

A new amendment to Part 21 - Regulation (EU) 2019/897 -

What is changing for me?

Changes related to the applications for minor
changes/repairs and ETSO

Your safety is our mission.

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Level of Involvement - The new rule

21.B.100

for EASA






(b) For the approval of a minor repair design, minor change or ETSO authorisation other than for APU, **the Agency shall determine its involvement at the level of the entire certification project, taking into account** any **novel** or unusual features, **complexity** of the design and/or demonstration of compliance, **criticality** of the design or technology, as well as the **performance and experience** of the applicant's design organisation.

(c) The Agency shall notify its level of involvement to the applicant **and it shall update** its level of involvement when this is warranted by information which has an appreciable impact on the risk previously assessed pursuant to point (a) or (b). The Agency shall notify the applicant about the change in the level of involvement.

To summarise

Application for		Applicant's Δ duties		Agency's Δ duties	
a new TC/RTC	Risk assessment per (meaningful grouping of) compliance demonstration activities and data and LOI proposal	21.A.15(b)(5)(6)	Establish and notify the LOI	21.B.100(a) and (c)	
a major change		21.A.93 (b)(3)(ii)(iii)			
a major repair		21.A.432C(b)(6)(7)			
an STC		21.A.113(b)(i)			
an APU ETSO		21.A.604(a), 21.A.15			
a minor change/repair	./.			21.B.100 (b) and (c)	
others ETSOs					

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The relevant guidance

AMC No 1
to 21.B.100(b)

- Explains how the Agency will establish its level of involvement for applications for minor changes / repairs

NEW

Minor changes/repairs

AMC No 1 to
21.B.100(b)

for EASA

→ For approval of minor changes/repairs, a proportionate approach is to be applied. Comparing this with the process for approval of major changes / repairs:



- ✓ Risk-based approach for LOI determination
- ✓ Same criteria to be considered
- ✓ The Agency determines and notifies LOI



- ✓ LOI @ project level (automatic grouping of all compliance demonstration activity and data into one CDI)
- ✓ No LOI proposal is required from applicants
- ✓ Simplified risk matrix

Risk class matrix for minor changes/repairs






		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 summarising the main results of the compliance demonstration, without any participation in compliance activities (witnessing of tests, audits, etc.).

Class B: in addition to the LoI defined for risk Class A, EASA's involvement is limited to the review of those compliance elements 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 (witnessing of tests, audits etc.).

Class C: EASA's involvement is limited to the review of all the compliance documents 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 (witnessing of tests, audits etc.).

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The relevant guidance

AMC No 2
to 21.B.100(b)

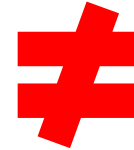
- Explains how the Agency will establish its level of involvement for applications for ETSO authorisations

NEW

→ For approval of ETSOA, a proportionate approach is to be applied. Comparing this with the process for approval of TCs, major changes / repairs:



- ✓ Risk-based approach for LOI determination
- ✓ Same criteria to be considered
- ✓ The Agency determines and notifies LOI



- ✓ LOI @ project level (automatic grouping of all compliance demonstration activity and data into one CDI)
- ✓ No LOI proposal is required from applicants
- ✓ Two steps approach
- ✓ Risk matrix and terminology

LOI determination for ETSO projects

→ workflow

for EASA

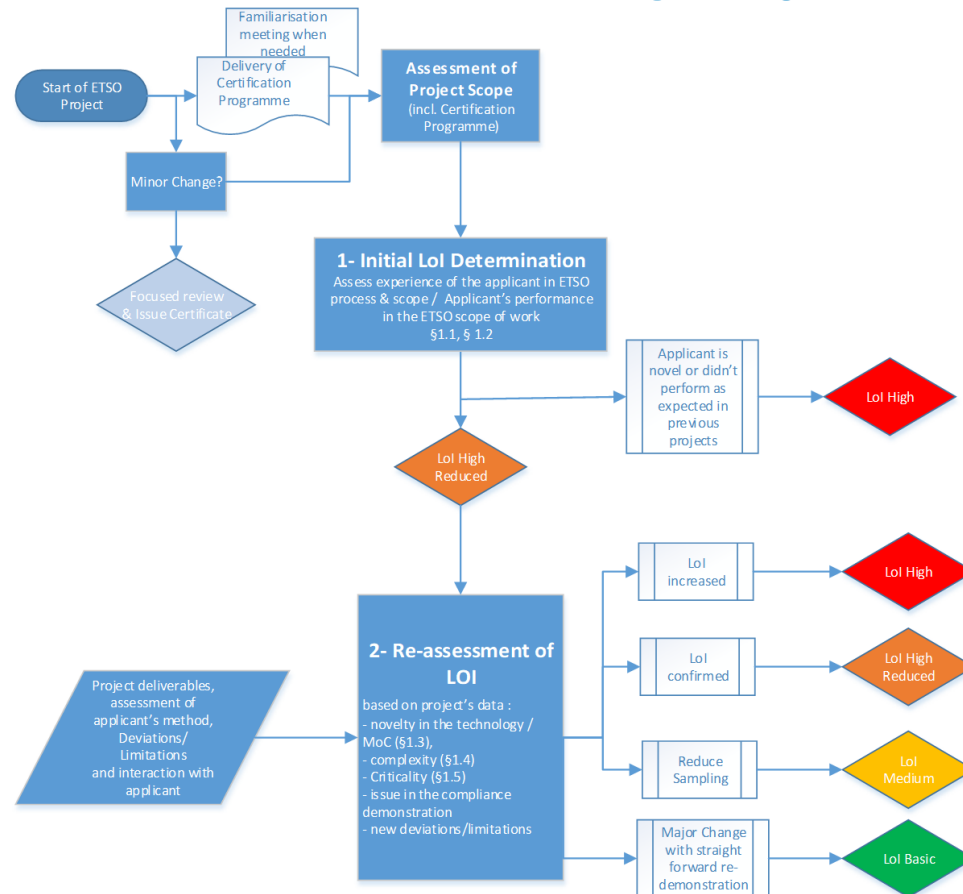







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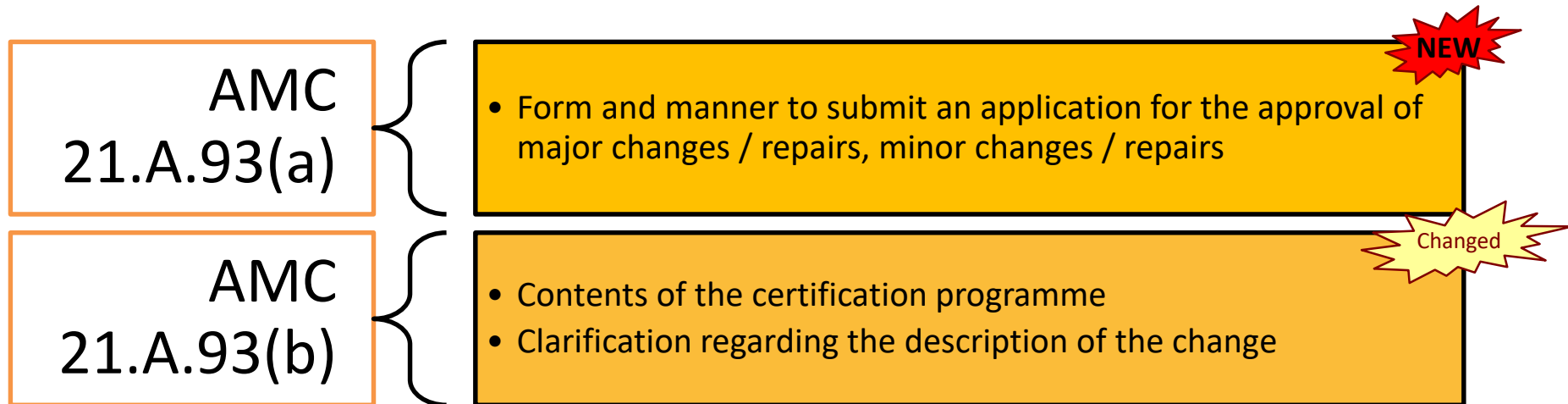
Application for approval of a change

b) An **application shall include**, or be supplemented after the initial application, **a certification programme** for the demonstration of compliance in accordance with point 21.A.20, consisting of:



1. a **description of the change identifying**:
 - (i) **the configuration(s)** of the product in the type certificate upon which the change is to be made;
 - (ii) all **areas** of the product in the type-certificate, including the approved manuals, **that are changed** or affected by the change; and
 - (iii) when the change affects the operational suitability data, any necessary **changes to the operational suitability data**;

The relevant guidance



Requirements for approval of a minor change

(b) A **minor change** to a type-certificate **shall only be approved**:

1. when it has been **demonstrated that the change** and areas affected by the change **comply with the type-certification basis and the environmental protection requirements** incorporated by reference in the type-certificate;
2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data **comply with the operational suitability data certification basis** incorporated by reference in the type-certificate;
3. when **compliance** with the type-certification basis that applies in accordance with point (1) **has been declared** and the justifications of compliance have been recorded in the compliance documents; and
4. when **no feature or characteristic** has been identified that may make the product unsafe for the uses for which certification is requested.

NEWNEW

(e) The applicant shall **submit** to the Agency **the substantiation data** for the change and a **statement that compliance has been demonstrated** in accordance with point (b).

The relevant guidance

AMC
21.A.95

- Describes an acceptable process to approve minor changes

NEW

GM
21.A.95(b)

- Clarifies that 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.

NEW

Application for approval of a repair design

This was a missing point in Part 21.

It is similar to application for a change (21.A.93) but:

→ No Certification programme required in case of minor repair

The relevant guidance

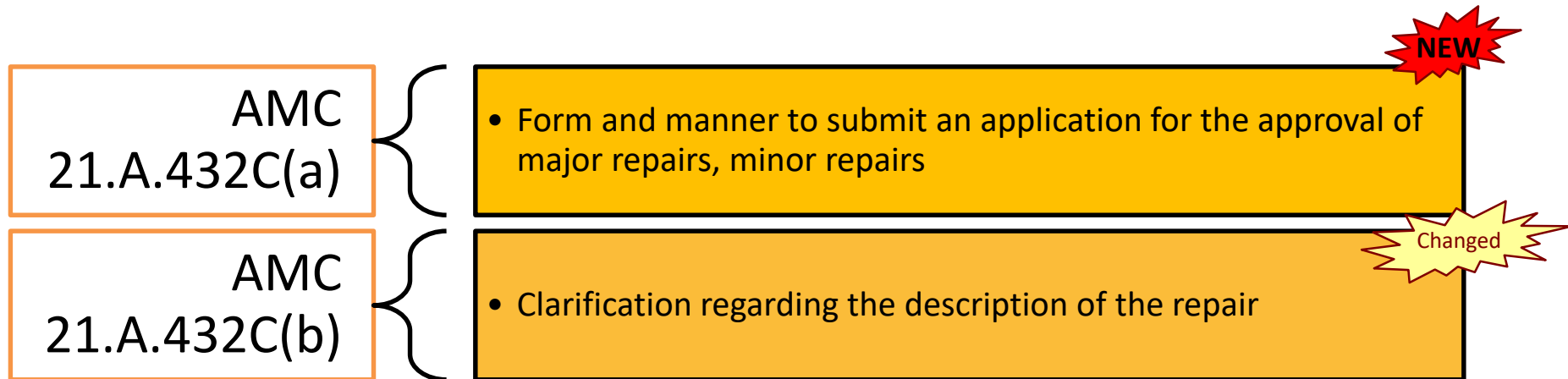







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Data requirements (for ETSOA)

→ The applicant shall submit the following data to the Agency :



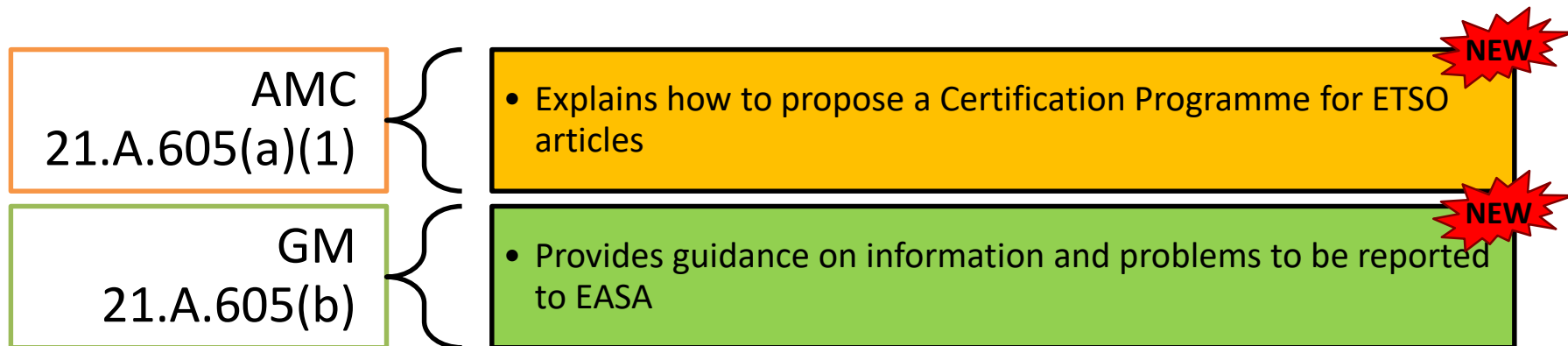
→ a certification programme defining the means to demonstrate compliance

→ In addition, the applicant shall:



→ report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation (=> so that the Agency's LOI can be updated as necessary)

The relevant guidance



Contents of Certification Programme

- (1) detailed description including configurations and the identification of any non-ETSO functions;
- (2) operating characteristics, limitation, deviations;
- (3) intended use of the article and the kind of operations;
- (4) applicable CS-ETSO requirements and any optional aspects;
- (5) proposed means of compliance;
- (6) assessment of safety aspects and main failure conditions;
- (7) way in which the applicant will record its justifications of compliance;
- (8) project schedule.

Reporting from compliance demonstration


The applicant should report 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 the '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 the AMC to 21.B.100(b); and
- any potential deviations discovered by the applicant.

Requirements for the issuance of an ETSO authorisation

In order to be issued an ETSO authorisation, the applicant shall:

(...)

→ declare that no feature or characteristic has been
 identified that may make the article unsafe for the uses
for which certification is requested

The relevant guidance

AMC
21.A.606(d)

- Provides guidance regarding the declaration to be made by ETSO applicants

NEW

The new declaration

- 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 functions and the non-ETSO functions
- Additionally, the applicant should demonstrate and declare that the non-ETSO functions do not interfere with the ETSO functions

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