragraphs (a)(i) and (a)(iii). Other points of paragraph (a) may be included where necessary. If the repair is outside the approved data, justification for classification is required.
- c) Special consideration should be given to repairs that impose subsequent limitations on the part, product or appliance, (e.g., engine turbine segments that may only be repaired a finite number of times, number of repaired turbine blades per set, oversizing of fastener holes, etc.).
- d) Special consideration should also be given to Life Limited parts and Critical Parts, notably with the involvement of the TC or STC holder, when deemed necessary under SIM-To-Lt-035 21.A.433(b).
- e) Repairs to engine or APU critical parts would normally only be accepted with the involvement of the TC holder.

SUBPART O - MILITARY TECHNICAL STANDARD ORDER AUTHORISATIONS

GM 21.A.601 Scope

For this Subpart:

- a) 'Article' means any part and appliance (including Government Furnished Equipment) to be used on military aircraft;
- b) 'technical standards and airworthiness specifications' referred to should consider published Technical Standard Orders (e.g. CS-ETSO, TSO standards issued by FAA) or equivalent that are accepted by the authority establishing the minimum performance requirements for the specified articles.
- c) An article produced under an MTSO authorisation is an approved article for the purpose of Subpart K.

AMC 21.A.602B(b)(2) Procedures for MTSO authorisations

1. Scope

- 1.1. A manual of procedures must set out specific design practices, resources and sequence of activities relevant for the specific projects, taking account of SIM-To-Lt-035 requirements.
- 1.2. These procedures must be concise and limited to the information needed for quality and proper control of activities by the applicant/holder, and by the Authority.

2. Management of the MTSO authorisation process

A procedure explaining how the application to the Authority certification process to obtain an MTSO authorisation will be made, must be established.

3. Management of design changes

- 3.1. A procedure taking into account SIM-To-Lt-035 21.A.611, must be established for the classification and approval of design changes on articles under MTSO authorisation.
- 3.2. Repairs and production deviations from the approved design data.

Procedure for the classification and approval of repairs and unintentional deviations from the approved design data occurring in production (concessions or non-conformance's) must be established.

4. Obligations addressed in SIM-To-Lt-035 21.A.609

The applicant should establish the necessary procedures to show to the Authority how it will fulfil the obligations under SIM-To-Lt-035 21.A.609.

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

5. Control of design subcontractors

The applicant must establish the necessary procedures to show to the Authority how it will control design subcontractors.

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

- a) For the purpose of the compliance demonstration in accordance with SIM-To-Lt-035 21.A.606(b), the applicant should:
 - 1) establish a certification programme;
 - 2) submit the certification programme to the Authority; and
 - 3) keep the certification programme updated during the authorisation process.
- b) The certification programme should contain the following information:
 - 1) a detailed description of the relevant technical standard order (MTSO) article, including all of its configurations to be certified, and the identification of MTSO and non-MTSO functions, if any;
 - 2) the applicable technical standards and airworthiness specifications, in case of different minimum performance standard (MPS) available, the selected MPS, the other requirements and any optional aspects (applicable standards, applicable requirements, choice of classes (if applicable)) as well as the expected deviations;
 - 3) the operating characteristics and the expected limitations;
 - 4) the intended use of the article and the kind of operations for which the approval is requested;
 - 5) the proposed means of compliance, including the list of documents and deliverables for the Authority;
 - 6) an overview of the safety assessment for the functions supported by the article, including the main failure conditions, their classification, the associated assumptions, and architectural features supporting the safety aspects;
 - 7) the way in which the applicant will record the justifications of compliance; and
 - 8) a project schedule, including major milestones.

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

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

1. an increase in the severity of the consequences of a certain condition (e.g. a failure mode) of the article;
2. one or more significantly reduced margins on the 'pass-fail' criteria of the compliance demonstration;
3. an unusual interpretation of the results of the compliance demonstration;
4. a deviation from the agreed means as defined in the certification programme;
5. a change to the conditions set out in the AMC No 2 to 21.B.100(b); and
6. any potential deviations discovered by the applicant.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact on the certification programme and, if necessary, they should amend the certification programme as per SIM-To-Lt-035 21.A.603.

AMC 21.A.606(d) Declaration

The related declaration should confirm that compliance with the applicable technical standards and airworthiness specifications is successfully demonstrated and that all the assumptions, constraints, deviations, limitations, and open problem reports that are relevant for the approval of the installation are defined for both the MTSO and the non-MTSO functions.

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

AMC 21.A.608 Declaration of Design and Performance

The EMAR Form DDP should be completed by the applicant.

GM 21.A.611 Design changes

A change to an MTSO article can either be seen:

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- under SIM-To-Lt-035 21.A.611 in the context of an MTSO authorisation, i.e., when an article as such is specifically approved under SIM-To-Lt-035 Section A Subpart O, with dedicated rules that give specific rights and obligations to the designer of the article, irrespective of any product type design or change to the type design. For a change to such an article, irrespective of installation on any aircraft, SIM-To-Lt-035 21 Section A Subpart O, and SIM-To-Lt-035 21.A.611 in particular, should be followed; or
- when an organisation is designing a change (based on data not published in the MTC holder or Original Equipment Manufacturer documentation) on an article installed on an aircraft, such a change can be considered as a change to the product in which the article is installed, not to the article taken in isolation. Therefore SIM-To-Lt-035 Section A Subpart D can be used for the approval of this change that will be identified as "change to product x affecting article y", but not "change to article y".

SUBPART P - MILITARY PERMIT TO FLY

GM 21.A.701 Scope

An aircraft to be used for flight testing by any organisation which has its principle place of business in a state other than the state of registry, remains under the Authority of its state of registry. The Authority of the flight testing organisation or an appropriately approved design organisation can provide, on request, technical assistance to the state of registry for the issue of a military permit to fly, under the state of registry applicable regulations.

GM 21.A.701(a) Military permit to fly when certificate of airworthiness or restricted certificate of airworthiness is not appropriate

A certificate of airworthiness or restricted category certificate of airworthiness may not be appropriate for an individual aircraft or aircraft type when it is not practicable to comply with the normal continued airworthiness requirements and the aircraft is to a design standard that is demonstrated to be capable of safe flight under defined conditions. SIM-To-Lt-035 21.A.701 identifies cases where the issuance of a (restricted) certificate of airworthiness may not be possible or appropriate and this GM provides further information and typical examples for clarification where appropriate:

Note: This list of examples is not exhaustive

- 1) Development:
 - testing of new aircraft or modifications;
 - testing of new concepts of airframe, engine propeller and equipment;
 - testing of new operating techniques.
- 2) Demonstration of compliance with regulations or certification requirements:
 - certification flight testing for type certification, supplemental type certificates, changes to type certificates or MTSO authorisation.
- 3) Design organisations or production organisations crew training:
 - Flights for training of crew that will perform design or production flight testing before the design approval or Certificate of Airworthiness (C of A) can be issued.
- 4) Production flight testing of new production aircraft:
 - For establishing conformity with the approved design, typically this would be the same programme for a number of similar aircraft.

- 5) Flying aircraft under production between production facilities:
 - green aircraft ferry for follow on final production.
- 6) Flying the aircraft for customer acceptance:
 - Before the aircraft is sold and/or registered.
- 7) Delivering or exporting the aircraft:
 - Before the aircraft is registered in the State where the C of A will be issued.
- 8) Flying the aircraft for Authority acceptance:
 - In the case of inspection flight test by the Authority before the C of A is issued.
- 9) Market survey, including customer's crew training:
 - Flights for the purpose of conducting market survey, sales demonstrations and customer crew training with non-military type certificated aircraft or aircraft for which conformity has not yet been established or for non-registered a/c and before the C of A is issued.
- 10) Exhibition and air show:
 - Flying the aircraft to an exhibition or show and participating to the exhibition or show before the design approval is issued or before conformity with the approved design has been shown.
- 11) Flying the aircraft to a location where maintenance or airworthiness review are to be performed, or to a place of storage:
 - Ferry flights in cases where maintenance is not performed in accordance with approved programmes, where an AD has not been complied with where certain equipment outside the Master Minimum Equipment List (MMEL) is unserviceable or when the aircraft has sustained damage beyond the applicable limits.
- 12) Flying an aircraft at a weight in excess of its maximum certificated take-off weight for flight beyond the normal range over water, or over land areas where adequate landing facilities or appropriate fuel is not available:
 - Oversees ferry flights with additional fuel capacity.
- 13) Reserved.
- 14) Flying aircraft meeting the applicable airworthiness requirements before conformity to the environmental requirements has been found:
 - Flying an aircraft which has been demonstrated to comply with all applicable airworthiness requirements but not with environmental requirements.
- 15) For individual aircraft or types for which a certificate of airworthiness or restricted certificate of airworthiness is not appropriate.

- For aircraft which cannot practically meet all applicable airworthiness requirements, such as certain aircraft without TC-holder (“generically termed orphan aircraft”) or aircraft which have been under national systems of military permit to fly and have not been demonstrated to meet all applicable requirements. The option of a military permit to fly for such an aircraft should only be used if a certificate of airworthiness or restricted certificate of airworthiness cannot be issued due to conditions which are outside the direct control of the aircraft owner, such as the absence of properly certified spare parts.

Note: The above listing is of cases when a military permit to fly MAY be issued, in accordance with national regulations; it does not mean that in the described cases a military permit to fly MUST be issued. If other legal means are available to allow the intended flight(s) they can also be used.

GM 21.A.703 Applicant for a military permit to fly

The applicant for a military permit to fly may be a person other than the registered owner of the aircraft. As the holder of this permit will be responsible for ensuring that all the conditions and limitations associated with the military permit to fly are continuously satisfied, the applicant for the permit should be a person or organisation suitable for assuming these responsibilities. In particular, the organisations designing, modifying or maintaining the aircraft should normally be the holder of the associated permits to fly.

GM 21.A.705 Authority of the State

Reserved.

GM 21.A.707(b) Application

The military permit to fly application form SVY921 (EMAR Form 21) should be obtained from the Authority.

GM 21.A.708(b) Flight conditions

SIM-To-Lt-035 21.A.708(b) requires recording of all conditions or restrictions that are necessary to ensure the safe operation of the aircraft. For military aircraft, the safe carriage or release of weapons and stores has to be equally considered. Therefore, any restrictions regarding the military kind of operations (e.g., Air to Air

refuelling, Low Level Flight, Ship-Based-Operations and Landing, carriage or release of weapons and stores) should be documented under (b)(4), as appropriate.

GM 21.A.708(b)(6) Continuing airworthiness

In most cases a simple reference to existing maintenance requirements will suffice for aircraft that have a temporarily invalid C of A.

For other aircraft it will have to be proposed by the applicant as part of the flight conditions. For approved organisations they can be included in their procedures.

GM No. 1 to 21.A.708(c) Safe flight

Safe flight normally means continued safe flight and landing but in some limited cases (e.g. higher risk flight testing) it can mean that the aircraft is able to fly in a manner that will primarily ensure the safety of over-flown third parties, the flight crew and, if applicable other occupants.

This definition of “safe flight” should not be interpreted as allowing a test pilot, equipped with a parachute and operating over a sparsely populated area, to set out on a test flight in the full knowledge that there is a high probability of losing the aircraft. The applicant should take reasonable care to minimise safety risks and to be satisfied that there is a reasonable probability that the aircraft will carry out the flight without damage or injury to the aircraft and its occupants or to other property or persons whether in the air or on the ground.

GM No. 2 to 21.A.708(c) Substantiations

The substantiations should include analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can perform safely a flight.

GM 21.A.708(d) Control of aircraft configuration

The applicant should establish a method for the control of any change or repair made to the aircraft, for changes and repairs that do not invalidate the conditions established for the military permit to fly.

All other changes should be approved in accordance with SIM-To-Lt-035 21.A.713 and when necessary a new military permit to fly should be issued in accordance with SIM-To-Lt-035 21.A.711.

AMC 21.A.709(b) Submission of documentation supporting the establishment of flight conditions

Together with the application, the documentation required by SIM-To-Lt-035 21.A.709(b) must be submitted with SVY918B (EMAR Form 18B) (see EMAR Forms Document), completed with all relevant information. If the complete set of data is not available at the time of application, the missing elements can be provided later. In such cases, the approval form should be provided only when all data are available, to allow the applicant to make the statement required in Block 9 of the Form.

GM 21.A.710 Approval of flight conditions

1. The approval of flight conditions is related to the safety of the design, when:
 - a) the aircraft does not conform to an approved design; or
 - b) an Airworthiness Limitation, a Certification Maintenance Requirement or an Airworthiness Directive has not been complied with; or
 - c) the intended flight(s) are outside the approved envelope.
 - d) the permit to fly is issued for the purpose of 21.A.701(a)(15).
2. Examples when the approval of flight conditions is not related to the safety of the design are:
 - a) production flight testing for the purpose of conformity establishment;
 - b) delivery / export flight of a new aircraft the design of which is approved;
 - c) demonstrating continuing conformity with the standard previously accepted by the Authority for the aircraft or type of aircraft to qualify or re-qualify for a (restricted) certificate of airworthiness.

AMC 21.A.711 Issue of a military permit to fly

As an alternative means of compliance to Subpart P requirements the military permit to fly for an aircraft allocated for flight test development should be issued in compliance with the Military Flight Test Permit (MFTP) procedure in defining the approval process for the flight test conditions. The MFTP process has been specifically developed for use in the Military Flight Test environment and enables closer cooperation between participating nations to utilise a single MFTP.

GM 21.A.711(e) Additional conditions and restrictions

The conditions and restrictions prescribed by the Authority may include airspace restrictions to make the conditions approved under SIM-To-Lt-035 21.A.710 more concrete, or conditions outside the scope of the ones mentioned in SIM-To-Lt-035 21.A.708(b) such as a radio station license.

GM 21.A.713 Changes

Changes to the conditions or associated substantiations that are approved but do not affect the text on the military permit to fly do not require issuance of a new military permit to fly.

In case a new application is necessary, the substantiation for approval of the flight conditions only needs to address the change.

GM 21.A.719 Transfer of a military permit to fly

A military permit to fly is issued based upon the applicant's declaration of many aspects of the proposed flight or flights, some of which are specific to the applicant. Accordingly, the basis upon which a military permit to fly has been issued necessarily is no longer fully in place when the holder of a military permit to fly changes, ownership changes, and/or there is a change of register. Such changes necessitate a new application under SIM-To-Lt-035 21.A.707.

SUBPART Q - IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

GM 21.A.804(a)(1) Identification of parts and appliances

It is not the intent of SIM-To-Lt-035 21.A.804(a)(1) to introduce an obligation for a production organisation (manufacturer) to mark new parts or appliances with information which is not identified by the design approval holder. Therefore, the physical marking of parts and appliances is only required when established by the design approval (TC, STC, MTSO, repair, change) holder.

The design approval holder is required to identify to the manufacturer how the marking in accordance with SIM-To-Lt-035 21.A.804(a)(1) should be done. This can be limited to identifying a marking field, possible depth and/or means etc., without prescribing the actual text or symbols to be used.

SECTION B PROCEDURES FOR COMPETENT AUTHORITIES

NOT APPLICABLE