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## Annex 1 to CRD 2017-20 — Draft resulting text

### 'AMC/GM to Part 21 — Issue X, Amendment Y'

The text of the amendment is arranged to show deleted text, new or amended text as shown below:

- deleted text is struck through;
- new or amended text is highlighted in grey;
- an ellipsis '[...]' indicates that the rest of the text is unchanged.

1. AMC 21.A.14(b) is amended as follows:

#### **AMC 21.A.14(b) Alternative Procedures**

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

1. Scope
  - 1.1 As an alternative to DOA, a manual of procedures must should be provided that sets out specific design practices, resources and sequence of activities relevant for the specific projects, taking account of Part 21 Part 21 requirements into account.
  - 1.2 These procedures must should be concise and limited to the information needed for quality and proper control of the activities undertaken by the applicant/holder, and by the Agency EASA.
2. Management of the (supplemental) type-certification process
  - 2.1 Certification programme: See AMC 21.A.2015(b) for type-certification and AMC 21.A.11493(b) for supplemental type-certification.
  - 2.2 Compliance demonstration: see GM 21.A.20.
  - 2.3 Reporting: see AMC 21.A.20(b).
  - 2.24 Compliance documentation: see AMC 21.A.20(c).
  - 2.5 Declaration of compliance: see GM 21.A.20(d).
3. Management of design changes to type certificate, repair designs and production deviations
  - 3.1 Approval Management of changes to a type design certificate or supplemental type certificate (hereinafter referred to as 'changes'), repairs designs and production deviations from the approved design data.

The TC or STC applicant must provide procedures acceptable to the Agency EASA for classification and approval of changes to type design (see paragraphs 3.2 and 3.3), and repairs designs and production deviations from the approved design data (see paragraph 3.4).

## 3.2 Classification

### 3.2.1 Content

The procedure must address the following points:

- the identification of the product configuration(s) to which the change is to be made,
- the identification of changes to type design areas of the product that are changed or affected by the change,
- the identification of any reinvestigations necessary (see point 21.A.93(b)(2)), including identification of applicable certification specifications or environmental protection requirements and means of compliance,
- airworthiness classification of the whole change and its individual components (i.e. a change to type design and OSD, see GM 21.A.91, Section 3.2),
- changes to type design initiated by sub-contractors,
- documents to justify the classification,
- authorised signatories,
- the criteria used for classification must be in compliance with 21.A.91 and the corresponding interpretations.

### 3.2.2 Identification of changes to type design

The procedure must indicate how the following are identified:

- major changes to type design,
- those minor changes to type design where additional work is necessary to demonstrate compliance with the certification specifications,
- other minor changes to type design that require no further demonstration of compliance.

### 3.2.3 Airworthiness classification Considerations of effects of the change

The procedure must show how the effects on airworthiness, operational suitability or environmental protection are analysed, from the very beginning, by reference to the applicable certification specifications.

If no specific certification specifications are applicable to the change, the above review must be carried out at the level of the part or system where the change is integrated and where specific certification specifications are applicable.

### 3.2.4 Control of changes to type design initiated by sub-contractors

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

### 3.2.5 Documents to justify the classification

All decisions of classification of changes to type design must be documented and approved by the Agency EASA. The documentation 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 Agency EASA for approval.

## 3.3 Approval of changes to type design

### 3.3.1 Content

The procedure must address the following points:

- compliance documentation,
- the internal approval process,
- authorised signatories.

### 3.3.2 Compliance documentation

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

### 3.3.3 Approval process

- A) For the approval of major changes to type design, a certification programme as defined in AMC 21.A.973(b) must be established.
- B) For major changes and those minor changes to type design where additional work to show demonstrate compliance with the applicable certification basis specifications is necessary, the procedure should define a document to support the approval process.

This document must include at least:

- identification and a brief description of the change and its classification,
- references to the applicable certification basis specifications,
- reference to the compliance documents,
- effects, if any, on limitations and on the approved design data documentation,
- the name of the authorised signatory.

- C) For the other minor changes, the procedure must should define a means:
- to identify the change,
  - to present the change to the Agency EASA for approval.

#### 3.3.4 Authorised signatories

The procedure must should identify the persons authorised to sign off the change before release to the Agency EASA for approval.

#### 3.4 Repairs designs and production deviations from the approved design data

A procedure following the principles of paragraphs 3.2 and 3.3 must should be established for the classification and approval of repairs designs and unintentional deviations from the approved design data occurring in production (concessions or non-conformances). For repairs designs, the a procedure must should be established in accordance with Part 21, Section A, Subpart M and the associated acceptable means of compliance (AMC) or guidance material (GM).

#### 4. Issue of design data and information and (including instructions) to owners, operators or others required to use the data and information

##### 4.1 General

Design data and information and instructions include the operational suitability data.

##### 4.2 Data related to changes

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

The design data and information or (including instructions) may be issued in a format of a Service Bulletin as defined in ATA 100 system, or in Structural Repair Manuals, Maintenance Manuals, Engine and Propeller Manuals, etc.

The preparation of this data involves design, production and inspection. 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(s) 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.

The persons authorised to sign off before release of design data and information and instructions to the Agency EASA for approval should be identified in the procedure.

The procedure should include the information ~~or~~ (including instructions) prepared by sub-contractors or vendors, and declared applicable to its products by the holder of the TC, STC, approval of changes to type design or approval of repair designs holders.

#### 4.4 Statement

The design data and information ~~and~~ (including instructions) should contain a statement showing Agency EASA's approval.

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

The applicant for alternative procedures to DOA should establish the necessary procedures to show to the Agency EASA how it will fulfil the obligations required under 21.A.44, 21.A.118A or 21.A.451, as appropriate.

6. Control of design sub-contractors

The applicant for alternative procedures to DOA should establish the necessary procedures to show to the Agency EASA how it will control design sub-contractors and ensure the acceptability of the parts or appliances designed or the design tasks performed.

2. The following AMC 21.A.15(a) is inserted:

#### **AMC 21.A.15(a) Form and manner**

The applicant should file an application using the web-based 'EASA Applicant Portal'<sup>1</sup> or the application form for a type certificate or restricted type certificate (FO.CERT.00030)<sup>2</sup>, which may be downloaded from the EASA website.

The form should be completed in accordance with the completion instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website<sup>3</sup>.

3. The following AMC 21.A.15(b) is inserted:

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

The certification programme is a document that allows the applicant and EASA to manage and control the evolving product type design or OSD, as well as the process of compliance demonstration by the applicant and its verification by EASA 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.

<sup>1</sup> <https://ap.easa.europa.eu> (changes to the link provided may not be reflected in this document)

<sup>2</sup> <http://www.easa.europa.eu/document-library/application-forms/focert00030> (changes to the link provided may not be reflected in this document).

<sup>3</sup> <https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals> (changes to the link provided may not be reflected in this document).

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 EASA, unless otherwise identified to EASA (e.g. within the DOA 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.

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 crew;
- 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);
- noise/emissions level; and
- other items, if considered to be more appropriate, that address the specific aeronautical product.

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.

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 CS-27 and 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 (AWOs), visual flight rules (VFR)/instrument flight rules (IFR), reduced vertical separation minima (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.
- Volcanic-ash operation (limitation or operation as per CS 25.1593 and 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).
- Other items, if considered to be more appropriate, that address the specific aeronautical product.

21.A.15(b)(4) 'a proposal for the initial type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, considering the requirements and options specified in 21.B.80, 21.B.82 and 21.B.85'

The proposed certification basis should include applicable certification specifications, proposed special conditions, proposed equivalent safety findings, as well as a proposed 'elect to comply' and proposed deviations, as applicable.

21.A.15(b)(5) 'a proposal for a breakdown of the certification programme into compliance demonstration items, including references to their proposed means of compliance and related compliance documents'

See AMC 21.A.15(b)(5) and 21.B.100(a) for compliance demonstration item (CDI) determination.

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 EASA panel or discipline affected by a proposed CDI. Further interpretative material on the necessary level of details is provided in AMC 21.B.100(a) and 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 EASA to determine its (initial) LoI. This should include the following, as far as this information is available at the time of submission to EASA:

- 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;
- 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 programmes) 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 CSs.

4. The following Appendix A to AMC 21.A.15(b) is inserted:

**Appendix A 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 product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports

Type of compliance	Means of compliance	Associated compliance documents
Equipment qualification	MC9: equipment qualification	Note: Equipment qualification is a process that may include all previous means of compliance at equipment level.

5. The following AMC 21.A.15(b)(5) is inserted:

**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 EASA 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.B.100(a) and 21.A.15(b)(6)), but should not have any effect on the compliance demonstration itself or on EASA'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 as specified in 21.B.80 and 21.B.82, or the environmental protection requirements as specified in 21.B.85.

A CDI may comprise any of the means of compliance 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, hydromechanical systems, OSD-cabin crew data (CCD), 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.B.100(a) and 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 EASA panel(s)/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.

### 6. The following GM 21.A.15(c) is inserted:

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

Point 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 EASA. 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;
- any change in the key characteristics of the product such as but not limited to any declared limits as intended to be recorded in the type certificate data sheet (TCDS);
- any change in the product design or 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 21.A.15(b)(6) and 21.B.100(a)(1) to (4);

- any change to the initial type-certification basis, OSD certification basis or environmental protection requirements, as applicable to the product, whether that change is initiated by EASA 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 EASA's level of involvement (LoI), as defined in 21.B.100;
- any relevant change to the design organisation approval (DOA) holder's personnel (and design organisation (DO) suppliers) involved in the project; and
- changes to the schedule that impact the EASA involvement.

Following each update to the certification programme as submitted by the applicant, EASA may update the determination of its LoI in accordance with 21.B.100(c).

7. GM No 1 to 21.A.15(d) is amended as follows:

**GM No 1 to 21.A.15(d) Clarification of the term 'as applicable' applicability of operational suitability data (OSD) constituents**

The term 'as applicable' indicates that not all OSD constituents as listed in 21.A.15(d)(1) through (5) are not always part of the OSD.

[...]

8. The following GM 21.A.15(e) and (f) is inserted:

**GM 21.A.15(e) and (f) Effectivity dates for the application for a type certificate (TC) or restricted type certificate (RTC)**

Point 21.A.15(e) establishes a maximum effectivity period 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 EASA in accordance with points 21.B.80, 21.B.82, and 21.B.85, remain effective. However, the effectivity 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 has the following two options (see 21.A.15(f)(1) and (2)):

1. Submit a new application

In this case, EASA establishes and notifies a new certification basis in accordance with points 21.B.80, 21.B.82, and 21.B.85, considering the standards that are available at the date of the new application.

In accordance with point 21.A.15(e), the new application has a maximum effectivity period equal to the first one, corresponding to the product category. Beyond this effectivity period, the applicant may need to choose again between the two options of either submitting a new application or applying for an extension of this application.

2. Apply for an extension of the original application

In this case, the applicant proposes to EASA a ‘new target date’ for the issuance of the certificate, and selects a date that becomes the reference date for the establishment of the certification basis by EASA. For the purposes of this GM, the selected reference date is referred to as ‘new effectivity date’ of the initial application.

The ‘new effectivity date’ of the initial application may be any date in the past between the following limits:

- the ‘new target date’ for a TC proposed by the applicant minus the time limit used under 21.A.15(e) (e.g. 5 years for large aeroplanes and large rotorcraft, 3 years for the other products); and
- the date at which the applicant applies for the extension of the application.

This calculation is visualised in Figure 1 below:

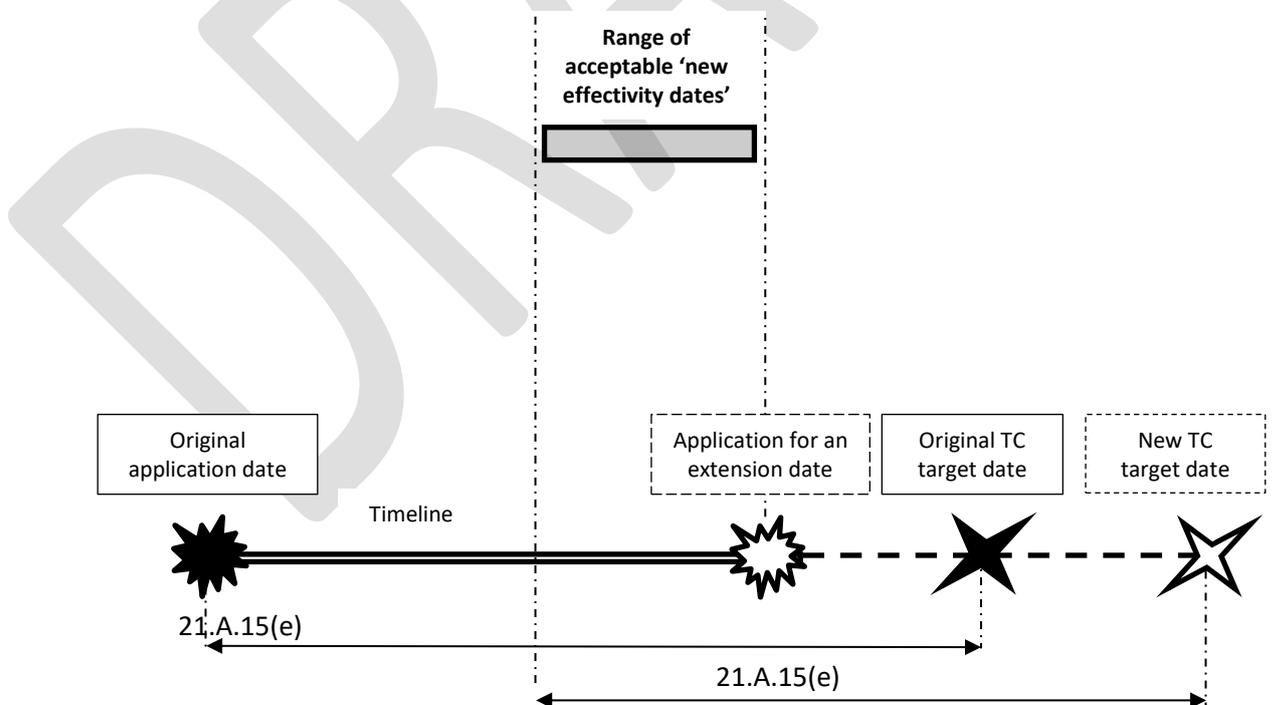


Figure 1

This ensures that the standards used to establish the certification basis are never older than the ones available at the start of the effectivity period required by point 21.A.15(e).

If the applicant is not able to complete the product certification by the new target date, the applicant may choose again between the two options of either submitting a new application or applying for a new extension of this application.

9. GM 21.A.16B is deleted.
10. GM 21.A.17B(a)(1) is deleted.
11. AMC 21.A.20(b) is deleted.
12. Appendix to AMC 21.A.20(b) is deleted.
13. GM 21.A.20(b) is deleted.
14. The following GM 21.A.20 is inserted:

#### **GM 21.A.20 Compliance demonstration process**

Point 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 Part 21, Subparts D and E, to compliance demonstration processes for major changes to a TC (see point 21.A.97(b)(3)) and an STC (see point 21.A.115(b)(4)).

Applicants for a TC (or an RTC) should apply point 21.A.20 in full. Applicants for a major change to a TC or an STC are required (see points 21.A.97(b)(3) and 21.A.115(b)(4)) to apply point 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 point 21.A.93, as accepted by EASA; and
- the certification basis (consisting of the type-certification basis, operational suitability data (OSD) certification basis, and the environmental protection requirements) is the one established by EASA in accordance with point 21.A.101 and notified to the applicant in accordance with point 21.B.105 (for a major change to a TC) or point 21.B.109 (for an STC).

Point 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 point 21.A.263(c)(8) or (9) (see also points 21.A.97(b)(3) and 21.A.115(b)(4)). As in this case there is no application and no EASA involvement, point 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 EASA for a major change or an STC when approved for the scope of the privilege as per point 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 point 21.A.20(a)) and the final declaration of compliance (see point 21.A.20(e)) should be kept on record and submitted to EASA only if EASA requests them during its DOA continued surveillance process.

15. The following GM 21.A.20(b) is inserted:

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

The applicant should report to EASA 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 points 21.A.33 or 21.A.35.

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

16. AMC 21.A.20(c) is amended as follows:

#### **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 certification basis and environmental protection requirements is demonstrated.
2. Each compliance document should normally typically contain:
  - ~~an adequate link with the corresponding certification programme~~
  - the reference of the certification specifications, 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 have a be unequivocally identified by its number reference and issue date. The various issues of a document should be controlled and comply with point 21.A.55.

17. GM 21.A.20(d) is amended as follows:

**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 point 21.A.33 and all flight tests in accordance with point 21.A.35, should be completed before the issuance of the final statement of compliance required by point 21.A.20(d).

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

‘No feature or characteristics’ in point 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.

Point 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 EASA, is aware of a feature or characteristic that may make the product unsafe for the uses for which certification is requested.

18. The following GM 21.A.21(a)(3)(i) is inserted:

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

A type certificate ‘determined’ in accordance with Part 21 means a type certificate, or a document that allows the issuance of a certificate of airworthiness, issued before 28 September 2003 by a Member State complying with Article 3(1)(a) of Regulation (EU) No 748/2012.

19. GM No 1 to 21.A.21(f), 21.A.23(b) and 21.A.103(a)(4) is amended as follows:

**~~GM No 1 to 21.A.21(f)(b), 21.A.23(b) and 21.A.103(a)(4)~~ 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.110(b) Approval of operational suitability data (OSD)**

It is acknowledged that it may not always be possible to have the operational suitability data available on the date of the issue of the (restricted) type certificate (TC), change approval or supplemental type certificate (STC). The derogation provided by points 21.A.21(f), 21.A.23(b) and 21.A.103(a)(4) 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.110(b) are intended for that case. The TC, change approval or STC can be issued before compliance with the operational suitability data OSD certification basis has been demonstrated.

However, the OSD have to needs to be approved before the data must be used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done upon before the entry into service of the first aircraft by an EU operator but could also be later for some of the OSD constituents, such as the definition of 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 in points 21.A.103(a)(4), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.110(b) 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, and also as well as to changes where only at least one of the OSD constituent changes is major.

However, there may be a need to make one or several OSD constituents available before the entry into service. For example, there may be a need to start training activities before all OSD constituents contained in the OSD application can be approved. Making use of the derogation of point 21.A.21(f), 21.A.23(b), or 21.A.103(a)(4), the relevant OSD constituent can be approved under the TC, a change approval or the STC, the use of which can then be limited to specific purposes.

There may, in some specific cases, even be a need to make provisional OSD available before the TC (or STC) is issued. In such cases, before the availability of a complete and fully compliant OSD, the Agency can confirm partial compliance of only one or several provisional OSD constituents.

20. GM 21.A.33 is amended as follows

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

The requirements of 21.A.33(a) should not preclude the applicant should inform EASA sufficiently in advance about the execution of inspections and tests that are used for compliance demonstration purposes unless EASA has explicitly excluded these inspections and tests from its involvement according to 21.B.100.

Additionally, the applicant requesting may propose to the Agency EASA to make perform or witness flight or other tests of particular aspects of the product during its development and before the type design is fully defined. and a Declaration of Compliance can be issued for all the applicable certification specifications (CS). However in case of flight test, before EASA performs or witnesses any flight test, the applicant should have performed subject these tests already before the Agency EASA tests and should ensure that no features of the product preclude the safe conduct of the evaluation requested.

The Agency EASA may require to repeat 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 compliance conformity with as per point 21.A.33(b)(c) is also required for the above tests.

21. The following AMC 21.A.33 is inserted:

#### **AMC 21.A.33 Inspections and tests**

Use of the term 'applicant': point 21.A.33 is applicable to type certification, major changes, major repairs and supplemental type certificates (STCs), and through reference in point 21.A.604 to ETSO for APUs. Despite using the word 'applicant', it is also applicable to major changes, major repairs and STCs approved under DOA privileges (see point 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 point 21.A.33(c) must address the conformity of the test specimen (see point 21.A.33(b)(1)) as well as of the test equipment and measuring equipment (see point 21.A.33(b)(2)).

Conformity of the test specimen: the statement of conformity required by point 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.

While it is convenient to define any possible non-conformity as early as possible, the applicant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed and justified in the statement of conformity or by cross reference to the test plan or other documents.

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 to the 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 point 21.A.33(c) should confirm that the test and measuring equipment conforms 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 point 21.A.33(e)(2)): if changes need to be introduced to the test specimen or to the test and measuring 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 EASA before the test if EASA 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 point 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 EASA, 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 point 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 EASA as per 21.B.100(c) should be taken into account: if EASA has determined that it will witness or conduct a certain test, this test may need to be repeated so that EASA 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 point 21.A.33(b), this aspect should be considered when issuing the statement of conformity required by point 21.A.33(c), and specific analyses or inspections may be required to support such a statement.

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

Availability of compliance data (see point 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 EASA.

Point 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, point 21.A.33(d)(1) is not limited to data and information related to compliance demonstration items (CDIs) in which EASA is involved.

22. GM to 21.A.90A is amended as follows:

#### **GM ~~to~~ 21.A.90A Scope**

The term 'changes to the type certificate' is consistently used in ~~Part 21~~ Part 21, 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 ~~concept~~ of the TC as defined in 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 ~~Agency~~ applicant has to demonstrates compliance;
- any other conditions or limitations prescribed for the product in the applicable certification specifications (CSs) and environmental protection requirements by EASA;
- 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 the OSD are only relevant for changes to aircraft TCs.

23. GM 21.A.91 is amended as follows:

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

[...]

### **3 ASSESSMENT OF A CHANGE FOR CLASSIFICATION**

#### **3.1 Changes to the TC**

21.A.91 addresses changes to all aspects of a TC. This includes changes to type design, as defined in 21.A.31, as well as to the other constituents of a TC, as defined in 21.A.41. ~~This GM provides guidance on changes to the type design and changes to the operational suitability data (OSD). A change to a TC can include a change to the type design and/or a change to the OSD.~~

#### **3.2 Separate classification for type design and OSD**



Although in the end, the change to the TC, which includes a change to a type design and a change to OSD, will have only one classification, it will be possible to classify the different changes to OSD components/constituents of the change independently. This will facilitate the approval of a major change, with no verification by EASA of the OSD component if the change to OSD is considered minor, or with no verification by EASA of the design change if the design change is considered minor (See also GM to 21.A.103/21.B.107 and 21.B.110).

### 3.3 Classification Process (see also the flow chart 'Classification process' in Appendix A to GM 21.A.91 attached diagram)

21.A.91 requires all changes to be classified as either major or minor, using the criteria of 21.A.91. Wherever there is doubt as to the classification of a change, the Agency EASA should be consulted for clarification.

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

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

The Reasons for a classification decision should be recorded.

### 3.4 Complementary guidance for the 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:

[...]

- (e) where the change alters the airworthiness limitations or the operating limitations;
- (ef) where the change is made mandatory by an airworthiness directive or the change is the terminating action of an airworthiness directive (ref. 21.A.3B), see Note 1; and;
- (fg) where the change introduces or affects functions where the failure effect is classified as catastrophic or hazardous.

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

Note 2: The above conditions listed in (a) through (g) above are an explanation of the criteria noted in 21.A.91.

For an understanding of how to apply the above conditions it is useful to take note of the examples given in Appendix A to GM 21.A.91.

### 3.5 Complementary guidance on the classification of changes to OSD

[...]

### 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 point 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 EASA;
    - (iii) conversions of previously Federal Aviation Administration (FAA)- or EASA-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 EASA-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 EASA;
    - (iii) conversions of previously FAA- or EASA-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 EASA-approved AFM supplement into the language of the State of design or the State of registration.

### 3.7 Complementary guidance for the classification of changes to environmental protection characteristics

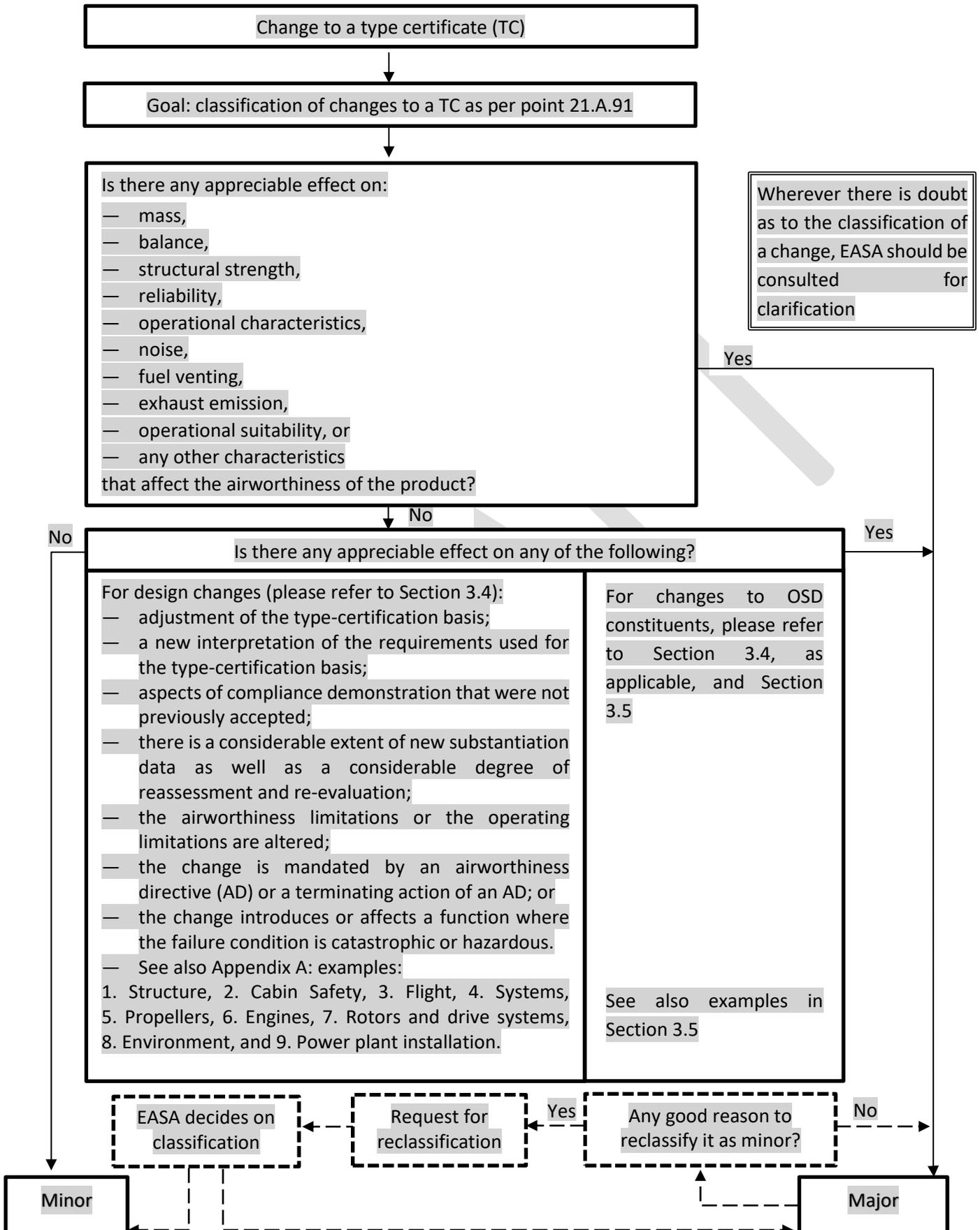
See Section 8 of Appendix A to GM 21.A.91.

### 24. Appendix A to GM 21.A.91 is amended as follows:

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

[...]

Classification process



25. The following AMC 21.A.93(a) is inserted:

**AMC 21.A.93(a) Form and manner**

The applicant should file an application using the web-based 'EASA Applicant Portal'<sup>4</sup> or the application forms for the approval of major changes/major repair designs (FO.CERT.00031)<sup>5</sup> or for the approval of minor changes/minor repair designs (FO.CERT.00032)<sup>6</sup>, which may be downloaded from the EASA website.

The forms should be completed in accordance with the completion instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website<sup>7</sup>.

26. GM 21.A.93(b) is amended as follows:

**AMC 21.A.93(b) Major Changes: Application 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/re-investigations referred to in point 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/certification specifications 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 points 21.A.91 and 21.A.101 should be performed using the corresponding GM. For repair designs, the analysis of point 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.

<sup>4</sup> <https://ap.easa.europa.eu> (changes to the link provided may not be reflected in this document).

<sup>5</sup> <https://www.easa.europa.eu/document-library/application-forms/focert00031> (changes to the link provided may not be reflected in this document).

<sup>6</sup> <https://www.easa.europa.eu/document-library/application-forms/focert00032> (changes to the link provided may not be reflected in this document).

<sup>7</sup> <https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals> (changes to the link provided may not be reflected in this document).

27. GM No 1 to 21.A.93(c) is amended as follows:

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

[...]

- (e) When the design change makes an OSD constituent applicable (see GM No 1 to 21.A.15(d) — Clarification of the term ‘as applicable’ 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. ~~In accordance with paragraph (e), this does not apply to the OSD constituents SIMD and MCSD.~~

28. GM No 2 to 21.A.93(c) is amended as follows:

**GM No 2 to 21.A.93(eb)(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 more convenient and economical air transportation for the public.

Therefore, not introducing an MMEL relief for new equipment, system or function has no effect on the safety of the operation. The introduction of an 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 if this change needs to be supplemented by a change to the MMEL. However, the update of 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 made available approved according to point 21.A.103(a)(4) 21.A.97(b)(2) and (c).

[...]

29. The following AMC 21.A.95 is inserted:

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

**(a) Applicability of point 21.A.95**

Point 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 approving minor changes under their own privileges.

Point 21.A.95(d), however, only applies to projects for which an application is submitted to EASA. For DOA holders approving minor changes under their privileges, the substantiating data and the statement of compliance required by point 21.A.95(d) should be produced but do not need to be submitted to EASA. They should be, however, kept on record and submitted to EASA on request during its 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 EASA. DOA holders approving 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 EASA, an application should be sent, as described in point 21.A.93(a) and (b) and GM 21.A.93(a).

(2) Certification programme

The certification programme should consist of the information defined in points 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 certification basis 'incorporated by reference in the type certificate' (see also the additional guidance below on the meaning of specifications that became applicable after those 'incorporated by reference in the type certificate'), which have been identified in accordance with point 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 point 21.A.93(b)(1)(i).

The certification basis contains the applicable airworthiness and (for aircraft only) operational suitability data (OSD) certification specifications (CSs), environmental protection requirements specified by 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, CSs 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 specifications 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 point 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.

See also the additional guidance in (e) below.

(3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

See also additional guidance below on embodiment/installation instructions (under (f)).

(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(e)

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) Certification specifications 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 point 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 CSs 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 CSs for the compliance demonstration. This does not affect the classification of the change; however, the applicant should also comply with any other CSs that EASA 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 certification basis.
- (j) Meaning of 'no feature or characteristics' in point 21.A.95(b)(4)  
See GM 21.A.20(d).

30. The following GM 21.A.95(b) is inserted:

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

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

31. AMC 21.A.97 is amended as follows:

**AMC 21.A.97 ~~Compliance demonstration process for major changes~~ Requirements for the approval of a major change**

1. ~~AMC/GM to 21.A.20 should be used for a major change.~~
2. ~~For major changes not requiring long and complex compliance demonstration activities, a certification programme, as described in AMC 21.A.20(b), can be submitted with the application in a simplified format. The certification programme should contain at least the following elements:~~
  - ~~— Purpose of change~~
  - ~~— Description of change~~
  - ~~— Applicability~~
  - ~~— Applicable certification specifications, special conditions, equivalent safety findings and environmental protection requirements~~

— The description on how compliance will be demonstrated, with selected means of compliance (see Appendix to AMC 21.A.20(b) for the codes to be used) and reference to compliance documents

— If relevant, the delivery schedule of compliance documents.

1. For major changes approved by EASA, the applicant should use all the AMCs 21.A.20, as well as the GM 21.A.20.
2. For the application of point 21.A.97(c), see GM 21.A.21(f)(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.110(b).
3. In accordance with point 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 point 21.A.263(c)(8), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

32. The following GM 21.A.97(b) is inserted:

#### **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 21.A.93(b) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

33. GM No 1 to 21.A.101(g) is amended as follows:

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

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

1. Minor changes
 

Minor changes to the OSD are automatically considered not significant under 21.A.101(b) outside the scope of point 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 CSs, unless the exceptions of point 21.A.101(b)(3) apply or unless the OSD change can be classified as minor as per point 21.A.91. The guidance of GM 21.A.101, chapter 3, paragraph 10 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 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 certification specification (CSs).
- e. ~~In accordance with Article 7a(3) of Regulation (EU) No 69/2014, the Operational Evaluation Board (OEB) reports and Master Minimum Equipment Lists (MMEL) issued in accordance with the JAA procedures or by the Agency before the entry into force of Regulation (EU) No 748/2012, are deemed to constitute the OSD approved in accordance with 21.A.21(e).~~

~~The original procedures, guidance material (GM), advisory circular joint (ACJ) and/or acceptable means of compliance (AMC), advisory material joint (AMJ) material, that were used to establish the original documents (JAA/Agency MMEL or OEB report), are deemed to be the original certification basis for these documents.~~

**Reserved**

- g. Point 21.A.101(c) provides an exception from the requirements of point 21.A.101(a) for a change to the OSD of certain aircraft under a specified maximum weight. If an applicant applies for a change to the OSD for an aircraft (other than rotorcraft) of 2 722 kg (6 000 lb) or less maximum weight, or for a non-turbine-powered rotorcraft of 1 361 kg (3 000 lb) or less maximum weight, the applicant can demonstrate that the changed OSD complies with the OSD certification basis incorporated by reference in the TC. The applicant can also elect to comply, or may be required to comply, with a later amendment. See also Chapter 4, Section 24.1 (GM No. 1 to 21.A.101) for specific guidance on this provision.

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

34. GM No 1 to 21.A.103, 21.A.115 and 21.B.70 is amended as follows:

**GM No 1 to 21.A.103, 21.A.115 and 21.B.70 21.B.107 and 21.B.110 Operational suitability data (OSD) considerations for the Approval of changes to type certificates (TCs)**

The requirement for the Agency EASA in 21.B.70 points 21.B.107(c) or 21.B.110(c), which should be, by analogy, also considered by design organisation approval (DOA) holders approving changes or issuing supplemental type certificates (STCs) under their privileges (without EASA's involvement), mainly addresses stand-alone changes to OSD. For such stand-alone OSD changes, there is a separate classification process (see GM 21.A.91, Sections 3.2 and 3.5), and the way to administer the changes depends on the extent of the change, but normally, an update of the TCDS is not required. However, the requirement can also be applied to combinations of design changes and OSD changes.

Changes to TCs can comprise several interrelated changes to ~~different components~~ of the TC. For example, a change to the cockpit design may trigger a change to the flight crew data, being part of OSD, and, therefore, included in the TC.

All ~~interrelated~~ **Interrelated** changes should ultimately be approved together under a single approval. However, before issuing such a comprehensive approval, it is possible that different processes are used for the ~~different parts of the change~~.

The complete change can be split up in a change to the type design and changes to the OSD constituents. Each part of the change can be classified as minor or major separately (see GM 21.A.91).

- ~~— In case all parts of the change are classified as minor, the design organisation approval (DOA) holder can approve the whole change.~~
- ~~— In case one or more parts of the change is/are classified as major, while the associated part(s) of the change is/are classified as minor, the approved design organisation can propose to the Agency not to verify the classification and the part(s) of the change classified as minor in accordance with its privilege under 21.A.263(b)2 or 3). The Agency should then accept the part(s) of the change classified as minor without further verification. Once it is satisfied that compliance has been demonstrated for the part(s) of the change classified as major, EASA can then issue the complete change approval or supplemental type certificate (STC).~~
- ~~— In case all parts of the change are classified as major, the Agency will issue the approval for the whole change once it is satisfied that compliance has been demonstrated.~~

35. The following AMC 21.A.113(a) is inserted:

**AMC 21.A.113(a) Form and manner**

The applicant should file an application using the web-based 'EASA Applicant Portal'<sup>8</sup> or the application form for a supplemental type certificate (STC) (FO.CERT.00033)<sup>9</sup>, which may be downloaded from the EASA website.

If the form is filled in offline, it should be completed in accordance with the completion instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website<sup>10</sup>.

36. AMC 21.A.114 is deleted.

37. The following AMC 21.A.115 is inserted:

<sup>8</sup> <https://ap.easa.europa.eu> (changes to the link provided may not be reflected in this document).

<sup>9</sup> <https://www.easa.europa.eu/document-library/application-forms/focert00033> (changes to the link provided may not be reflected in this document).

<sup>10</sup> <https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals> (changes to the link provided may not be reflected in this document).

**AMC 21.A.115 Requirements for the issuance of a supplemental type certificate (STC)**

- (a) For STCs approved by EASA, the AMCs and GM to point 21.A.20 should be followed by the applicant.
- (b) For an application under point 21.A.115(c), see GM 21.A.21(f), 21.A.23(b) and 21.A.115(c).
- (c) In accordance with point 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 type certificate considering the type certificate data sheet and the relevant optional installations. The demonstration of compliance should cover these specific applicable configurations. Consequently, the approval of the STC excludes any other configurations, 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 point 21.A.263(c)(9), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

DRAFT



38. GM No.1 to 21.A.239(a) is amended as follows:

**GM No. 1 to 21.A.239(a) Design assurance system**

[...]

3.1.5 Maintenance and Operating Instructions

(a-) Ensuring the preparation and updating of all maintenance and operating instructions (including instructions for continued airworthiness and Services Bulletins) needed to maintain airworthiness (continuing airworthiness) in accordance with the relevant CSs. For that purpose, the applicant should:

- establish the list of all documents it is producing to comply with the CS 2X.1581 and with the Appendix referred to in CS 2X.1529, CS-25.1529, CS-27.1529, CS-29.1529, CS-E 20/25 or CS-P 40 (NPA-P-3);
- establish a system to collect in-service experience to be used for the improvement of the instructions;
- define their procedures and their organisation to produce and issue these documents, using where applicable and so elected 21.A.263(c)(3) privilege under the obligation of point 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 points 21.A.57, 21.A.61, 21.A.107, 21.A.119, 21.A.120A and 21.A.449, ensuring that these documents are provided to all affected known operators and involved authorities.

3.1.6 Operational Suitability Data (OSD)

(a-) Ensuring the preparation and updating of all operational suitability data OSD in accordance with the relevant CSs. For that purpose, the applicant should:

- establish the list of all the documents it is producing to comply with CS-MMEL or CS-GEN-MMEL, CS-FCD, CS-CCD, CS-SIMD and CS-MCSD, as applicable;

- define their procedures and their organisation to produce and issue these documents, using where applicable and so elected 21.A.263(c)(3) privilege under the obligation of point 21.A.265(h); the procedure should cover the aspects described in 3.1.5(a) above.

[...]

39. GM 21.A.263(b) is deleted.

40. AMC 21.A.263(b)(1) is deleted.

41. AMC No 1 to 21.A.263(c)(1) is amended as follows:

**AMC No 1 to 21.A.263(c)(1) Procedure for the classification of changes to a type certificate (TC) or to a supplemental type certificate (STC) and of repairs designs as 'minor' or 'major'**

1. INTENT

This AMC provides the means to develop a procedure for the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repairs 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 21.A.263(c)(1).

2. PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TYPE CERTIFICATE, APU ETSO, OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND REPAIRS DESIGNS

2.1 Content

The procedure should address the following points:

- the identification of changes to a TC, APU ETSO type certificate or to that part of the product covered by an STC, and repairs designs,
- classification,
- justification of the classification,
- authorised signatories, and
- supervision of changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC, and repairs designs initiated by sub-contractors.

For changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC, the criteria used for the classification should be in compliance with point 21.A.91 and as further explained in GM 21.A.91.

For repairs, the criteria used for classification should be in compliance with point 21.A.435 and as further explained in GM 21.A.435.

2.2 Identification of changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC, and repairs designs

The procedure should indicate how the following are identified:



- major changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC or major repairs;
- those minor changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC or minor repairs where additional work is necessary to demonstrate compliance with the CS and environmental protection requirements; and
- other minor changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC or minor repairs requiring that require no further demonstration of compliance.

### 2.3 Classification

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

If no specific CS 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 CS or environmental protection requirements are applicable.

### 2.4 Justification of the classification

All decisions of classification of changes to a TC, APU ETSO type certificate or to that part of the product covered by an STC, and repairs 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 Agency EASA for sample checking.

### 2.5 Authorised signatories

All classifications of changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC, and repairs designs should be accepted by an appropriately authorised signatory, belonging to or tasked by the Office of Airworthiness, as explained in GM1 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 sub-contractors, 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 type certificate, APU ETSO or to that part of the product covered by an STC, and repairs designs initiated by sub-contractors

The procedure should indicate, directly or by cross-reference to written procedures, how changes to a TC type certificate or to that part of the product covered by an STC, and repairs designs may be initiated and classified by sub-contractors and are controlled and supervised by the DOA holder.

42. AMC No 2 to 21.A.263(c)(1) is amended as follows:

**AMC No 2 to 21.A.263(c)(1) Privileges — Organisations designing 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 ETSO type certificate or to that part of the product covered by an STC, and repairs designs;
- classification in compliance with point 21.A.91 and considering 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 type certificate, APU ETSO or to that part of the product covered by an STC, and repairs designs

The procedure should indicate how the following minor changes to a type certificate or minor repairs are identified:

- those minor design changes to a type certificate or minor repairs where additional substantiation data is necessary to demonstrate compliance with the CS or environmental protection requirements;
- other minor design changes to a type certificate or minor repairs that require requiring no further demonstration of compliance.

3. Classification

The procedure should show how the effects on airworthiness, 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 CS or environmental protection requirements are applicable.

For repair, see also GM 21.A.435.

4. Justification of the classification

All decisions on classification of changes to a TC type certificate, APU ETSO or to that part of the product covered by an STC, and repairs designs as 'minor' should be recorded and, for those which are not straightforward, also documented.

These records should be easily accessible to the Agency EASA for sample checking.

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

5. Authorised signatories



All classifications of changes to a ~~TC~~ type certificate, APU ETSO or to that part of the product covered by an STC, and repairs designs 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.

43. AMC No 1 to 21.A.263(c)(2) is amended as follows:

**AMC No 1 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (TC), APU ETSO or a supplemental type certificate (STC), and ~~or~~ minor repairs**

1. INTENT

This AMC provides the means to develop a procedure for the approval of minor changes to a ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC, and ~~or~~ 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 21.A.263(c)(2).

2. PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A ~~TYPE CERTIFICATE~~ TC, APU ETSO OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND ~~OR~~ 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 ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC or minor repairs handled by sub-contractors.

2.2 Compliance documentation

For those minor changes to a ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC, and ~~or~~ minor repairs where additional work to demonstrate compliance with the applicable CS and environmental protection requirements is necessary, compliance documentation should be established and independently checked as required by point 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 ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC, and ~~or~~ minor repairs where additional work to demonstrate compliance with the applicable CS 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:

- the identification and brief description of the change or repair and the reasons for the change or repair;
- the applicable CS or environmental protection requirements and methods of compliance;
- references 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 point 21.A.263(c)(2) by an authorised signatory; and
- the date of the approval.

For repairs, see AMC 21.A.433(a).

2.3.2 For the other minor changes to a ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC, and ~~or~~ minor repairs, the procedure should define a means to identify the change or repair and the 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 point 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

2.5 Supervision of minor changes to a ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC, and ~~or~~ minor repairs handled by sub-contractors

For the minor changes to a ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC, and ~~or~~ minor repairs described in 2.3.2, ~~that~~ which are handled by sub-contractors, the procedure should indicate, directly or by ~~cross-reference~~ cross reference to written procedures, how these minor changes to a ~~type certificate~~ TC, APU ETSO or to that part of the product covered by an STC, and ~~or~~ minor repairs are approved at the sub-contractor level and the arrangements made for control and supervision by the DOA holder.

44. AMC No 2 to 21.A.263(c)(2) is amended as follows:

#### **AMC No 2 to 21.A.263(c)(2) Privileges — Organisations designing minor changes to a type certificate (TC), APU ETSO or a supplemental type certificate (STC) and minor repairs to products: procedure for the approval of minor changes to a TC, APU ETSO 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 type certificate TC, APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CS and environmental protection requirements is necessary, compliance documentation should be established and independently checked as required by point 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 type certificate TC, APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CS 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 the reason for change or repair;
- (b) the applicable CS or environmental protection requirements and methods of compliance;
- (c) references 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 point 21.A.263(c)(2) by an authorised signatory; and
- (g) the date of the approval

For repairs, see also AMC 21.A.433(a).

### 3.2. For the other minor changes to a type certificate TC, APU ETSO or to that part of the product covered by a STC, and minor repairs, the procedure should define a means to identify the change or repair and the 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 point 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

45. The following AMC No 3 to 21.A.263(c)(2) is inserted:

**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 Assessment of a change for its impact on the AFM**

The procedure should include an assessment of whether or not the AFM is impacted by the change.

**2.3 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 type certificate 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 EASA 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 EASA 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 point 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 point 21.A.263(c)(2) should be issued under the obligation of point 21.A.265(h) (see point 21.A.265(h) and the related GM) with a respective statement in the log of revisions.

46. GM 21.A.263(c)(3) is deleted.

47. GM 21.A.263(c)(4) is deleted.

48. AMC 21.A.263(c)(6) is amended as follows:

### **AMC 21.A.263(c)(6) Procedure for the approval of the conditions for issuing of a 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 certification basis applicable to the aircraft category.

Each DOA applicant or holder must should develop its own internal procedure following this AMC, in order to obtain the privilege to make this determination and approve associated conditions without Agency EASA's involvement, under 21.A.263(c)(6). When the privilege does not apply, the DOA holder will prepare all the necessary data required for the determination in accordance with the same procedure required for the privilege, and will apply for Agency EASA's approval.

The establishment of flight conditions may include conditions related to engines/propellers without a type certificate or with unapproved changes that are fitted on the aircraft, for which a permit to fly is requested. These conditions (i.e. 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 the ultimate responsibility of the organisation responsible for the design of the aircraft.

[...]

49. The following AMC No 1 to 21.A.263(c)(5), (8) and (9) is inserted:

#### **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 point 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 European technical standard order (ETSO) authorisation; or
- (b) major repairs to products or APUs for which the DOA holder does not hold the TC or the STC or ETSO authorisation and that meet the criteria of 3(a), (b) and (c) below.

##### **1.1 Criteria for limitations on eligibility**

An EASA approval may be required in cases of major repairs proposed by DOA holders who are the TC, STC or APU ETSO authorisation 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 certification specifications (CSs), certification review items (CRIs) for special conditions, equivalent safety findings, deviations or 'elect to comply'); and
- (b) related to the application of a CS 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 EASA-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 point 21.A.263(c)(8)(9) are changes similar to those that have been previously approved by EASA 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 point 21.B.80, or the operational suitability data (OSD) certification basis as specified in point 21.B.82, or the environmental protection requirement as specified in point 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 EASA;
- (d) changes that are intended to be used as alternative means of compliance (AltMoC) to an airworthiness directive (AD);
- (e) changes that are made mandatory by an AD or that are the terminating action of an AD;
- (f) changes that are classified as significant in accordance with point 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 certification requirements are applicable which were not used in the description of the EASA-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 EASA;
- (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 point 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 EASA 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 point 21.B.80 or OSD certification basis as specified in point 21.B.82 or an environmental protection requirement as specified in point 21.B.85.

(c) Performance and experience in previous projects

EASA should have classified as 'medium' or 'high' the level of performance of the organisation during at least the latest project referenced, to demonstrate 'similarity' and 'repetitiveness'.

In addition, EASA should have classified as 'low' or 'very low' the likelihood of an unidentified non-compliance 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 EASA's level of involvement 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 point 21.A.263(c)(5), (8) and (9) is described in AMC No 2 to 21.A.263(c)(5), (8) and (9).

50. The following AMC No 2 to 21.A.263(c)(5), (8) and (9) is inserted:

**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', 'certain major changes' to a TC and 'certain supplemental type certificates' as defined in paragraphs 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 applying for the privileges referred to in point 21.A.263(c)(5), (8) or (9) should do the following:

- (a) Submit to EASA an application for a significant change in the design assurance system (see points 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 point 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 EASA-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 EASA-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 EASA, 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 supplemental type certificates'.

- (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 point 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 point 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 EASA on a regular basis, as agreed with EASA.

- (5) Extension of the 'list associated with the privilege' after the privilege is granted.

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 EASA agreement, 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 21.A.263(c)(5), (8) and (9), is summarised in Figure 1 below:

DRAFT

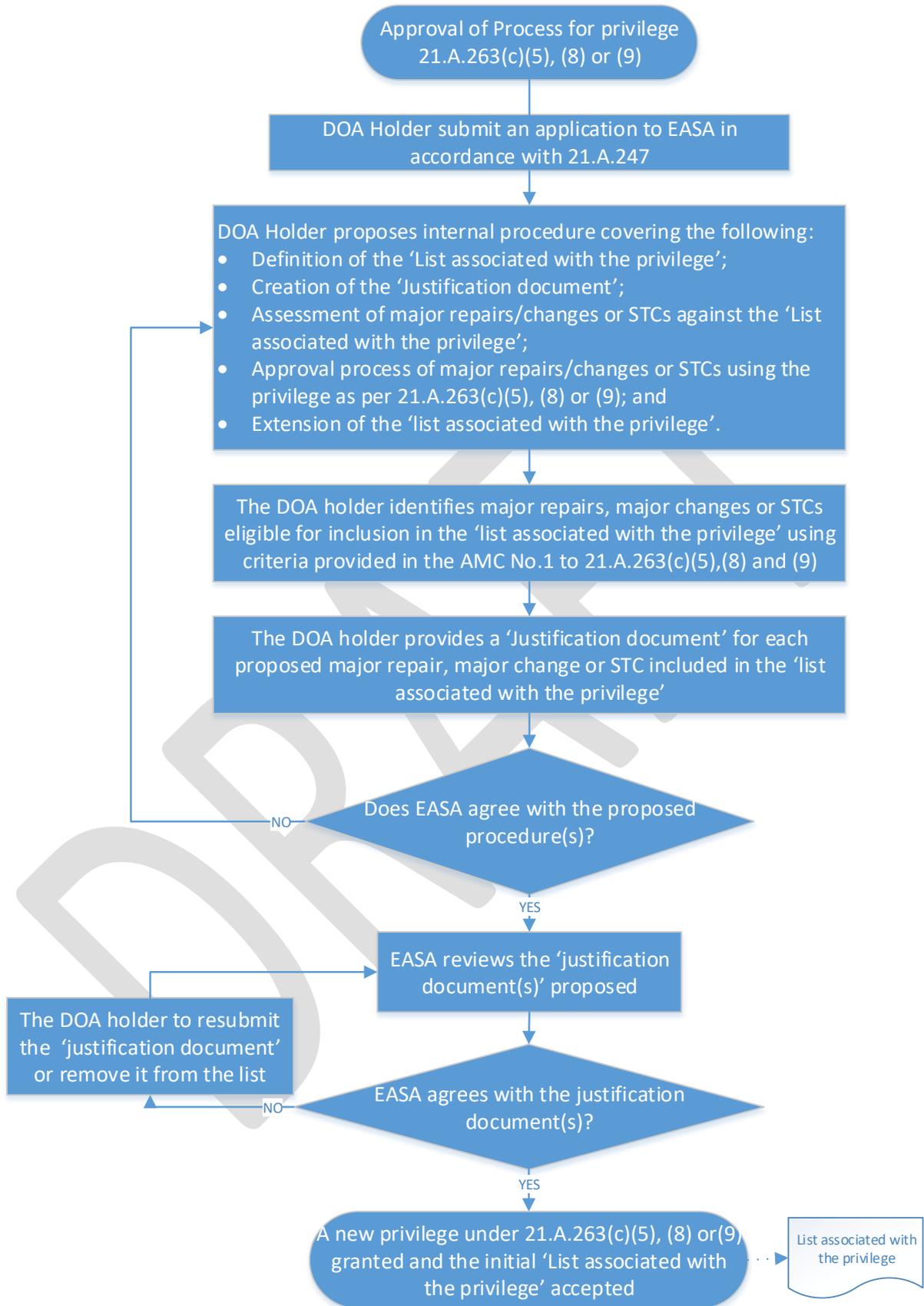


Figure 1

The privilege referred to in point 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 EASA;
- (b) the major repair/change/STC to be approved falls under the 'list associated with the privilege' agreed by EASA; 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 EASA's involvement.

Note: If a DOA holder applies for a third-country validation after having approved a modification under its DOA holder privilege, EASA 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 EASA, as described in Section 1(b)(2) above. After EASA agrees with the updated 'privilege list' as part of the DOA holder's procedure, the DOA holder may proceed as per Section 4 below.

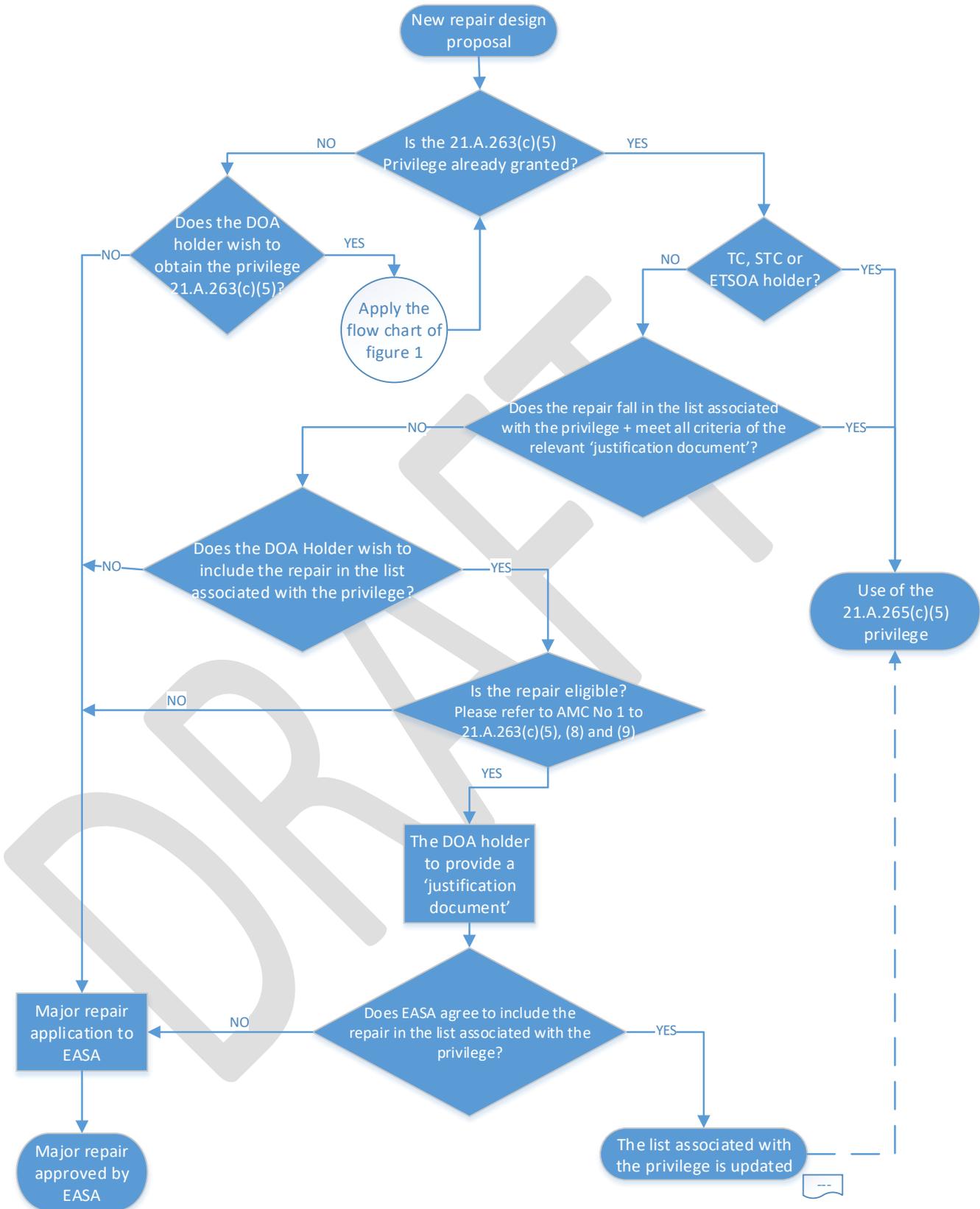


Figure 2

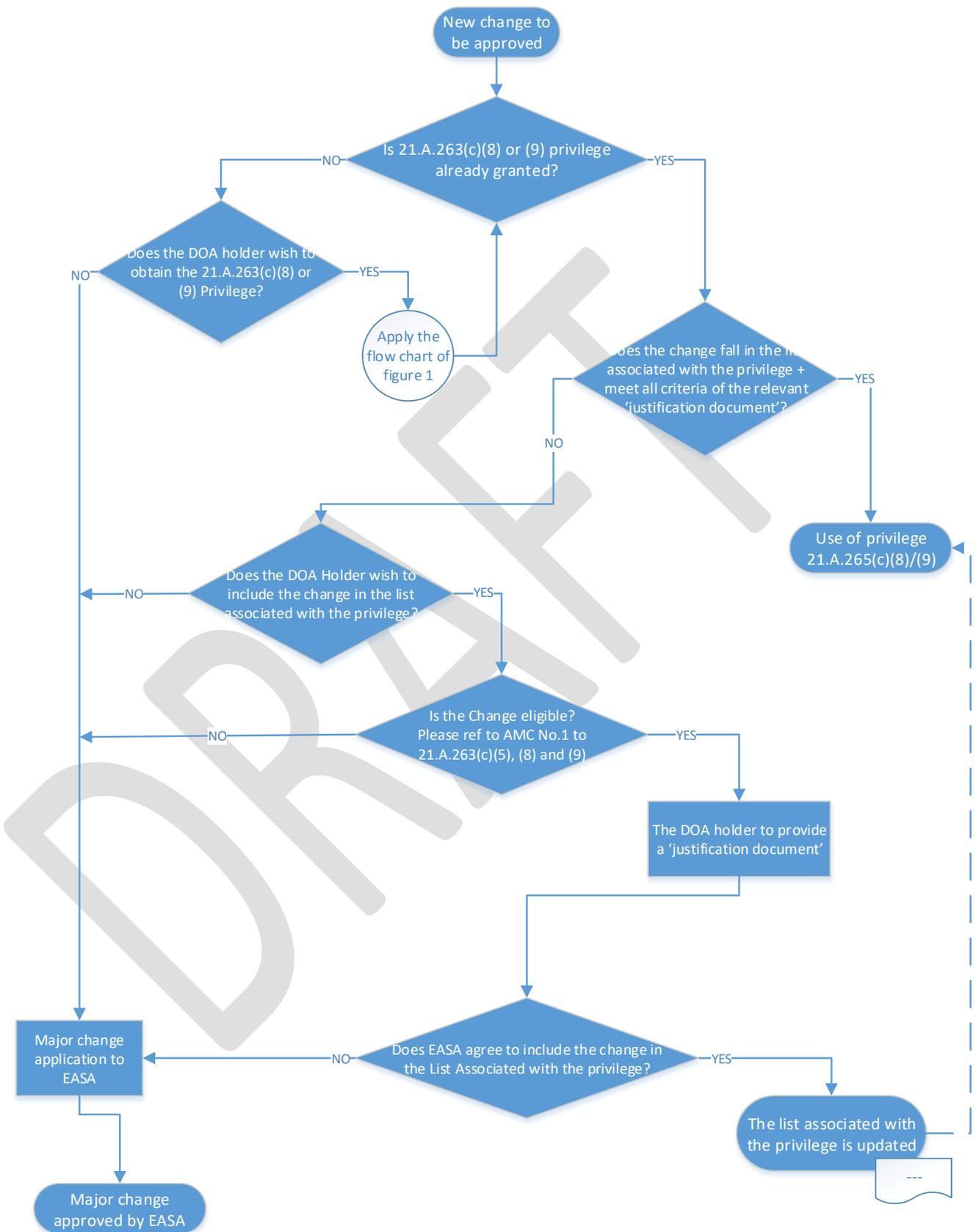


Figure 3

### 3. TC, STC OR APU ETSOA HOLDER APPROVAL OF A MAJOR REPAIR UNDER A MAJOR REPAIR PRIVILEGE — SPECIFIC CONSIDERATIONS

TC, STC or APU ETSOA holders that intend to approve a major repair design under the privilege of point 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 EASA 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 ETSO authorisation holders;
- major changes; and
- STCs,

by a DOA holder under the privilege of point 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

The DOA holder should use the following forms for the issuance of an approval under their privilege:

- EASA Form XXX<sup>11</sup> for a major repair;
- EASA Form XXX<sup>12</sup> for a major change; and
- EASA Form XXX<sup>13</sup> for an STC.

If the DOA holder chooses to use their own forms, it must be ensured that at least the same information as requested on the EASA forms is present.

<sup>11</sup> A link to this EASA Form will be created when EASA publishes the Decision amending Decision N° 2012/020/R ('AMC and GM to Part-21').

<sup>12</sup> A link to this EASA Form will be created when EASA publishes the Decision amending Decision N° 2012/020/R ('AMC and GM to Part-21').

<sup>13</sup> A link to this EASA Form will be created when EASA publishes the Decision amending Decision N° 2012/020/R ('AMC and GM to Part-21').

For the numbering of major changes to TCs, STCs, as well as of major repairs approved under the privilege, please refer to GM 21.A.263(c)(5), (8) and (9).

4.3 Approval under the DOA holder’s privilege

When the DOA holder makes use of the privilege of point 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 CS 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 point 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 points 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 off the approval under the privilege of point 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 point 21.A.263(c)(5), (8) and (9).

51. The following GM 21.A.263(c)(5), (8) and (9) is inserted:

**GM 21.A.263(c)(5), (8) and (9) Numbering system for supplemental type certificates (STCs), major changes, and major repairs issued by design organisation approval (DOA) holders, and information to EASA**

STCs, major changes and major repairs issued by a DOA holder under their privilege of point 21.A.263(c)(5), (8) and (9) should each be given a unique and consecutive reference number.

The following numbering system may be considered:

DOA holder reference	Type of certificate	Year of approval	Dash	Sequential number	Issue reference
21Jxxx	STC or MCH or MRE	17	—	001	A

Example: 21J999STC17—001A

Note: 'MCH' refers to 'major changes', and 'MRE' to 'major repairs'.

With reference to STCs only, after the STC approval, the DOA holder should send a copy of the STC to EASA in a timely manner (as agreed with EASA).

52. The following GM 21.A.265(h) is inserted:

### **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 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 point 21.A.265(h) also includes instructions.

Data and information referred to in point 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 Part 21 or the applicable CSs (such as the aircraft flight manual (AFM), rotorcraft flight manual, instructions for continuing 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, instructions for continuing airworthiness).

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 subcontractors or vendors that the DOA holder has declared as applicable to their products. The technical content of the statement is related to the design data and information. The approval included in the statement means that:

- the design 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 design data.

Note: Data and information related to the measures required by point 21.A.3B(b) (airworthiness directives (ADs)) are submitted to EASA to ensure their compatibility with the content of an AD (see point 21.A.265(e)), and contain a statement that they are, or will be, subject to an AD issued by EASA.

53. GM 21.A.431(a) is amended as follows:

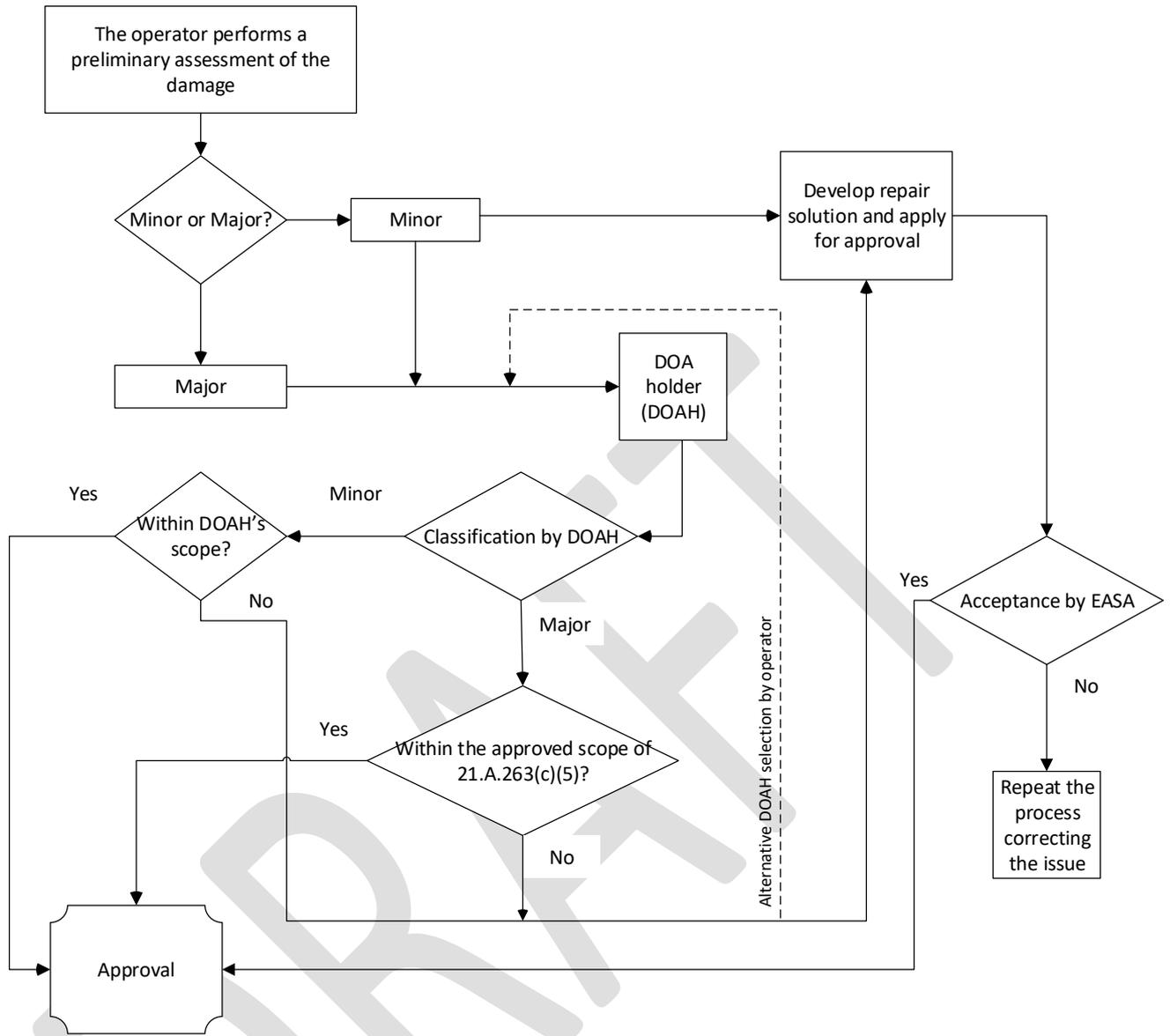
**GM 21.A.431(a) Scope**

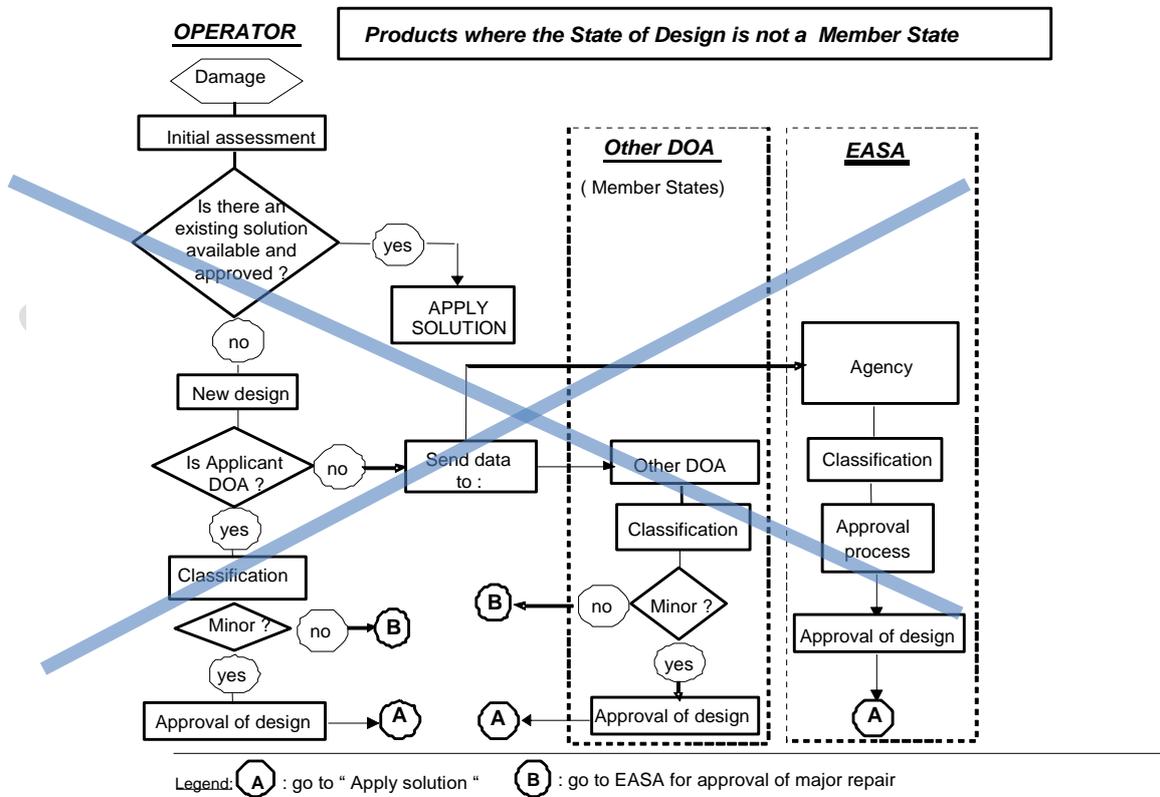
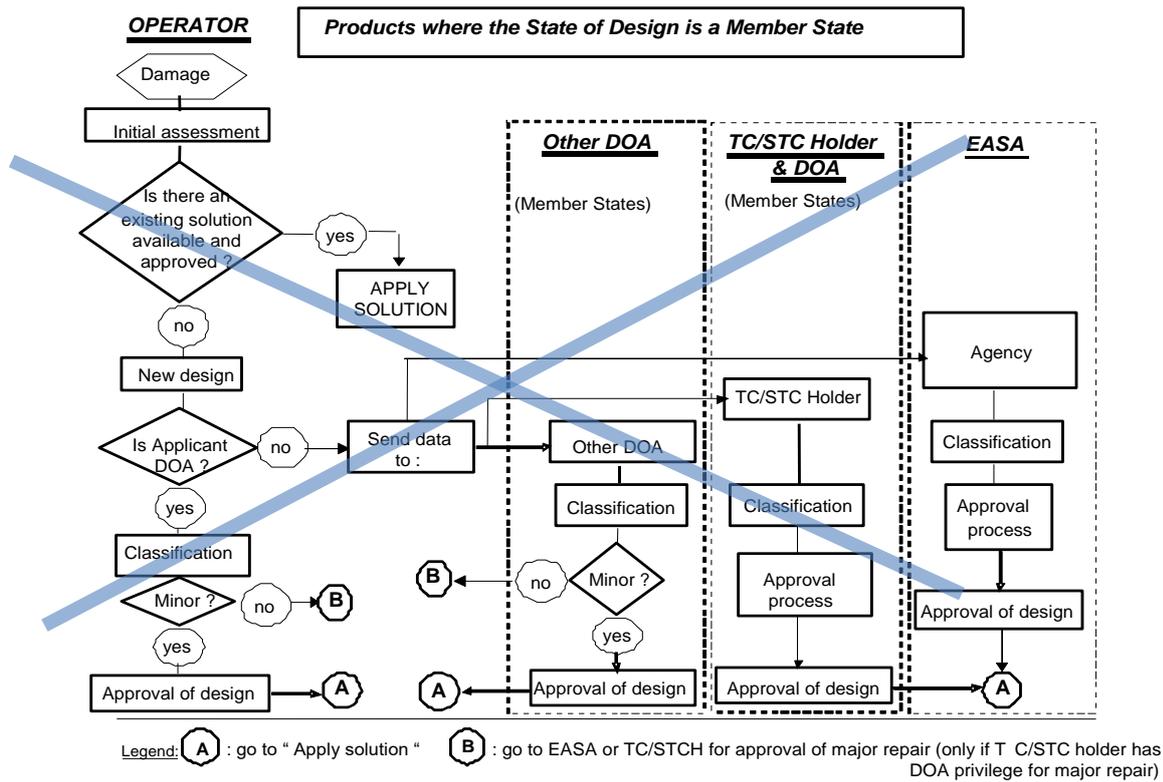
[...]

~~NB: Flow Chart 1 addresses the procedures that should be followed for products where the State of design is a Member State~~

~~Flow Chart 2 addresses procedures that should be followed for products where the State of design is not a Member State.~~

[...]





54. GM 21.A.431(d) is amended as follows:

**GM 21.A.431A(e)(d) Repairs to European technical standard order (ETSO) articles other than auxiliary power units (APUs)**

[...]

55. The following AMC 21.A.432B(b) is inserted:

**AMC 21.A.432B(b) Alternative procedures**

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

56. The following AMC 21.A.432C(a) is inserted:

**AMC 21.A.432C(a) Form and manner**

The applicant should file an application using the web-based 'EASA Applicant Portal'<sup>14</sup> or the application forms for the approval of major changes/major repair designs (FO.CERT.00031)<sup>15</sup> or for the approval of minor changes/minor repair designs (FO.CERT.00032)<sup>16</sup>, which may be downloaded from the EASA website.

The forms should be completed in accordance with the completion instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website<sup>17</sup>.

57. The following AMC 21.A.432C(b) is inserted:

**AMC 21.A.432C(b) Certification programme for a repair design approval**

Clarification of 21.A.432C(b)(1): the description of the repair should consist of:

- the pre- and post-repair configuration;
- a drawing or outline of the repair;
- a list of the detailed features;
- a description of the type and extent of the inspection; and
- an outline of the damage.

<sup>14</sup> <https://ap.easa.europa.eu> (changes to the link provided may not be reflected in this document).

<sup>15</sup> <https://www.easa.europa.eu/document-library/application-forms/focert00031> (changes to the link provided may not be reflected in this document).

<sup>16</sup> <https://www.easa.europa.eu/document-library/application-forms/focert00032> (changes to the link provided may not be reflected in this document).

<sup>17</sup> <https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals> (changes to the link provided may not be reflected in this document).

Clarification of 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 certification specifications (CSs), together with the means of compliance.

58. AMC 21.A.433(a) and 21.A.447 is amended as follows:

**AMC 21.A.433(ab) and 21.A.447 Repair design and record keeping**

1. Relevant substantiation data associated with a new major repair design and record keeping should include:
  - a. the identification of the damage identification and the reporting source;
  - b. the major repair design approval sheet identifying the applicable specifications and references of justifications;
  - c. the repair drawing and/or instructions and scheme identifier;
  - d. the correspondence with the holder of the type certificate (TC), supplemental type certificate (STC), or auxiliary power unit European technical standard order (APU ETSO) authorisation holder, if its advice on the design has been sought;
  - e. the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to this data;
  - f. the effect on the aircraft, engines and/or systems, (performance, flight handling, etc., as appropriate);
  - g. the effect on the maintenance programme;
  - h. the effect on Airworthiness Limitations, the Flight Manual and the Operating Manual;
  - i. any weight and moment changes; and
  - j. special test requirements.
2. Relevant minor repair documentation includes paragraphs 1(a) and (c). Other points of paragraph 1 may be included where necessary. If the repair is outside the approved data, a justification for the classification is required.
3. 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, the number of repaired turbine blades per set, oversizing of fastener holes, etc.).
4. Special consideration should also be given to life-limited parts and critical parts, notably with the involvement of the type certificate TC or STC holder, when deemed necessary under point 21.A.433(b)(a)(4).
5. Repairs to engine or APU critical parts would normally only be accepted with the involvement of the TC holder.

59. The following GM 21.A.435(b) is inserted:



**GM 21.A.435(b) Repair design approval****(a) REPAIR DESIGN APPROVAL BY EASA**

- (1) Products first type-certified by EASA or first type-certified by a Member State (covering those type-certified through Joint Aviation Authorities (JAA) procedures or under national regulations and those nationally certified without a type certificate (TC)).

EASA approval is required in cases of major repair designs proposed by design organisation approval (DOA) holders that do not hold the necessary privilege as per point 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 the competent authority (CA) of a third country

EASA approval is always required for major repairs on products first type-certified by the CA of a third country. Approval privileges granted to DOA holders (see point 21.A.435(b)) are not available to TC holders of products first type-certified by the CA of a third country unless this third country has since joined EASA as a Member State. TC holders of products first type-certified by the CA of a third country may need to be involved in a repair design when an arrangement with the TC holder has been determined to be necessary under point 21.A.433(a)(4).

For repairs approved by the CA of a third country, conditions for acceptance may be defined in the bilateral arrangement between EASA and the third country. In the absence of such an arrangement, the repair data should follow the approval route of Part 21.

**(b) REPAIR DESIGN APPROVAL BY THE DOA HOLDER**

- (1) Approval by the DOA holder

Approval of repairs through the use of procedures agreed with EASA implies that the DOA holder issues the approval without EASA's involvement. EASA 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 point 21.A.435, and the service period should be defined when the temporary repair is approved.

(4) **Fatigue and damage tolerance**

When the repaired product is released to service before the fatigue and damage tolerance evaluation has been completed, the release should be for a limited service period defined when the repair is issued.

60. GM 21.A.437 is deleted.

61. GM 21.A.437(a) is deleted.

62. AMC 21.A.437(b) is deleted.

63. The following AMC 21.A.605(a)(1) is inserted:

**AMC 21.A.605(a)(1) Certification programme**

(a) For the purpose of the compliance demonstration in accordance with point 21.A.606(b), the applicant should:

- (1) establish a certification programme;
- (2) submit the certification programme to EASA; and
- (3) keep the certification programme updated during the approval process.

(b) The certification programme should contain the following information:

- (1) a detailed description of the relevant European technical standard order (ETSO) article, including all of its configurations to be certified, and the identification of any non-ETSO functions, as well as safety means (if applicable);
- (2) the operating characteristics and limitations or deviations from ETSO requirements;
- (3) the intended use of the article and the kind of operations for which the approval is requested;
- (4) the applicable CS-ETSO requirements and any optional aspects (applicable standards, demonstration of compliance with certification memoranda);
- (5) the proposed means of compliance, including the list of documents and deliverables for EASA;
- (6) an assessment of the safety aspects related to (1) to (5) above, and of the main failure conditions, in particular for any novel or unusual features;
- (7) the way in which the applicant will record its justifications of compliance; and
- (8) a project schedule, including major milestones.

64. The following GM 21.A.605(b) is inserted:

**GM 21.A.605(b) Reporting from the compliance demonstration process and updates to the certification programme**

The applicant should report to EASA any unexpected difficulty or event encountered during the compliance demonstration which invalidates or appreciably affects the assumptions previously made, e.g.:

- an increase in the severity of the consequences of a certain condition (e.g. a failure mode) of the article;
- one or more significantly reduced margins on pass-fail criteria of the compliance demonstration;
- an unusual interpretation of the results of the compliance demonstration;
- a deviation from the agreed means as defined in the certification programme;
- a change to the conditions set out in AMC to 21.B.100(b) and 21.A.605(a)(8) for the assessment of EASA's level of involvement (LoI); and
- any potential deviations discovered by the applicant.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact the certification programme and, if necessary, they should amend the certification programme as per point 21.A.603.

65. The following AMC 21.A.606(d) is inserted:

**AMC 21.A.606(d) Declaration**

A European technical standard order (ETSO) authorisation is granted in accordance with point 21.B.117 and only if no interference with non-ETSO functions is ensured.

The related declaration should confirm that compliance with the applicable ETSO 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 both for the ETSO and the non-ETSO functions.

66. The following GM 21.B.75 is inserted:

**GM 21.B.75 Special conditions**

The term 'novel or unusual design features' should be judged in view of the applicable certification basis for the product. A design feature, in particular, should be judged to be a 'novel or unusual design feature' when the certification basis does not sufficiently cover this design.

The term 'unsafe condition' is used with the same meaning as described in GM 21.A.3B(b).

The term 'newly identified hazards' is intended to address new risks that may be recognised in the design (e.g. questionable features) or its operational characteristics (e.g. volcanic ash) for which there is not yet enough in-service experience.

67. The following GM 21.B.80 is inserted:



**GM 21.B.80 Type-certification basis for a type certificate (TC) or restricted type certificate (RTC)****1. INTRODUCTION**

This GM addresses the type-certification basis for a TC or an RTC.

**2. APPLICABLE CERTIFICATION SPECIFICATIONS (CSs) (see point 21.B.80(a))**

The type-certification basis for a TC or an RTC consists of the airworthiness CSs that were effective on the date of application and were applicable for that certificate.

The effectivity date of the initial application may be changed, as per point 21.A.15(f)(2), when the effectivity period of an application for a type certificate is exceeded, or it is evident that it will be exceeded, and the applicant requests an extension; see GM 21.A.15(e) and (f).

The certification basis is then revised accordingly.

**3. ELECT TO COMPLY (see point 21.B.80(a)(1))**

It is also possible for an applicant to elect to comply with a CS that entered into force after the date of application.

EASA should assess whether the proposed certification basis is appropriate to ensure that the 'elect to comply' proposal includes any other CSs that are 'directly related' to one or several of the CSs in it.

Directly related CSs are those that are deemed to contribute to the same safety objective by building on each other's requirements, addressing complementary aspects of the same safety concern, etc. Typically, they are adopted simultaneously with, or prior to, the CSs with which the applicant has elected to comply.

**4. EQUIVALENT LEVEL OF SAFETY (see point 21.B.80(a)(2))**

In cases when the applicable CS(s) cannot be literally complied with, either in part or fully, EASA may accept a suitable alternative which provides an equivalent level of safety through the use of appropriate compensating factors.

In cases in which the requirements contain not only objectives but also prescriptive parts, an equivalent level of safety may be accepted if:

- the objectives are met by designs or features other than those required in the CS; or
- suitable compensating factors are proposed.

**5. ALTERNATIVE MEANS OF COMPLIANCE (AltMoC) (see point 21.B.80(a)(3))**

If the intent of the CSs defined in point 21.B.80(a) cannot be met, EASA may accept mitigating factors to the CSs provided that the safety objective is met.

In the case of a TC, the AltMoC should provide a demonstration of compliance with the essential requirements for airworthiness laid down in Annex I to Regulation (EC) No 216/2008.

In the case of an RTC, the AltMoC should provide a sufficient level of safety for the intended use.

Note: 'AltMoC' should not be confused with 'AMC'.

**6. SPECIAL CONDITIONS (see point 21.B.75)**

EASA may also prescribe special conditions in accordance with point 21.B.75. Guidance on special conditions is provided in GM 21.B.75.

68. The following AMC 21.B.100(a) and 21.A.15(b)(6) is inserted:

**AMC 21.B.100(a) and 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) or a major repair design**

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 identified in the certification programme, which can be considered in isolation for the purpose of performing a risk assessment.

**EASA panel:** an EASA panel is composed of one or more experts who are responsible for a particular technical area. Each technical area addressed during product certification is covered by an EASA panel.

**EASA discipline:** a discipline is a technical sub-area of an EASA panel.

**EASA's level of involvement (LoI):** the compliance demonstration activities and data that EASA 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 point 21.A.15(b). The applicant has to break down the certification programme into CDIs and provide their proposal for EASA's LoI.

The applicant may also indicate the EASA panel(s) affected by each CDI.

This AMC explains:

(a) how to propose EASA's LoI for each CDI as per points 21.A.15(b)(6), 21.A.93(b)(3)(iii), as well as 21.A.113(b); and

(b) how EASA will determine its LoI on the basis of the criteria established in point 21.B.100.

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

Additionally, in accordance with point 21.A.20, the applicant has the obligation to update the certification programme, as necessary, during the certification process, and report to EASA 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 EASA has other information that affects the assumptions on which the Lol was based, EASA will revisit its Lol determination.

In accordance with points 21.A.33, 21.A.447, and 21.A.615, irrespective of the Lol, EASA 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

EASA 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 EASA's Lol.

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

- novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
- complexity of the design and/or compliance demonstration;
- performance and experience of the design organisation of the applicant in the domain concerned;
- criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and
- data and activities to be retained by EASA.

Note: Additional panel-specific criteria are available in further informative material published by EASA<sup>18</sup>. This material should not be considered to be AMC.

For simple products, panel-specific criteria should only be considered for CDIs that affect noise, propulsion, development assurance and safety assessment (DASA), operational suitability data (OSD), and software and airborne electronic hardware. For the purpose of this AMC, simple products are products other than those related to CS-23 commuter, CS-25, CS-27, and CS-29 aircraft.

The criteria used to determine the likelihood and the potential impact of an unidentified non-compliance generally allow a proportionate approach to be applied, in particular in order to differentiate between CS-25 and general aviation (GA) aircraft projects.

#### 3.1. Lol determination at CDI level

<sup>18</sup> Such draft additional criteria are contained as an attachment to the following proposed Certification Memorandum (CM), available at: <http://www.easa.europa.eu/documents/public-consultations/proposed-cm-21a21b-001>.

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

The applicant should demonstrate that all the affected elements of the type-certification basis as specified in point 21.B.80 and the OSD certification basis as specified in point 21.B.82, and of the environmental protection requirements as specified in 21.B.85, 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 EASA 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 an EASA 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;
- an unusual location of a part or a system, or an unusual construction;
- a new or unusual use;
- new functions;
- new kind 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);
- new flight 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 CS paragraphs with which the applicant has little or no experience;
- new or adapted special conditions;
- new or adapted equivalent safety findings;
- 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 EASA's familiarity with these standards and methods;
- a change in methodology, tools or assumptions (compared to those previously applied by the applicant), including changes in software tools/programmes;
- 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 in the form of new certification memoranda (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. those that 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 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 that may potentially result in a low 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 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 LoI 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, EASA uses relevant data to consider the design organisation's expected performance at an organisational, panel or discipline level, depending on the availability of data<sup>19</sup>.

This data stems from design organisation audits, the applicant's measured level of performance on previous projects, and their performance during the familiarisation phase. EASA shares this data with the respective design organisations (in the form of the design organisation approval (DOA) dashboard).

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 EASA 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' performance level 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 that shown 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.

For applicants for which EASA has agreed in accordance with point 21.A.14(b) to use procedures setting out specific design practices as an alternative means to demonstrate their capability (excluding European technical standard order (ETSO) applicants, covered by point 21.B.100(b)), or for applicants who demonstrate their capability by providing EASA with the certification programme in accordance with point 21.A.14(c), the performance of the organisation is not known to EASA. Therefore, the assumed level of performance is 'unknown'.

Exceptionally, EASA 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:

<sup>19</sup> The ultimate objective is to define the organisation's performance at the discipline level.

- a CDI with which EASA 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 in determining 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 EASA’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 EASA, and on whether the CDI is novel or complex, as follows:

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

3.3. Criticality

The second step necessary to determine the risk class is the assessment of the potential impact of a non-compliance on part of the certification basis regarding 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 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 a failure effect is classified as hazardous or catastrophic at the aircraft level, for instance for ‘equipment, systems and installations’, e.g. where applicable, as defined in 2X.1309;

- a CDI has an appreciable effect on the 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 as per 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 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 EASA as non-critical due to the involvement of EASA 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 LoI 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 risk class provides the order of magnitude of EASA's involvement and is used as a qualitative indicator for the determination of EASA's involvement described in Section 3.5 below.

Under specific circumstances, the risk class 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 EASA,

The CDI may be accepted as being similar, resulting in a reduced LoI, as the likelihood of an unidentified non-compliance is low.

Furthermore, when a truly identical CDI is reused for the compliance demonstration in a new project, the LoI is reduced to the acceptance of the certification plan, as the likelihood of an unidentified non-compliance is very low.

### 3.5. Determination of EASA's LoI

EASA's LoI in compliance demonstration verification should be proposed by the applicant and determined by EASA 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.

EASA's LoI is reflected in a list of activities and data, in which EASA retains the verification of compliance demonstration (e.g. compliance data review and acceptance, test witnessing, 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. EASA 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 LOI should be proposed for each of the EASA disciplines involved.

Depending on the risk classes determined in Section 3.4 above, EASA's LoI in:

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

may be as follows:

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

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

- initial issues of, and changes to, a flight manual (for those parts that require EASA approval 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 EASA, 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.

EASA 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 sampling of the 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.

#### 69. The following AMC No 1 to 21.B.100(b) is inserted:

##### **AMC No 1 to 21.B.100(b) Level of involvement (Lol) in projects for minor changes and minor repairs**

In contrast to 21.B.100(a), the assessment of the Lol for minor repair designs and minor changes is performed by EASA at the level of the certification project.

EASA reviews the information provided by the applicant in accordance with point 21.A.93(b) for novel or unusual features, the complexity of the design and/or the compliance demonstration, as well as the criticality of the design or technology.

An application for EASA's approval of a minor change implies that the applicant either does not hold a design organisation approval (DOA) or that the change is outside the DOA holder's terms of approval. However, EASA takes into account the performance and experience of the applicant with similar design changes, for which data may be already available at EASA. The applicant may be also requested to present its experience with similar design changes if insufficient information is available at EASA.

By definition (see point 21.A.91), a minor change has no appreciable effect on the airworthiness of the product. Therefore, the potential impact of a non-compliance with part of the certification basis regarding the airworthiness or environmental protection aspects of the product should, in most cases, be non-critical.

This facilitates the assessment of the likelihood of an unidentified non-compliance.

A process similar to the one described in AMC 21.B.100(a) and 21.A.15(b)(6) should be used to justify and document EASA’s Lol.

Following a first assessment of the criticality of the described design or technology, EASA evaluates the existence of any novel or unusual features, as well as the complexity of the design and/or the compliance demonstration.

Depending on the results of this evaluation, and based on the table below, EASA determines its Lol as follows:

		Risk class	
Non-critical	Non-novel and non-complex	Class A	Class A
	Novel and/or complex	Class B	Class C
Critical	All cases	Class C	Class C
		Level of experience: high or medium	Level of experience: low or unknown

- Class A: EASA’s involvement is limited to the review of the information that summarises the main results of the compliance demonstration, without any participation in compliance activities (witnessing of tests, audits, etc.).
- Class B: in addition to the Lol defined for risk Class A, EASA’s involvement is limited to the review of those compliance elements that are related to the identified novel or unusual features, complexity of the design and/or compliance demonstration. EASA may exceptionally participate in the related compliance activities (by witnessing tests, audits etc.).
- Class C: EASA’s involvement is limited to the review of all the compliance documents that are related to the identified criticality of the design or technology, if applicable, or to the identified novel or unusual features. EASA may participate in the related compliance activities (by witnessing tests, audits etc.).

70. The following AMC No 2 to 21.B.100(b) is inserted:

**AMC No 2 to 21.B.100(b) Level of involvement (Lol) in European technical standard order authorisation (ETSOA) projects**

The applicant for an ETSOA is required to demonstrate its capability by obtaining EASA’s agreement for the use of procedures that incorporate its specific design practices.

The assessment by EASA that these procedures are properly applied is performed solely through the various ETSOA projects of the applicant. No regular audits of the organisation are performed by EASA outside the ETSOA projects.

A properly completed Form 34 and the certification programme, including a technical description of the proposed design of the ETSO article, are the basis for the determination of the initial EASA's Lol.

EASA assesses the compliance of the proposed ETSO article with the ETSO requirements as defined in the applicable CS-ETSO standards, as well as compliance with Part 21 Subpart O (e.g. the declaration of design and performance (DDP), ETSO Marking, rating of performance, etc.). The ETSOA applicant should deliver a complete data package per point 21.A.605.

EASA's Lol is further reassessed and adapted throughout the certification project until the ETSOA is issued, depending on the applicant's data, as well as on the ETSO project changes regarding the applicant's compliance demonstration (e.g. methods, design changes, deviations, limitations, problem reports, etc.).

## 1. Principles

EASA's Lol in ETSO projects is defined based on both the responsibility of EASA to assess the applicant's demonstration of compliance and on the risk evaluated, according to the following criteria:

- the applicant's level of experience in the ETSO process and scope of work;
- the applicant's level of performance in the ETSO scope of work;
- the use of novelties in the technology/design or in the means of compliance; and
- the complexity of the ETSO article.

### 1.1 Applicant's experience in the ETSOA process and scope of work

This section addresses the experience of the applicant's organisation in the ETSOA process, as well as in the scope of the certification basis of the ETSO article, and of the related requirements. The presence of any of the following aspects contributes to EASA's identification of the risk related to the level of experience of the applicant in the ETSOA process, or to the scope of work of the article:

- the applicant is new and has just applied for the acceptance of its procedures by EASA, or it is the first project of the applicant after EASA has accepted such procedures;
- the organisation has changed significantly the agreed procedures; and
- the scope of work of the ETSOA project (ETSO standards) is new to the applicant.

### 1.2 ETSOA applicant's performance within its scope of work

The ETSOA applicant's level of performance within its scope of work is evaluated using criteria that enable EASA to identify risks in the applicant's performance due to the following situations:

- the applicant has deficiencies in the procedures that it uses to demonstrate compliance with the certification requirements;
- the applicant has changed its methods or procedures to demonstrate compliance with the certification requirements;

- the assessment of the applicant's compliance on previous projects in the same ETSO scope of work has revealed significant issues in complying with the certification requirements, in the completion of data, or in the repetition of errors;
- the scope of work is new to the applicant's team at the facilities where the project is developed, or the team had significant issues on preceding projects;
- EASA has not conducted an ETSOA project assessment of the applicant in the same ETSO scope of work for a long period (i.e. 2 or 3 years); and
- the applicant did not regularly report minor changes or occurrences in a timely manner.

### 1.3 Novelty in the technology or in the means of compliance

A 'novelty' is understood to be the use of new technology, new sensors, new material, the use of new requirements or the use of new means of compliance. When an applicant is faced with technology for the first time, or when that applicant is relatively unfamiliar with the technology, this is considered to be 'novel' even if other applicants may be already familiar with that technology.

Also related to novelty is the extent to which requirements, means of compliance or guidance need to be adapted due to particular novel features of the design.

The following list includes some examples:

- recently issued standards within CS-ETSO, with which the applicant has limited experience;
- novel deviations;
- new guidance;
- new 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);
- the use of new industry standards or new in-house methods, as well as EASA's familiarity with these methods and standards;
- changes in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs.

Technology or means of compliance may be new/novel either from a global industry, applicant or EASA perspective.

### 1.4 Complexity

Complexity may result from the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), as well as from the variety of ETSOs with which the applicant intends to comply, and their possible interactions.

The demonstration of compliance may be 'complex' for complex (or highly integrated) equipment, so it typically requires more effort from the applicant.

### 1.5 Criticality of the design and of the technology

The criticality levels of the design and of the technology of the ETSO article are considered, but have a minor impact on the definition of EASA's Lol. The main reasons are:

- the assessment of ETSO compliance is as important for an ETSO article that hosts a critical function as it is for equipment that host less critical functions (e.g. flight data recorders); and
- the criticality of the design or technology is not always defined for an ETSO article, and it may depend on the installation of the design or technology (e.g. a multifunction display), which may only occur later.

## 2. Determination of EASA's Lol

EASA's Lol in the assessment of the applicant's compliance demonstration is determined by EASA on the basis of the qualitative risk class and EASA's responsibilities in assessing the ETSO project certification data package, together with the procedures for compliance with the ETSO requirements (Part 21 Subpart O, and CS-ETSO).

EASA's Lol is defined in the following paragraph 2.1 and, as per point 21.B.100(c), the EASA Lol that is applicable to each project is notified to the applicant.

To every Lol class corresponds a list of activities that govern EASA's involvement. By means of these activities, EASA verifies the demonstration of compliance (e.g. by document review and acceptance, test witnessing, sampling on the applicant's site, desktop assessments, etc.).

The ETSO applicant is responsible for providing a complete ETSO certification data package.

### 2.1 Definition of the Lol classes

EASA's Lol for an ETSO certification project is classified as one of the following:

- class high,
- class high reduced,
- class medium, or
- class basic.

Class 'high reduced' is, by default, EASA's initial Lol in an ETSO project.

The following is a description of each class:

- High

EASA evaluates and samples/checks in an extensive manner all the compliance data to assess the applicant's demonstration of compliance with the applicable ETSO standards. EASA assesses the applicant's DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews, as well as on-site assessments of compliance demonstrations. This occurs when design and verification evidence is available.

- High reduced

EASA assesses all the compliance data; sampling/checking is significant and adapted to the likelihood of an unidentified non-compliance. The sampling rate may be reduced if the content of the life cycle data provides confidence in compliance and is focused in the area

where confidence needs to be gained. EASA assesses the DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews and performs an on-site assessment of the applicant's compliance demonstration. This occurs when design and verification evidence is available.

— Medium

EASA assesses all the compliance data, but for some compliance data it performs no or limited sampling/checking. EASA adapts its sampling and focuses it on the likelihood of an unidentified non-compliance, taking into account the level of complexity and novelty of the project. EASA assesses the DDP and general compliance with Part 21 Subpart O.

EASA performs desktop reviews and may perform an on-site assessment of the applicant's compliance demonstration.

— Basic

EASA assesses the DDP and general compliance with Part 21 Subpart O, and verifies the completeness of the data package.

Generally, EASA performs a desktop assessment.

3. The process of determining EASA's Lol

The determination of EASA's Lol is captured as a process.

This process is performed as illustrated in the following figure:

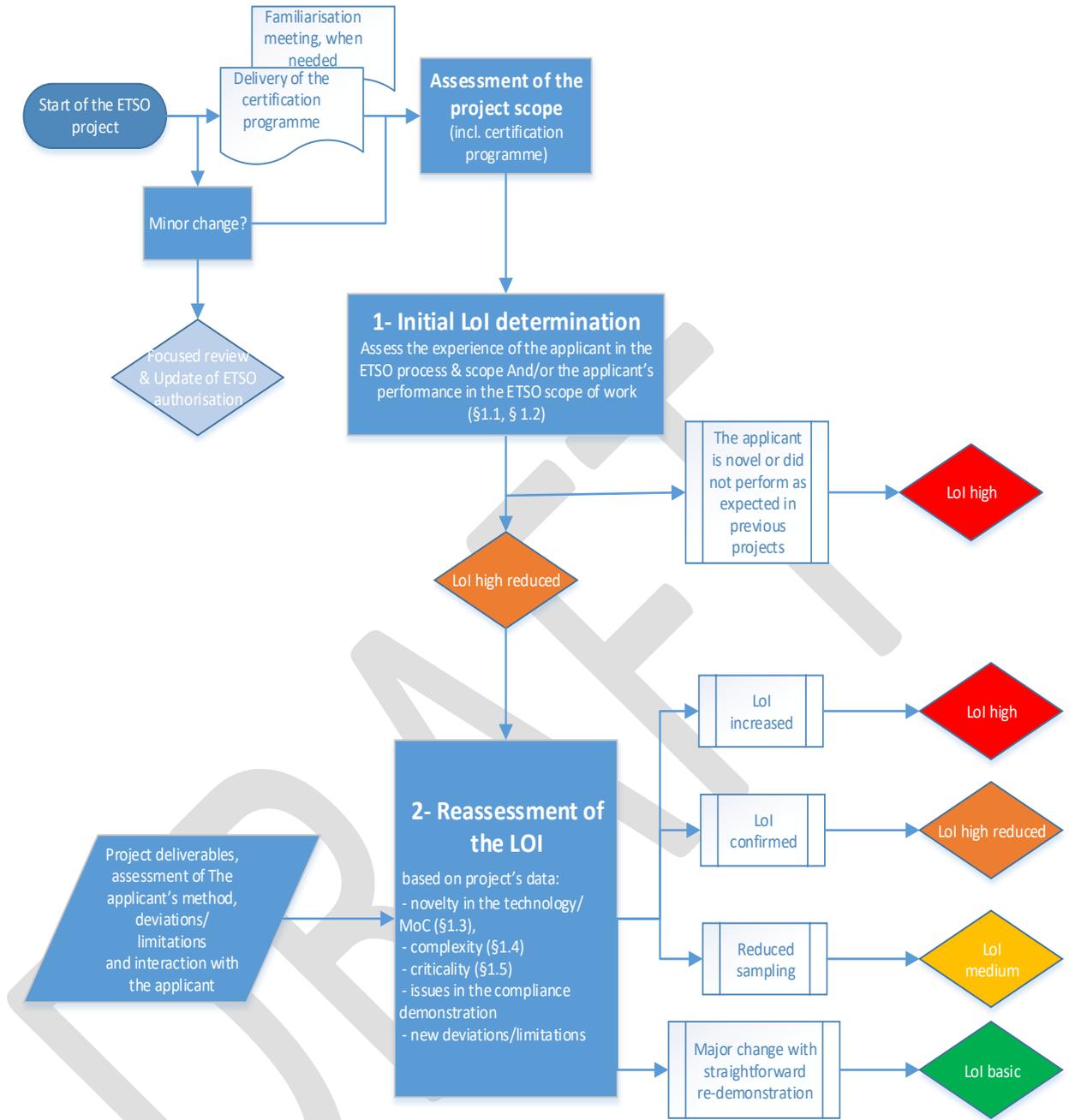


Figure 1 — Process of determination of EASA’s LoI in ETSO certification projects

Step 1 consists of the initial Lol determination which EASA evaluates by assessing:

- 1.1 Applicant’s experience in the ETSOA process and scope of work according to Section 1.1 above, and
- 1.2 ETSOA applicant’s performance within its scope of work according to Section 1.2 above.

The result of this initial Lol determination is either high or high reduced.

Step 2 consists of reassessing EASA’s Lol. Throughout the ETSO project, EASA receives project deliverables (e.g. plans, reports), means of compliance, requests for deviations, limitations, etc., and interacts with the applicant.

If EASA’s Lol has been initially set to high reduced, EASA re-evaluates it considering:

- the [1.3 Novelty in the technology or in the means of](#) compliance according to Section 1.3 above, and
- the complexity of the ETSO project according to Section 1.4 above.

The result of this reassessment may vary from high to medium according to the following table:

Assessment results	Lol adaptation
The ETSO article is novel and complex or a significant issue is detected during the compliance demonstration.	Lol is increased to high.
The ETSO article is novel or complex or a new deviation is requested <sup>(1)</sup> .	Lol is confirmed as high reduced.
The ETSO article is non-novel and non-complex, no issue is detected during the compliance demonstration or method, and no novel deviation or new limitation is requested.	Lol is decreased to medium.
There is a major change with straightforward redemonstration of the ETSO compliance <sup>(2)</sup> .	Lol is reduced to basic.

<sup>(1)</sup> It refers to deviations from ETSO minimum operational performance standards (MOPs), excluding deviations for requesting compliance with a new revision of an industry MOPS standard.

<sup>(2)</sup> When EASA agrees that a major change only requires a straightforward redemonstration of the ETSO compliance using previous methods, without any identified risk, then EASA’s Lol is reduced to basic. Please note that this may only be defined after a minimum assessment of the applicant’s compliance demonstration methods.

Note: For a minor change, this process does not apply; in that case, EASA’s Lol consists of an assessment of the minor change classification, an update of the certificate, and an assessment of the DDP, when needed.