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# Evolution of European Technical Standard Order Authorisation process

Webinar – 23rd June 2025

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# Welcome / Introduction

# Objectives of the webinar

- Present the principles of the main contemplated changes in the requirements applicable for ETSO Authorisation applicants / holders
- Familiarise the stakeholders with the content of the upcoming NPA
- Collect the views of the stakeholders on the envisaged changes

# Agenda

| Time | Topics for Discussion | Presenter(s) |
|---|---|---|
| **09:00** | Welcome / Introduction | **Mr Grégory LIEVRE**<br>Head of Department, CT.3<br>**Ms Marcella MIANO**<br>Section Manager, CT.5.1 |
| **09:15** | Rulemaking Task RMT.0727-4 / General Presentation | **Mr Alexandru ENACHE**<br>Senior Regulation Officer, CT.5.1 |
| **09:25** | Options for design capability demonstration<br>(an overview of options considered for (design) capability demonstration up to the current concept) | **Mr Francesco CARIDEI**<br>Section Manager, ETSO Section CT.3.3 |
| **09:50** | DOA vs. ADOA<br>(main differences of the current two systems) | **Mr Alexandru ENACHE**<br>Senior Regulation Officer, CT.5.1 |
| **10:15** | Q&A (Slido) | |
| **10:40** | Break | |
| **11:00** | Evolution of ADOA concept<br>(Declared Design Organisation – main requirements) | **Mr Alexandru ENACHE**<br>Senior Regulation Officer, CT.5.1<br>**Mr Francesco CARIDEI**<br>Section Manager, ETSO Section CT.3.3 |
| **11:45** | Q&A (Slido) | |
| **12:15** | **Lunch break** | |

# Agenda (continued)

| Time | Topics for Discussion | Presenter(s) |
|---|---|---|
| 13:30 | Classification and approval of ETSO article design changes<br>(clarification of change classification and approval process) | **Mr Pasquale CONTE**<br>Senior PCM ETSO, CT.3.3<br>**Mr Daniele SGROI**<br>PCM ETSO, CT.3.3 |
| 14:00 | Q&A (Slido) | |
| 14:30 | EASA Level of Involvement (LOI) in ETSOA<br>(improved means to determine the LOI when the applicant has a DOA) | **Mr Pasquale CONTE**<br>Senior PCM ETSO, CT.3.3<br>**Mr Francesco CARIDEI**<br>Section Manager, ETSO Section CT.3.3<br>**Mr Daniele SGROI**<br>PCM ETSO, CT.3.3 |
| 15:00 | Q&A (Slido) | |
| 15:30 | Break | |
| 15:45 | DOA privileges for ETSOA<br>(minor changes and certain major changes (LOI=0)) | **Mr Francesco CARIDEI**<br>Section Manager, ETSO Section CT.3.3 |
| 16:15 | Miscellaneous<br>(transferability, DO-PO arrangements, transition measures, etc.) | **Mr Francesco CARIDEI**<br>Section Manager, ETSO Section CT.3.3 |
| 16:45 | Wrap-up | **Mr Grégory LIEVRE**<br>Head of Department, CT.3 |
| 17:00 | **END** | |

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Q&A sessions are planned after each main agenda topic.

Q & A – use of slido.com

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# Disclaimer


The content of some the following slides is including principles and draft text which is currently under development for the inclusion in the EASA Notice of Proposed Amendment (NPA) – rulemaking task RMT.0727-4.

**This content may change up to the moment the NPA will be published by EASA**.

The audience shall take note of the draft character of this material. Therefore, this material cannot be used or referred in any ETSO Authorisation projects.

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# Rulemaking Task RMT.0727-4 /

# General Presentation

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# RMT.0727, Subtask 4, Background

After the adoption of Regulation (EU) 2018/1139 – known as 'new Basic Regulation' – a rulemaking task (RMT.0727) has been created to for the alignment of Part 21 with new Basic Regulation. The main subtasks were:

- RMT.0727-1 – for the definition of simple and proportionate rules for GA. This subtask let to Part 21 Light

- RMT.0727-3 – certification of non-installed equipment (NIE) and review of the ETSO system

Following consultations with the industry, in 2023 EASA decided to split the two subjects in separate rulemaking subtasks:

- RMT.0727, Subtask 3 - certification of non-installed equipment (NIE); and
- **RMT.0727, Subtask 4 - ETSOA system review**

*(see EPAS, vol. II, edition 2024)*

# RMT.0727, Subtask 4 - Objectives

Improve system's efficiency:

- on ETSOA process (privileges, LoI, performance of organisation)
- at aircraft level (by leveraging as much as possible ETSO credits)

Introduce scalability/proportionality

Fix long-lasting pain points

Keep/improve international transferability of articles and 'level-playing field'

Preserve or improve safety

# RMT.0727, Subtask 4

## Timeline

2021-2024

Pre-rulemaking phase

Q4/2025

NPA

Q4/2026

EASA Opinion

Q1/2027

Commission Regulation


Q1/2027

EASA ED Decision (Part 21 AMC/GM)

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# Options for design capability demonstration

## Overview of options considered for (design) capability demonstration up to the current concept

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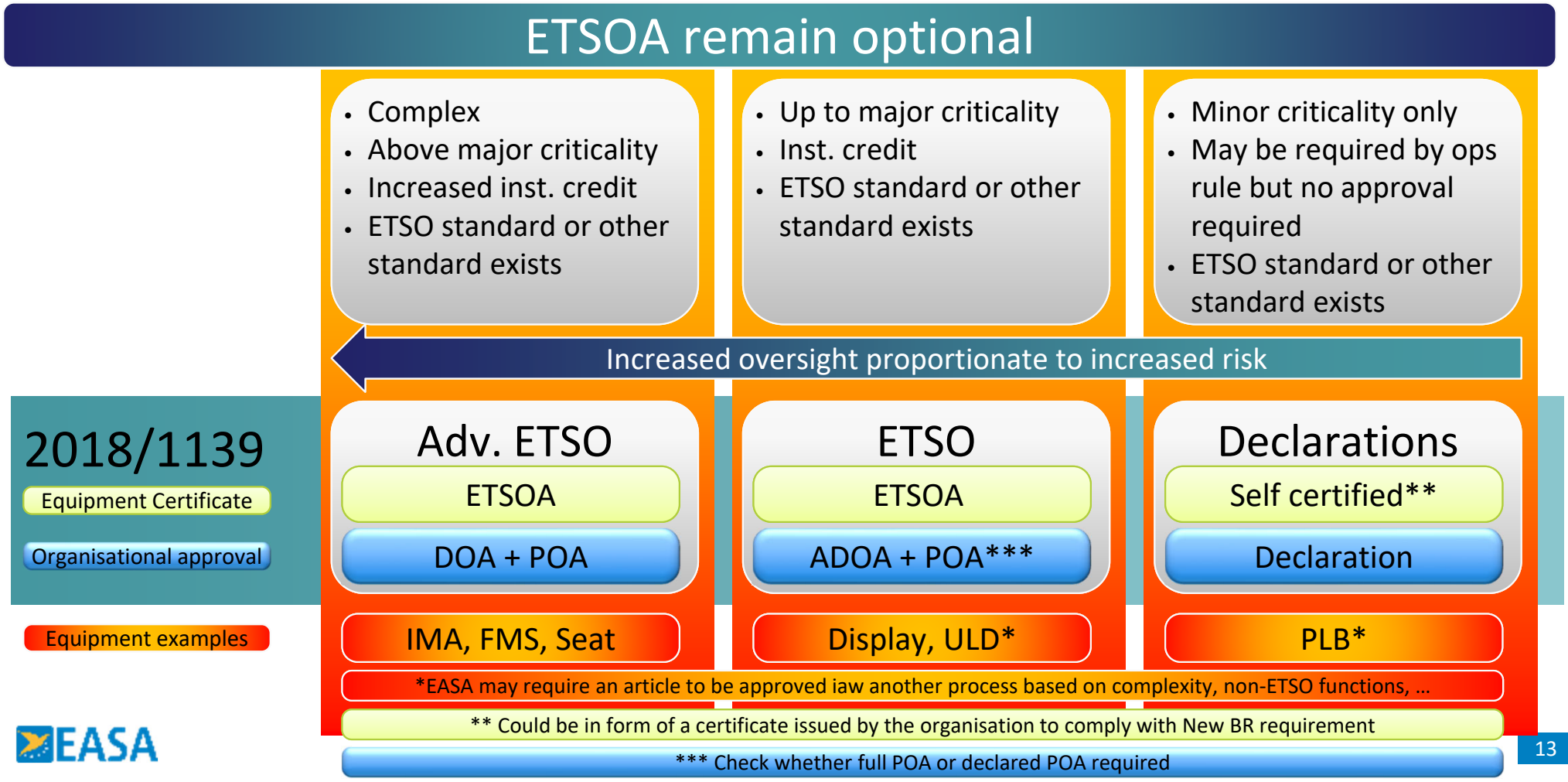
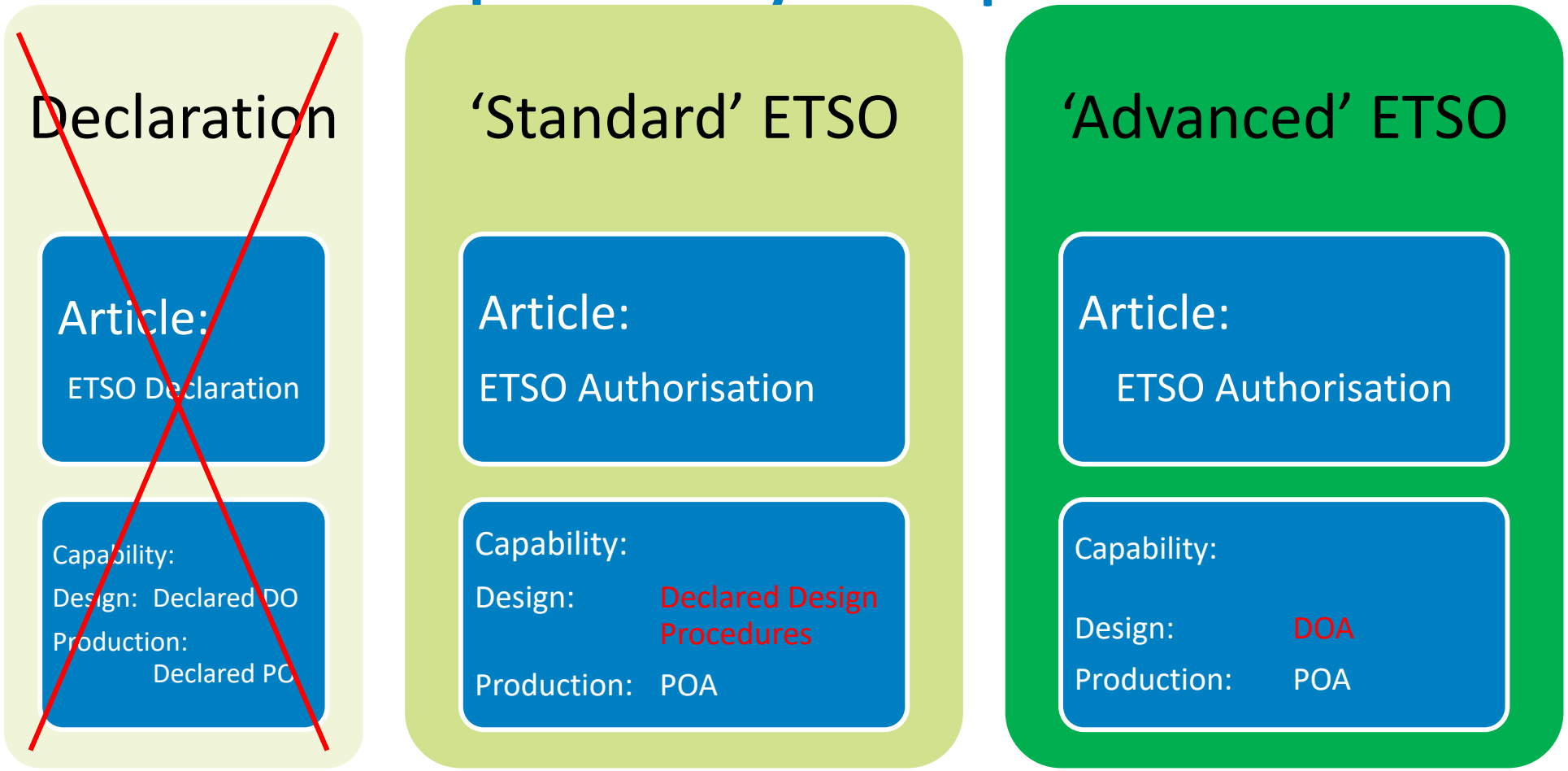
# Initial proportionality concept



# Revised ETSO Proportionality Concept



# Concept retained for implementation

No more categories (‘advanced’ / ‘standard’)

No more mandatory DOA

Privileges for DOA (all minor changes, ‘streamlined’ major changes)

Benefits

→ Simpler (no more categories)

→ Less prescriptive (‘incentive’ for DOA)

→ Preserves potential for efficiency gains (EASA and Industry)

→ No risk of blockage by bilateral partners (streamlined major change approvals still issued by EASA)

→ Does not affect mutual recognition

→ Preserves level-playing field (very aligned with FAA approach)

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# DOA vs. ADOA

## Main differences of the current two systems

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# Demonstration of capability for design – current framework

Capability demonstration requirements unchanged since initial issue of EASA Part 21 (Regulation (EC) No 1702/2003):

- DOA for APU
- 'for all other articles, by using **procedures** setting out the specific design practices, resources and sequence of activities […]'

AMC 21.A.602B(b)(2) -> **Manual of procedures**

Due to similarity with capability demonstration for product certification in 21.A.14(b), these procedures have been called '**alternative procedures**'.

(the acronyms used: AP, AP to DOA, ADOA)

# Demonstration of capability for design – current framework

What should be the content / coverage of these procedures? (see AMC 21.A.602B(b)(2))

- management of ETSO authorisation process
- management of design changes
    - classification and approval
    - should also cover repairs and production non-conformities
- obligations of ETSOA holder
    - including, issuance of information and instructions (manuals)
- control of design subcontractors

*(see also, EASA Template for ETSO ADOA Manual)*

Process

- Application for Alternative Procedure to Design Organisation Approval (DOA) – Form 81
- desk review by EASA (iteration(s) until satisfactory) + in parallel first project with PCM ETSO
- EASA finding of compliance

# Design Organisation Approval (DOA)

We are proposing opening the DOA path for ETSOA applicants / holders on a voluntary basis.

A DOA is more then a set of procedure (like in the case of ADOA)

The design organisation shall establish, implement and maintain a design management system

- sufficient staff (number and competence);
- clearly allocated responsibilities;
- adequate facilities;
- well defined policies, processes and procedures.

**DOA** has

- **recognised capabilities** *(i.e. fulfils eligibility criteria for applying for certain design approvals)*
- **privileges** *(e.g. approval of changes, repairs, flight conditions)*
- **obligations** *(observe the procedures, ensure designs are compliant with technical specifications, CAW, coordination DO-PO, record keeping)*

# Design Organisation Approval (DOA)

What are the main 'features' of the Design Management System:

- airworthiness function

  (managing the certification process, managing the continued airworthiness, interfacing with EASA)

- independent verification function of the demonstration of compliance (a.k.a. CVE function)

  (verification by a person that did not create the compliance data)

- independent monitoring function to verify compliance of the organisation with the relevant requirements of Part 21 as well as the compliance with and adequacy of the design management system

  ('simplifying': internal audits)

- safety management system

  (safety policy & objectives, safety risk management, safety assurance, safety promotion)

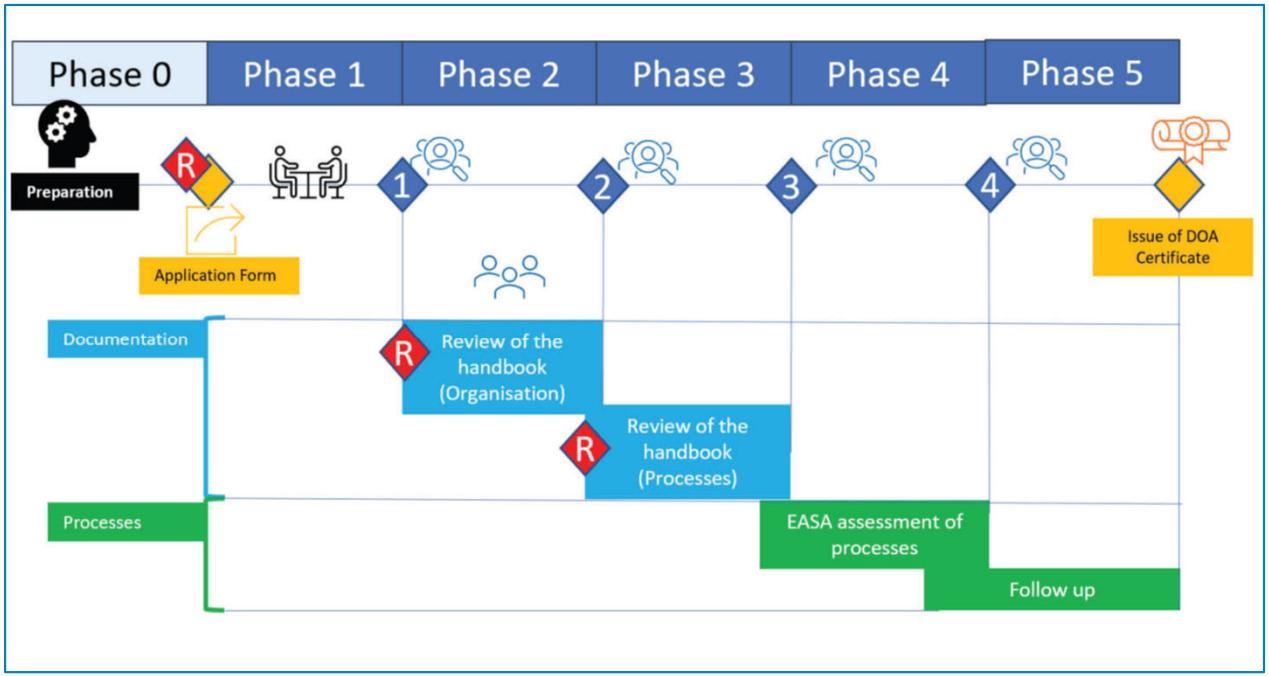
- key management positions

  (HDO, CoAF, CoIMF, SM)

- staff competence

# Design Organisation Approval (DOA)

DOA initial certification process




*Note* *Fore more details please refer to the 'DOA Initial Investigation Information Package' published on EASA DOA webpage (here), in the section 'Downloads'.*

# Design Organisation Approval (DOA)

DOA oversight principles

- verification that the DOA continue to comply with Part 21
- risk based approach (scope and volume of work, privileges, performance)
- includes: assessments, audits (process and product), inspections, sampling
- oversight cycle / programme (normally, 2-year cycle)
- recommendation report on the continuation of the approval
- findings and corrective actions

# How big is the ‘step’ towards a DOA?

Some ‘pioneers’ exist already!

What do I need?

- handbook / procedures — ? (ADOA Manual already existent / gap analysis)
- key management positions — ? (already in place / need for additional nomination(s))
- airworthiness function — ? (already nominated staff responsible for managing the ETSOA process and interfacing with EASA)
- CVE function — ? do you have someone verifying the compliance doc.? (most probably, YES)
- independent monitoring — are you performing internal audits? (EN/AS 9100, supplier req., POA)
- SMS — ? (it is already implemented in your POA / extension needed)
- staff competence — ? probably you are already managing the staff competence (need for additional training)

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# Evolution of ADOA concept

## Declared Design Organisation – main requirements

# From ADOA to Declared Design Capability (Declared Design Organisation)

**ADOA**

- set of procedures established by the applicant / holder
- reviewed by EASA
- EASA Finding of Compliance

**Declared Design Organisation**

- set of procedures established by the applicant / holder
- self-declaration by the applicant/holder
- registration of the declaration by EASA
- oversight by EASA during ETSOA projects (and, when required, through specific activities)

**Main advantages**

No prior review by EASA (reduced burden, in particular, for new ETSOA applicants)

Flexibility for the Declarant (ETSOA holder) to manage its own procedural system and keep it updated / fit for purpose.

# Proposed implementation in Part 21 of the requirements for Declared Design Organisation

## New Subpart N (21.A.5xx)

- 21.A.501 Scope
- 21.A.503 Eligibility
- 21.A.505 Declaration of Design Capability
- 21.A.507 Management system for design
- 21.A.509 Resources of the declared design organisation
- 21.A.511 Scope of work
- 21.A.513 Findings and observations
- 21.A.515 Notification of changes and cessation of activities

# Proposed implementation in Part 21 of the requirements for Declared Design Organisation

## New Subpart N (21.A.5xx)

administrative req.

technical req.

- 21.A.501 Scope
- 21.A.503 Eligibility
- 21.A.505 Declaration of Design Capability
- 21.A.507 Management system for design
- 21.A.509 Resources of the declared design organisation
- 21.A.511 Scope of work
- 21.A.513 Findings and observations
- 21.A.515 Notification of changes and cessation of activities

# New Subpart N (21.A.5xx) – administrative requirements

- 21.A.501 **Scope**

  Establish the procedural requirements for making a declaration of design capability.

  Is also prescribing the obligations of the declarant.

- 21.A.503 **Eligibility**

  Any natural or legal person required by point 21.A.602B(b)(2) to demonstrate their design capability

*Note The scope and eligibility for the declaration of design capability may be extended in the future to cover other design approvals in Part 21 (replacing the 'Alternative Procedures').*

# New Subpart N (21.A.5xx) – administrative requirements

➢ 21.A.505 **Declaration of Design Capability**

The form and manner is established by EASA (there will be an EASA Form xyz for the declaration)

Contents of the Declaration

- ✓ name and address of the organisation
- ✓ the names and contact details of the head of the design organisation;
- ✓ the intended scope of work;
- ✓ a statement confirming that the organisation:
  - (i) has a management system for design in accordance with point 21.A.507; and
  - (ii) will maintain the management system for design in compliance with this Subpart;
- ✓ a statement confirming that the organisation will adhere to the processes and procedures
- ✓ a statement that the organisation agrees to undertake the obligations of a declared design organisation in accordance with this Subpart.

# New Subpart N (21.A.5xx) – administrative requirements

- 21.A.511 **Scope of work**
  Type of design work (initial certification, changes, repairs)
  Categories of ETSO articles (by reference to the applicable ETSO)
  Functions and obligations (all or (for certain articles) only continued airworthiness)

- 21.A.513 **Findings and observations**
  After receiving a finding notification
    - establish corrective action plan
    - demonstrate to EASA the implementation of the corrective actions
  Corrective actions shall be performed in the established period
  Observations

- 21.A.515 **Notification of changes and cessation of activities**
  Changes affecting Declaration contents
  Changes significant for the demonstration of compliance for the article(s) designed
  Termination of some or all activities covered by declaration

# New Subpart N (21.A.5xx) – technical requirements

- 21.A.507 **Management system for design**

Proportionate with the nature and complexity of the activity.

Established under the accountability of a single manager (Head of Design Organisation).

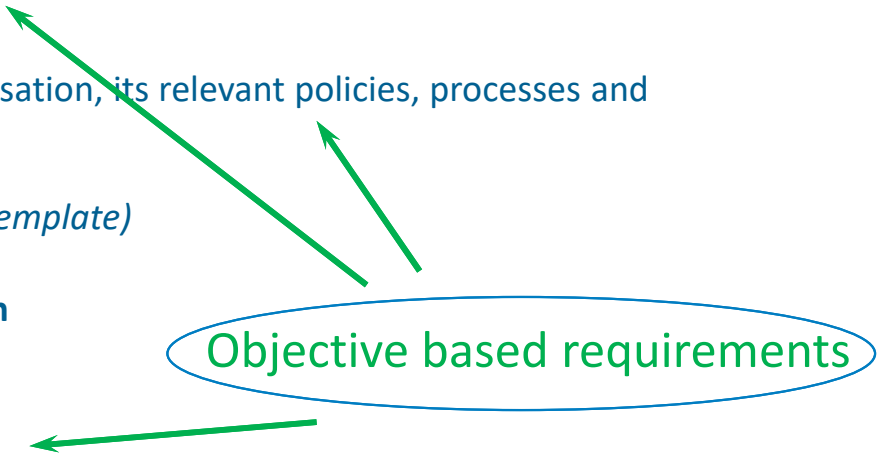
Ensure the control and supervision of the design, and of design changes of articles and their compliance with the technical conditions of the applicable ETSO.

Handbook that describes, directly or by cross reference, the organisation, its relevant policies, processes and procedures. The Handbook shall be maintained up to date.

*(planned AMC/GM for the content of the Handbook and example/template)*

- 21.A.509 **Resources of the declared design organization**

Nomination of a Head of Design Organisation
Sufficient staff (number and experience) and adequate facilities



# New Section B / Subpart N (21.B.46x) – Procedural requirements for competent authorities (EASA)

- 21.B.461 **Registration of a declaration of design capability**

Declarant eligibility check

Declaration completeness check

When the checks are successful, EASA confirms the registration of the declaration and publishes the name of the declarant and the sope of work in the List of of registered Part 21 Declared Design Organisations.

- 21.B.463 **Oversight activities**

The oversight activities will be triggered by the Declarant performance during the ETSOA projects.

- 21.B.465 **Findings and corrective actions; observations**

Findings level 1 and level 2 (with different urgency for corrective actions implementation: 21 working days or 3 months, respectively)

Observations – improvement suggestions or issues which may later develop into findings

- 21.B.467 **Changes to the declaration**

Check and register the updated declaration.

If relevant, update the published list.

# Declared Design Organisation – final remarks

- The concept of 'Declaration of Capability' is not new

- It has been introduced through Regulation (EU) 2018/1139 (Basic Regulation)
  - defined in Art. 3(10)
  - the basis for inclusion in Part 21 (for design organisation) provided through Art. 19(1)(g)

- It was already introduced in the Initial Airworthiness domain, in Part 21 Light (through amending Regulation (EU) 2022/1358)

- However, the requirements for Declared Design Organisation in Part 21 Light (Subpart J) and the contemplated requirements for Declared Design Organisation in Part 21 (Subpart N) are not the same:
  - similar in terms of 'administrative' requirements;
  - but, different in terms of 'technical' requirements

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# Classification and approval of ETSO article design changes

## Clarification of change classification and approval process

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# What we have and what will get...

| ETSO Application | | Today | Tomorrow | |
|---|---|---|---|---|
| Organization Requirements | | ADOA | Declared DO | Approved DOA |
| Production Requirements[1] | | POA | POA | POA |
| EASA LoI | | 21.B.100(b) | 21.B.100(b)[2] | 21.B.100(b)[2] |
| "Major" | Major | EASA[3] | EASA[2] | EASA[2] |
| | Privilege | N/A | N/A | EASA[5] |
| "Minor" | Non-Anticipated | EASA | EASA | Self[6] |
| | Anticipated | Self[4] | Self[4] | Self[6] |
| | Administrative | EASA[5] | EASA[5] | EASA[5] |

1) POA may be exempted for SW Only NIE ETSOs (RMT.727-3)

2) EASA LOI as per AMC2 21.B.100(b) (to be moved in Section B- Subpart O and reviewed)

3) Current 21.A.611 requires application for a new Authorization for Major Changes

4) Self approval of pre-agreed list of specific Anticipated minor changes in APDOA/DDO Manual

5) EASA LoI = 0, involvement limited to administrative re-issuance of revised ETSOA Certificate

6) Self approval under new DOA privilege for minor change to ETSOA

# Major Changes

Application for Major Changes will be available to all the ETSO Applicants (DDO, DOA).

Under the current requirements, a major change has to be treated as a new ETSOA authorisation.


It is proposed to no longer apply for an initial ETSOA for major changes.
A process for approval of major changes will be provided within revised 21.A.611.


For certain major changes, it will be possible to use for the compliance demonstration the ETSO referred in the ETSOA.

An Applicant can always elect to apply for Initial Investigation (latest ETSO standard revision applies).

EASA will be involved in a technical investigation according to the Applicable LoI determined per the applicable criteria of 21.B.100(a/b) [AMC will be revised for DDO and DOA].

# Major Changes – with impact on CB

The following criteria are valid to determine if an application needs an updated certification basis (i.e. applicable ETSO at the revision level at the time of application):

- → Have the assumptions used for an existing Certification been invalidated?
- → Is the Change introducing a New ETSO Revision [e.g. from C127c to 127d]?
- → Is the Change introducing a new ETSO in addition to the existing one?
- → Is the Change introducing a New ETSO Deviation ?
- → Does proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required (> 80%) ?

<u>If any of the questions is answered “Yes” => the major change has to comply with the latest ETSO revision.</u>

# Major Changes – without impacts on CB

The following criteria are valid to determine if an application should be accepted without changing the Certification Basis:

- → Is there a change to the principle of intended design ?
- → Is the change necessitate new guidance materials means of compliance to Certification basis?
- → Is the Change a corrective action (to be) mandated of by an AD?
- → Is the change introducing a significant amount of complexity / novelty in the compliance demonstration
- → Is there a significant impact on performance and/or environmental qualification
- → It's the change affecting Form, Fit and Functions (including Non-ETSO ones)?
- → Is the POA reference changed and a new DO-PO is required?
- → Does proposed change to design is so extensive that a significant investigation of compliance with the applicable certification basis is required (between 50% and 80%) ?

If ALL the questions in the **previous slide** are answered "NO", AND

If any of the questions above is answered "YES" => the major change has to comply with the ETSO revision referred in the original ETSOA.

# Minor Changes – Non-Anticipated

Application for Non-Anticipated minor changes is available to **DDO** ETSO Applicants, as **DOAs may have the privilege** of classifying and self-approving all the Minor Changes.

EASA will be involved in the technical investigation according to the Applicable LoI as per applicable criteria of 21.B.100(b) [AMC will be revised for DDO].

The following criteria are valid to determine if an application shall be considered a Minor Change introduced to an existing design:

→ None of the major criteria met

→ Not an agreed Anticipated Minor Changes

# Minor Changes – Anticipated

Anticipated minor changes is a subset of Minor Changes that **DDOs** can agree with EASA and include in their Scope of Work and self approve their introduction into an ETSO Authorized design.

Pre-Agreed Anticipated Minor Changes can be listed/attached in the DDO Manuals.

Each Anticipated Minor Change shall be detailed described, including the MoC to be used for compliance demonstration.

Anticipated Minor Changes introduced to an ETSOA design shall be reported to the Agency on a regularly basis.

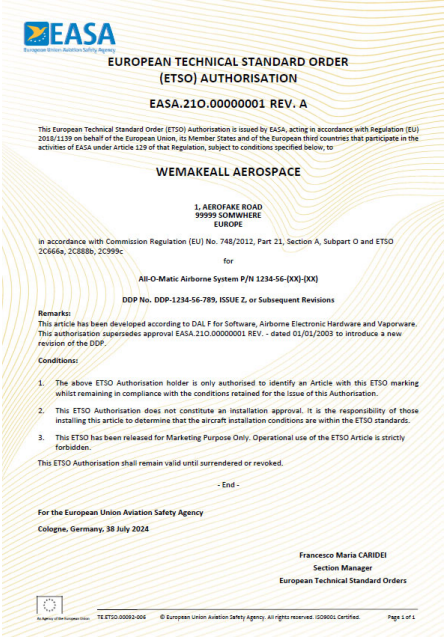
# Administrative Changes

Administrative Changes to ETSO Authorisations are those related to the need of updating the references on the ETSOA Certificates without affecting the technical compliance demonstration.

Common examples of Administrative Changes are:

- → Need to reference a new company name on the certificate
- → Need to reference a new legal address of the ETSOA Holder

EASA will always re-issue the ETSO Authorisation.



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EUROPEAN TECHNICAL STANDARD ORDER
(ETSO) AUTHORISATION

EASA.21O.00000001 REV. A

This European Technical Standard Order (ETSO) Authorisation is issued by EASA, acting in accordance with Regulation (EU) 2018/1139 on behalf of the European Union, its Member States and of the European third countries that participate in the activities of EASA under Article 129 of that Regulation, subject to conditions specified below, to

WEMAKEALL AEROSPACE

1, AEROFAKE ROAD
99999 SOMWHERE
EUROPE

in accordance with Commission Regulation (EU) No. 748/2012, Part 21, Section A, Subpart O and ETSO 2C666a, 2C888b, 2C999c

for

All-O-Matic Airborne System P/N 1234-56-[XX]-[XX]

DDP No. DDP-1234-56-789, ISSUE Z, or Subsequent Revisions

Remarks:
This article has been developed according to DAL F for Software, Airborne Electronic Hardware and Vaporware. This authorisation supersedes approval EASA.21O.00000001 REV. - dated 01/01/2003 to introduce a new revision of the DDP.

Conditions:

1. The above ETSO Authorisation holder is only authorised to identify an Article with this ETSO marking whilst remaining in compliance with the conditions retained for the issue of this Authorisation.
2. This ETSO Authorisation does not constitute an installation approval. It is the responsibility of those installing this article to determine that the aircraft installation conditions are within the ETSO standards.
3. This ETSO has been released for Marketing Purpose Only. Operational use of the ETSO Article is strictly forbidden.

This ETSO Authorisation shall remain valid until surrendered or revoked.

- End -

For the European Union Aviation Safety Agency

Cologne, Germany, 38 July 2024

Francesco Maria CARIDEI
Section Manager
European Technical Standard Orders

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# Qualitative vs. Quantitative


Substantially complete investigation

No appreciable Effects


Significant investigation

Affecting the airworthiness

Requirements

Tests


Documents

Lines of code

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# EASA Level of Involvement (LOI) in ETSOA

Current methodology and future insights

# Summary

- → The Level of Involvement (LoI) Regulatory references
- → Regulation and related AMCs
- → Brief AMCs outline and main concepts
- → AMCs comparison (Products vs ETSO projects) and main differences
- → Outlook into LoI possibilities for DDO and ETSO DOA
  - → AMCs still in development phase
  - → Potential for simplification

# Introduction – Regulatory Framework

- → The Level of Involvement (LoI) concept was introduced by the Commission Delegated Regulation (EU) 2019/897 (12 March 2019).
- → This amendment modified Annex I (Part-21) of Regulation (EU) 748/2012.
  - → Point 21.B.100 Level of involvement
    - → *(a) The Agency shall determine its involvement in the verification of the compliance demonstration activities and data related to the application for a type-certificate, restricted type-certificate, major change approval, supplemental type certificate, major repair design approval or ETSO authorisation for APUs.*

# Introduction – Regulatory Framework

→ *It shall do so on the basis of an assessment of meaningful groups of compliance demonstration activities and data of the certification programme. That assessment shall address:*

*— the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements; and*

*— the potential impact of that non-compliance on product, UAS and CMU safety or environmental protection,*

*and consider at least the following elements:*

*1. novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;*

*2. complexity of the design and/or demonstration of compliance;*

*3. criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and*

*4. performance and experience of the design organisation of the applicant in the domain concerned.*

# Introduction – Regulatory Framework

→ *(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 organization*

→ *(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.*

# AMC 21.B.100(a): LoI for TC, major change to a TC, STC, major repair and, ETSOA for APU

- 1. Definitions
- […]
  - Compliance demonstration item (CDI): a meaningful group of compliance demonstration activities and data of the certification programme, which can be considered in isolation for the purpose of performing a risk assessment.
- 2. Background
- […]
  - (a) propose EASA's LoI for each CDI
  - (b) how EASA will determine its LoI
- 3. Principles and generic criteria for the LoI determination
  - EASA determines its LoI 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)
  - — 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 LoI.
  - […]

Note: additional criteria are contained as an attachment to the EASA Certification Memorandum (CM) CM-21.A/21.B-001, available at: https://www.easa.europa.eu/documentlibrary/product-certification-consultations/cm-21a21b-001

# AMC 21.B.100(a): LoI for TC, a major change to a TC, a STC, a major repair and, ETSOA for APU

- → 3.1. LoI determination at CDI level
- → […]
- → 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
- → 3.2.3. Complexity
- → 3.2.4. Performance of the design organisation

# AMC 21.B.100(a): LoI for TC, a major change to a TC, a STC, a major repair and, ETSOA for APU

→ 3.2.5. Likelihood of an unidentified non-compliance

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

# AMC 21.B.100(a): LoI for TC, a major change to a TC, a STC, a major repair and, ETSOA for APU

→ 3.3. Criticality

The second step that is necessary to determine the risk class is the assessment of the potential impact of a non-compliance on part of the certification basis regarding the airworthiness or the environmental protection of the product.

→ 3.4. Method for the determination of risk classes

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

# AMC 21.B.100(a): LoI for TC, a major change to a TC, a STC, a major repair and, ETSOA for APU

- 3.5. Determination of EASA's LoI
  - 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: there is no 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 large number of compliance activities (witnessing of tests, audits, etc.).

# What is Level of Involvement for DOA/Products?

- → LOI is a risk-based framework to define EASA's involvement in verifying compliance.
- → Applicants must:
  - → Segment their certification program into compliance demonstration items (CDIs).
  - → Assess the likelihood and impact of unidentified non-compliances.
  - → Propose a level of involvement for each CDI.
- → Agency Role and Final Determination
  - → The applicant's risk assessment guides EASA’s review depth.
  - → The Agency ultimately determines the final LOI for each CDI.
- → This approach optimizes EASA’s reviews/involvement based on potential risk.

# AMC No 2 to 21.B.100(b) Level of involvement (LoI) in ETSOA projects

→ 1. Principles

— 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.

# AMC No 2 to 21.B.100(b) Level of involvement (LoI) in ETSOA projects

→ 2.1. Definition of the LoI classes EASA's LoI for an ETSO certification project is classified as one of the following:

— class high,

— class high reduced,

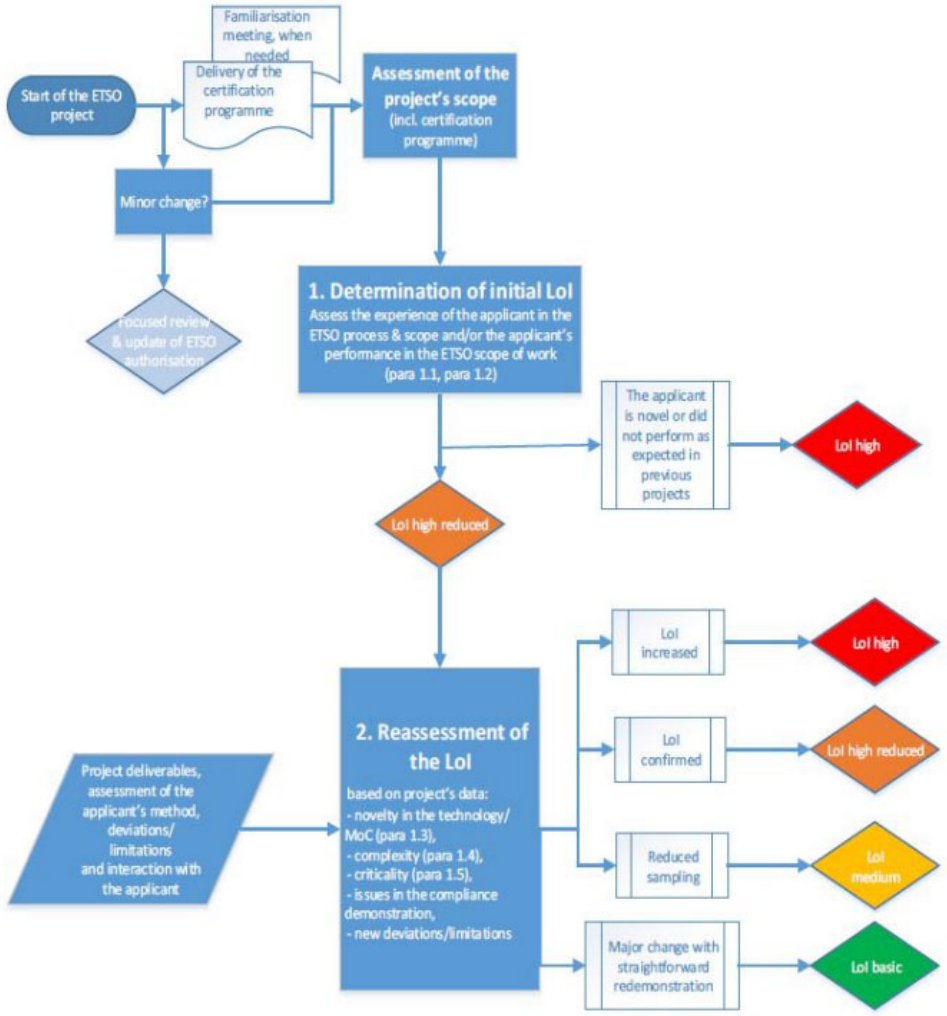
— class medium, or

— class basic.

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

# AMC No 2 to 21.B.100(b) Level of involvement (LoI) in ETSOA projects

→ Two step process



# AMC No 2 to 21.B.100(b) Level of involvement (LoI) in ETSOA projects

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

| Assessment results | LoI adaptation |
|---|---|
| The ETSO article is novel and complex or a significant issue is detected during the compliance demonstration. | LoI is increased to high. |
| The ETSO article is novel or complex or a new deviation is requested ([1]). | LoI 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. | LoI is decreased to medium. |
| There is a major change with straightforward redemonstration of the ETSO compliance ([2]). | LoI is reduced to basic. |

# Comparison

- For Products
  - Approved design organizations
  - LoI is proposed -> Agency to agree
  - Initial agreed LoI can be in a low risk category
  - Retained documents

- For ETSO other than APU
  - AP to DOA is not an approved design organization
  - Agency determines the LoI based on the outlined AMC no2
  - Default LoI is High/High Reduced
  - All compliance documents are submitted

# Declared Design Organization (DDO) LoI for ETSOA

- → Principles would be in line with current AMC no.2, driven by:
  - → No regular oversight
  - → Procedures/Performances are assessed only at project level
  - → No functions as per 21.J (Airworthiness, IMF, CVE etc.)
- → Possible variations
  - → Reduction of Risk Class to three (high, medium, low) or align risk categories with AMC (a) Product level LoI for consistency
  - → Entry point at any Risk Class w/o re-assessment since the beginning, with possibility to increase at any instance during the project conduction
  - → Submission of the whole data package will remain, with possibility of clear EASA document retention

# Design Organization (DOA) LoI for ETSOA

- → Principles would be in line with current AMC (a)
  - → Methodology is consolidated
    - → For organizations with ToA not limited to ETSOA a unique methodology applies
  - → DOA Performances are monitored through established processes
    - → Shared with the DOA
- → Possible variation
  - → There will be a need to tailor certain portions of the wording of the AMC (a) to include the ETSOA case.
  - → The plan is to move the ETSO LoI AMC(s) from Section B/Subpart B to Section B/Subpart O or in a dedicated AMC based on adapted content

# Design Organization (DOA) LoI for ETSOA

→ Possible variation (cont.)

→ Compliance Demonstration Items (CDI) would be a new concept applied to ETSO. The CDI will not be formally requested in the rule as part of the Certification Programme.
The revised AMC may introduce this concept and the applicant should decide if for a project to define several CDIs or it will be only one (i.e. full project).

→ The advantage for a DOA to define several CDI will be the ability to propose later different LOI per each CDI.

→ Guidance material in the form of GM or CM similarly to EASA CM No.: CM-21.A/21.B-001 Issue 03 for LoI determination

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# DOA privileges for ETSOA

# DOA privileges for ETSOA

The DOA privileges are specified in 21.A.263(c).

The DOA privileges are not granted by default together with the DOA. The DOA holder needs to demonstrate its capability to exercise the respective privileges (organisation, responsibilities, competence, procedure).

For design organisation having the scope of ETSOA, two new privileges are contemplated:

*(c) The holder of a design organisation approval shall be entitled, within the scope of its terms of approval issued under point 21.A.251 and under the relevant procedures of the design management system:*

*[…]*

*(10) for ETSO Authorisation for which they are the holder, to classify changes to an ETSO Authorisation and approve minor changes;*

*(11) for ETSO Authorisation for which they are the holder, to obtain the approval of certain major changes to an ETSO Authorisation without further verifications by the Agency when submitting the declaration required under point 21.A.608.*

# Major Changes – Privilege

Certain Major Changes to existing ETSO design will be eligible for **DOA privilege.**

*'to obtain the approval'* - EASA LoI = 0. (Why?)

The following criteria are valid to determine if a Major Change can be eligible for the privilege:

- → Certification assumptions not invalidated
- → No new ETSO Standard/Revision, no New Deviation
- → Not an AD corrective action
- → No novelties in compliance demonstration and no new means of compliance
- → Compliance investigation <80%
- → Possible to have change in design principles
- → Possible to have significant impact on performance and/or environmental qualification

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# Miscellaneous
## (transferability, DO-PO arrangements, transition measures)

# Miscellaneous

**Transferability** (21.A.621)

It is intended to relax the current transferability requirements (currently, allowed only in case of change of ownership) allowing the transfer to natural or legal person that is able to undertake the obligations of the ETSOA Holder (including the demonstration of capabilities for design and production).

An additional condition will request to manage such transfer as a major change to ETSO Authorisation.

**DO-PO arrangements** (21.A.602B(a))

Currently, the production capability is demonstrated by holding a POA. In case the ETSOA applicant / holder wants to use a different organisation for producing the article, point 21.A.2 has to be used.

To simplify the production capability demonstration path, it will be proposed to accept directly DO-PO arrangements with an organisation that holds a POA.

Change of POA will be considered a partial transfer of the approval and the provision of 21.A.621 will apply.

**Transition measures**

As there is no intention to mandate the DOA, it is considered that no extensive transition period will be necessary.

The transition from current ADOA to Declared Design Organisation should be straight forward. However, to allow the current ETSOA Holders to review their procedures and follow the administrative steps for the registration of their Declaration of Design Capability, a transition period of up to 6 months will be considered.

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