

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

What is changing for me?

Changes related to the applications for a TC / STC /
major repairs-changes or APU ETSO

Your safety is our mission.

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- Introduction and overview of the main changes
- Changes to the Application and to the Certification Basis
- New requirements for determining the Level of Involvement (LOI) 
- How to apply the new LOI determination?
- Examples of LOI proposals 
- The advanced application of new LOI concept
- Best practices and overall EASA considerations 

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Introduction

- Introduction of a documented risk-based Level Of Involvement (LOI) approach in Part 21
 - which is part of the certification programme
 - which is part of the application



Overview of changes to the Certification Process

APPLICANT

Files

(complemented with a first version of the certification programme)

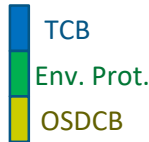


Application

Accepts

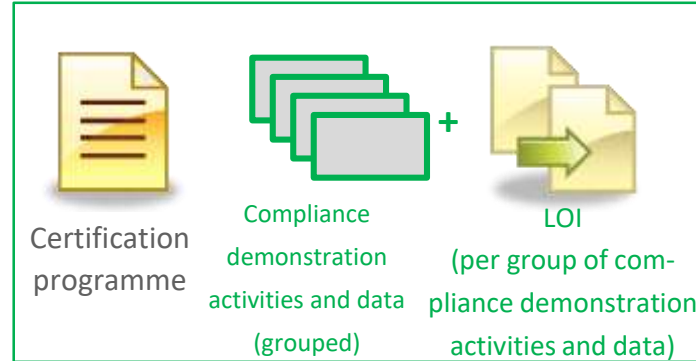
EASA

Makes a proposal



Establishes and notifies

Provides



Accepts

Makes a proposal (based on risk assessment)

Changes in green..
Informs EASA in case of difficulty

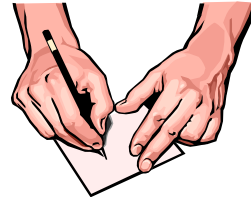
Demonstrates and verifies compliance



Compliance demonstration (and verification)

Verifies compliance by sampling

Declares compliance



Compliance declaration

Verifies declaration and that 21.A.21 is complied with

Determines and notifies

May adjust LOI

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Application

Changes do not impact the **application forms and**
administrative processing currently in use



- Clarification on points 21.A.15 / 93 / 113 / 432C
 - In line with wide practice applied in the past

- Application shall include
 - as a minimum, a preliminary description of the product, the intended use of the product and the kind of operations for which certification is requested
 - a certification programme for the demonstration of compliance in accordance with point 21.A.20 (may be added after initial application)

Application

- As part of the application, the certification programme shall include
 - Detailed technical description
 - Operating characteristics and limitations
 - Intended use of the product, kind of operations
 - Proposal of the certification basis including MoC and related compliance data and (new related to LOI)
 - A breakdown of the certification project into meaningful groups of compliance demonstration activities and data to facilitate a risk assessment, and
 - A corresponding proposed EASA involvement at this grouped level

Certification basis

- To be proposed by the applicant as part of the certification programme
- 3 elements
 - Type certification basis (point 21.B.80),
 - OSD certification basis (point 21.B.82) and
 - applicable environment protection requirements (point 21.B.85)
- Moved from Section A to Section B

→ Clarification on the elements for the establishment of the type certification basis: EASA establishes it based on

The CS designated from those applicable to the product on the date of application, unless ..

- the applicant chooses to comply with a CS which became applicable after the date of application, or is required to comply with such because the TC could not be issued during validity of the application,
- EASA accepts an alternative, with compensating factors providing an equivalent level of safety, or
- EASA accepts or prescribes other means that demonstrate compliance with the ERs (or in the case of RTC provide a level of safety adequate with regard to the intended use)

elect to comply
/ later effective
amendment

equivalent
safety finding



deviation

and any special condition prescribed by the Agency.

Issuance of a TC/RTC (and similar)

21.B.103, 21.B.107,
21.B.111, 21.B.453

The Agency will issue the certificate when:

- The applicant has complied with all the applicable Section A requirements (e.g. point 21.A.21);
-  → the Agency, through its investigations **in accordance with point 21.B.100(a) or (b)**, as applicable, has not found any non-compliance with the applicable certification basis (TC, OSD, EP, as applicable); and
-  → no feature or characteristic **has been identified** that may make the product unsafe for the uses for which certification is requested



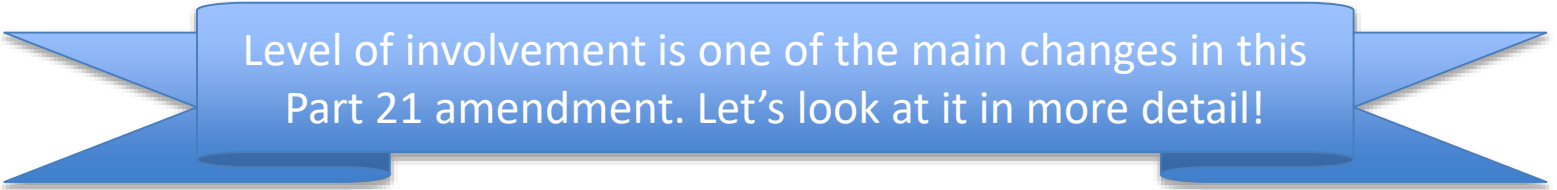
“...no feature or characteristic makes the product unsafe for the uses for which certification is requested.”

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Level of involvement

- New requirement to propose the Agency's involvement as part of the certification programme
 - Now explicitly required
 - Based on a risk assessment
 - For the Agency's compliance verification



Level of involvement is one of the main changes in this Part 21 amendment. Let's look at it in more detail!

Level of involvement – Issue

- While the applicant demonstrates and (in approved DOs) independently verifies compliance ...
- ... the Agency (before issuing the certificate) has to be convinced that this is performed correctly
 - This is done by sampling via (a second) verification
- The past Part 21 implicitly recognised the non-exhaustiveness of the Agency's verification activities, but
 - Had no criteria for determining the Agency's LOI
 - Did not reflect safety management principles



Level of involvement - Objectives

- To include a risk-based approach to the Agency's compliance verification in Part 21
 - to focus resources on certification aspects that pose higher risks => qualitative improvement
- To initiate the implementation of ICAO Annex 19
- To develop objective criteria and transparent processes to ensure
 - increased efficiency
 - controlled processes
 - equal treatment of applicants



Level of Involvement - Benefits

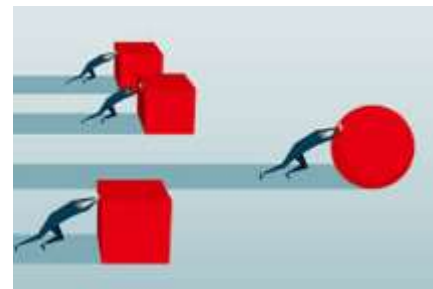
The new process forces us all to invest more effort at the beginning of a certification project, in the familiarisation and the risk assessment. This means that, on average, applicants receive comments and potential findings earlier - thus facilitating the rest of the compliance demonstration process.

→ Efficiency increase in time

- it is easier to implement changes and to take into account those comments early in the process
- the increased predictability improves the project planning

→ Efficiency increase in costs

- it is cheaper to adapt or correct the certification programme at the beginning than later on



Level of Involvement - The new rule

21.A.15 & similar

for applicants

An application for a type-certificate or restricted type-certificate shall include, as a minimum, preliminary descriptive data of the product, the intended use of the product and the kind of operations for which certification is requested. In addition, it **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**: [...]

5. a proposal for a **breakdown of the certification programme into meaningful groups of compliance demonstration activities and data**, including a proposal for **the means of compliance and related compliance documents**;

6. a proposal for **the assessment of the meaningful groups of compliance demonstration activities and data, addressing 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 safety or environmental protection. The proposed assessment shall **take into account** at least the elements set out in subpoints (1) to (4) of **point 21.B.100(a)**. Based on this assessment, the application shall **include a proposal for the Agency's involvement** in the verification of the compliance demonstration activities and data; and [...]

Level of Involvement - The new rule

21.B.100

for EASA

(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 APU. 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 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.

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.

Level of Involvement – overview new rules

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					

Deletion of point 21.A.263(b)

(b) Subject to point 21.A.257(b), the Agency shall accept without further verification the following compliance documents submitted by the applicant for the purpose of obtaining:

1. the approval of flight conditions required for a permit to fly; or
2. a type-certificate or approval of a major change to a type-certificate; or
3. a supplemental type-certificate; or
4. an ETSO authorisation under point 21.A.602B(b)(1); or
5. a major repair design approval.



This is now covered by the new LOI concept

LOI – Risked based approach

- Introduction of a documented risk-based Level of Involvement (LOI) approach in Part 21
 - which is part of the certification programme; which itself is part of the application
- **Key to LOI**: what is the risk on which the LOI determination is based on? Part 21 describes it explicitly
 - The **likelihood** that a non-compliance with the certification basis remains unidentified
 - The potential **impact** of that unidentified non-compliance on product safety or environmental protection



LOI at a glance

Applicant proposes

EASA determines

1. Certification programme is broken down into **meaningful groups** of compliance demonstration activities and data.
2. **Proposal/determination** of the likelihood of an unidentified non-compliance with the certification basis based on the novelty, complexity, and DOA specific performance **per meaningful group**.
3. **Proposal/determination** of the impact of such unidentified non-compliance at the product level based on the criticality **per meaningful group**.
4. These result in a risk class (between 1 and 4) **per meaningful group**.
5. **Proposal/determination** of the EASA involvement in the verification of the compliance demonstration activities and data **per meaningful group** based on the risk class.

Questions and answers



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How to apply the new requirements on LOI?

AMC 21.B.100(a)
and 21.A.15(b)(6)

- Explains how to propose EASA's LOI for each meaningful group of compliance demonstration activity and data as per points 21.A.15(b) (6), 21.A.93(b)(3)(iii), as well as 21.A.113(b); and
- how EASA will determine its LOI on the basis of the criteria established in point 21.B.100

NEW

AMC 21.A.15(b)(5)

- Explains how to break down the certification programme into meaningful group of compliance demonstration activity and data

NEW

GM 21.A.15(c)

- Provides guidance on updating the certification programme

NEW

GM 21.A.20(b)

- Provides guidance on the reporting of unexpected difficulties or events encountered during the compliance demonstration

NEW

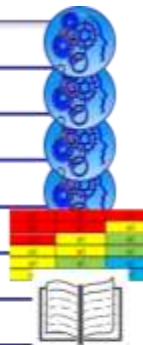
Additional informative material: CM on LOI

*Mirrored in the AMC
21.B.100(a) and 21.A.15(b)(6)*

*Generic criteria
for LOI
determination
applicable to all
Panels*

*Panel specific
criteria*

- Criteria for determining novelty
- Criteria for determining complexity
- Criteria for determining the performance of the organisation
- Determination of the likelihood of an unidentified non-compliance
- Criteria for determining severity
- Determination of the level of involvement
- Definition of the activities associated with each level
- Specific aspects of novelty
- Specific aspects of complexity
- Specific aspects of the performance of the organisation
- Specific aspects of severity
- Specific aspects related to the involvement per LOI level



- ❑ The **generic criteria** are applicable to all aspects of the certification project,
- ❑ **Specific criteria** complement them at the panel level

The overall picture: How to determine the LOI?



Compliance demonstration data / activities retained by the Agency.

	<u>Risk Class 1:</u> no further involvement
	<u>Risk Class 2:</u> few documents, no or low participation
	<u>Risk Class 3:</u> class 2 “plus” ..
	<u>Risk Class 4:</u> class 3 “plus” ..

Identification of Risk Class

Step 1: Likelihood of an unidentified non-compliance

Performance of the organisation (e.g. design, production, maintenance)	Low	Medium	High
Low	Low	Medium	High
Medium	Medium	High	Very High
High	High	Very High	Critical

Step 2: Risk classes

Severity	Low	Medium	High
Low	Class 1	Class 2	Class 3
Medium	Class 2	Class 3	Class 4
High	Class 3	Class 4	Critical

Assessment of likelihood of unidentified non-compliance and its criticality...

... using the 4 criteria provided by Part 21 (novelty, complexity, organisation performance + criticality)

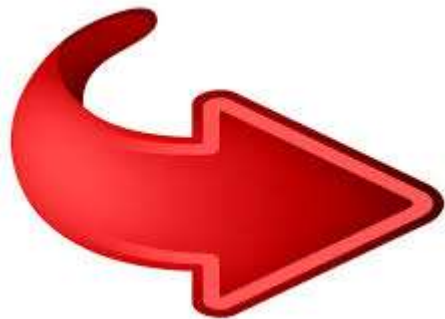
How?

How?

How?

Preparation of LOI proposal

- According to point 21.A.15(b)(5), as a first step, the applicant has to propose a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data



Such a breakdown is referred to as a CDI in the AMC/GM.

CDI = Compliance Demonstration Item

Preparation of LOI proposal

Why the grouping (into CDI)?

It is a tool to facilitate the risk assessment at a meaningful level !



Preparation of LOI proposal

The grouping of compliance demonstration activities and data into CDI ...

... may be **per panel, discipline, ATA chapter, or MOC**;

... may result in various **sizes, natures and compositions of CDIs**, but should group meaningfully related items;

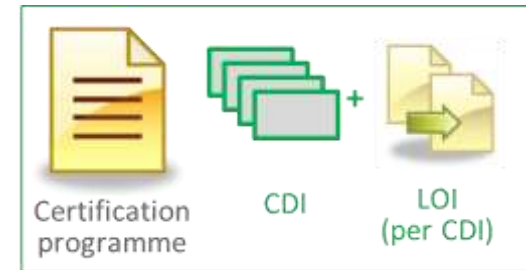
... may be tailored to the scope and size of the project.



... on **simple projects**, involving only one discipline, may be performed at the level of the project.

Preparation of LOI proposal

The breakdown of the Certification Programme into CDIs ...



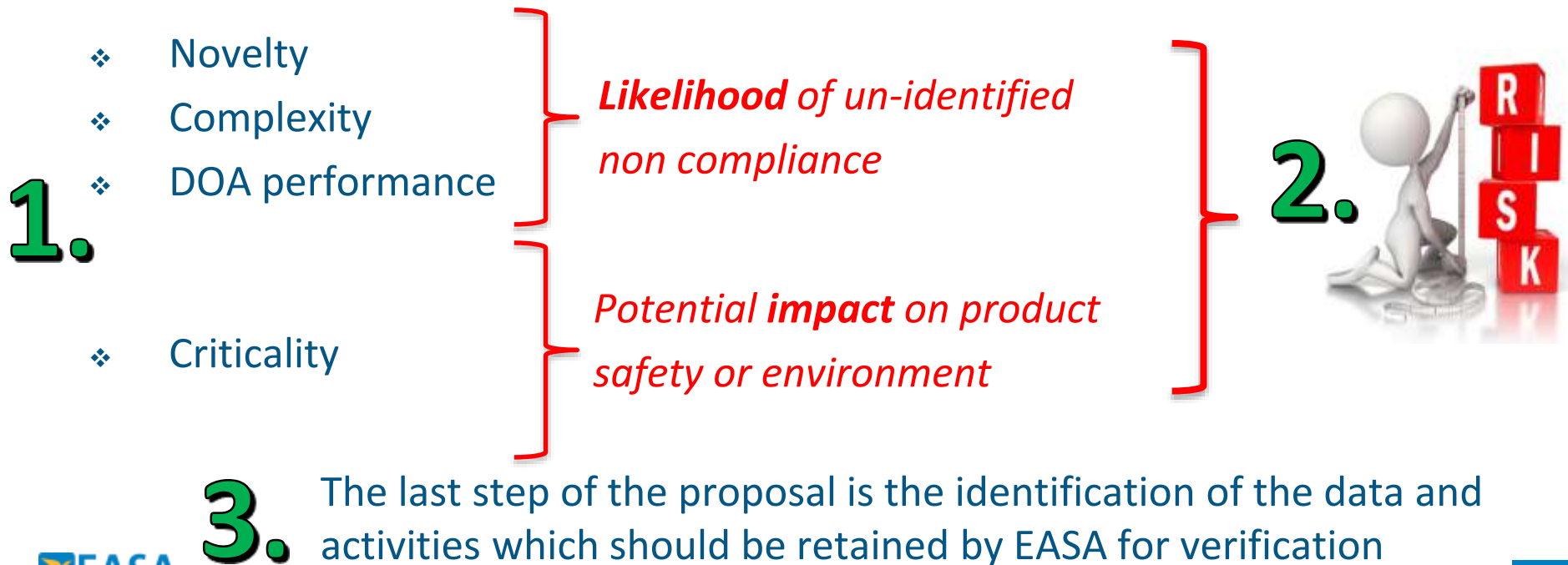
EXAMPLE

Paragraph	Title	ToR	MoC	Report	Compliance Demonstration Item
1303	Flight and navigation instruments	6(P)	1	<ul style="list-style-type: none"> ✓ Report No 2008/211 – Avionic System for MOD2008/037 ✓ Report No 2008/212 – Avionics and Cockpit Layout, Design Criteria Validation and Verification for MOD2008/037 	✓ CDI2008/037_01 – Avionic System
1309	Equipment, systems and installation	5(P) 6(P)	3	<ul style="list-style-type: none"> ✓ Report No 2008/217 – FHA for MOD2008/037 ✓ Report No 2008/218 – SSA for MOD2008/037 	✓ CDI2008/037_03 – FHA and SSA
1321	Arrangement and visibility	6(P)	1	✓ Report No 2008/211 – Avionic System for MOD2008/037	✓ CDI2008/037_01 – Avionic System
		6(P)	1	✓ Report No 2008/212 – Avionics and Cockpit Layout, Design Criteria Validation and Verification for MOD2008/037	✓ CDI2008/037_01 – Avionic System
1331	Instruments using a power supply	6(P)	1	✓ Report No 2008/211 – Avionic System for MOD2008/037	✓ CDI2008/037_01 – Avionic System
		5(P)	1	✓ Report No 2008/215 – Electric System for MOD2008/037	✓ CDI2008/037_02 – Electric System
1351 (a)(b)	General	5(P)	1	✓ Report No 2008/215 – Electric System for MOD2008/037	✓ CDI2008/037_02 – Electric System
		5(P)	2	✓ Report No 2008/216 – Electric Load Analysis for MOD2008/037	
		5(P)	5	<ul style="list-style-type: none"> ✓ Report No 2008/221 – Ground Test Plan for MOD2008/037 ✓ Report No 2008/222 – Ground test Results for MOD2008/037 	

... when grouping into **large CDIs**, which may trigger the involvement of several panels, the applicant may also identify which parts of the CDI affect which panel.

Preparation of LOI proposal

Three steps for determining the LOI, using the risk-based approach and the four criteria in Part 21



The 3 steps

Step 1: Likelihood of an unauthorised use (unintentional)

	no novel or complex aspects	no novel, but complex aspects	novel, but no complex aspects
High	Very low	Low	Medium
Medium	Low	Medium	High
Low or unknown	Very low	Low	Medium

Step 2: Risk classes

Likelihood	Very low	Low	Medium	High
Severe	class 1	class 2	class 3	class 4
Significant	class 1	class 2	class 3	class 4
Minor/Critical	class 1	class 2	class 3	class 4

An arrow points from the 'High' row of Step 1 to the 'Severe' row of Step 2.

- Novelty
- Complexity
- Organisation performance

1) Assessment Likelihood

2) Determination Risk classes

- Assessment of Criticality
- Determination of risk based on likelihood & criticality

- Definition of data and activities, for which Agency will be involved

3) List of Retained Data & Activities



The 3 steps

Step 1: Likelihood of an unauthorised use (regardless of the number of complex aspects)				Step 2: Risk classes			
Performance of the organisation		Novelty, but no complex aspects		Novel, but no complex aspects		Novel and complex aspects	
High	Medium	Very low	Low	Very low	Low	Medium	High
Very low	Low	Very low	Low	Very low	Low	Medium	High
Medium	High	Very low	Low	Very low	Low	Medium	High
Low or unknown	Very low	Very low	Low	Very low	Low	Medium	High

- Novelty
- Complexity
- Organisation performance

1) Assessment Likelihood

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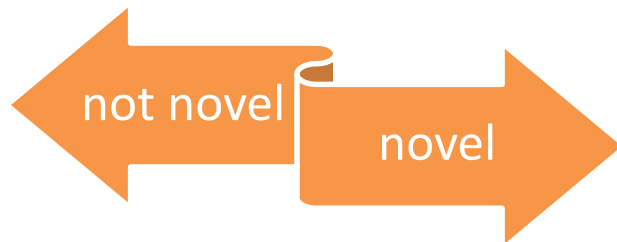
- Definition of data and activities, for which Agency will be involved

3) List of Retained Data & Activities



Assessment of the Novelty

Ratings:



→ Novelty regarding

- Technology
- Operations
- Installation
- Requirements
- Use of MOC

→ Novel for applicant or for Agency

→ Also considering time between last and current project

1) Assessment
likelihood



Examples of Novelty

CM on LOI,
attachments

AMC 21.B.100(a)
and 21.A.15(b)(6)

New Special Conditions

Recently issued or amended CS paragraphs

New Equivalent Safety Finding

New deviations

New Guidance or interpretative material

New or unusual MOC

Use of new industry standards

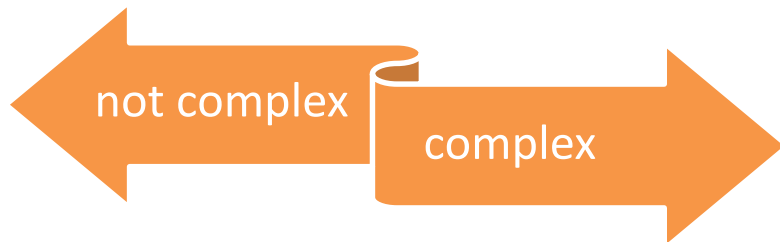
Change in methodology, tools or assumptions

Novel interpretation of the results of compliance demonstration

New guidance / interpretative material in form of CM, in case incorrect application may lead to unidentified non-compliance

Assessment of the Complexity

Ratings:



→ Complexity of

- Design
- Technology or associated manufacturing process
- Compliance demonstration (incl. test set up or analysis)
- Interpretation of results of compliance demonstration
- Interface with other technical disciplines or CDIs
- Requirements

→ Independent from the experience/performance of the applicant

1) Assessment
likelihood



Examples of complexity

CM on LOI,
attachments

AMC 21.B.100(a)
and 21.A.15(b)(6)

Complex or highly integrated system requiring more efforts from applicant

Requirements of subjective nature

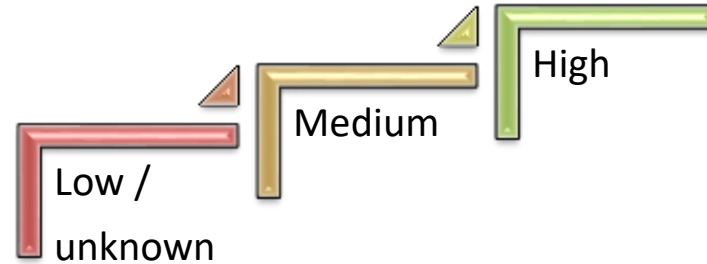
Requirements for which no MOC are described

Where complexity cannot be determined at early stage of the certification project, it shall be estimated conservatively; it can be adapted later

Performance of the organisation

AMC 21.B.100(a)
and 21.A.15(b)(6)

Ratings:



1) Assessment
likelihood



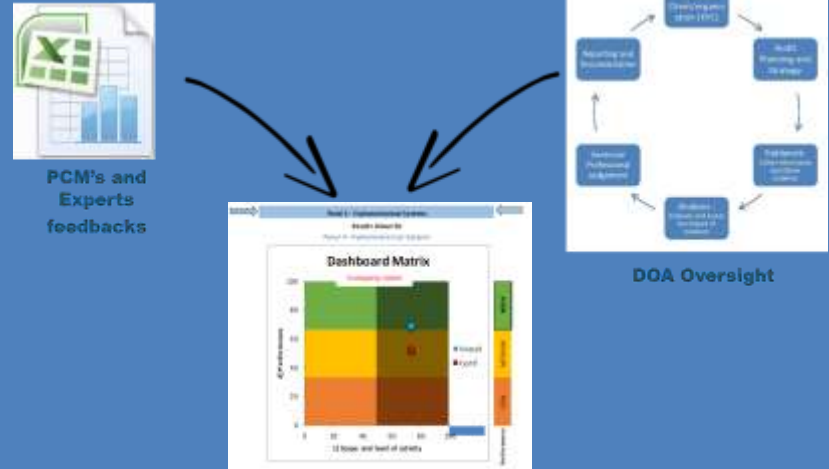
- Expected performance during the certification project applied for – based on past experience
- Different approach for DOA holders and other design organisations

Performance of the organisation - DOA holder

The performance of the DOA holder is assessed by using

- data collected by the EASA DOA Team during surveillance activities, and
- data and feedback from EASA PCMs and Experts collected at the end of, or during, a certification project.

The tool used is called 'DOA Dashboard'.



The DOA Dashboard will be updated by the EASA DOATL on a yearly basis, made available to the EASA PCM and Experts and communicated to the DOA holder.

The DOA holder uses this data in order to propose the LOI when presenting its Certification Programme and Plans.

Performance of the organisation – DOA holder

AMC 21.B.100(a)
and 21.A.15(b)(6)

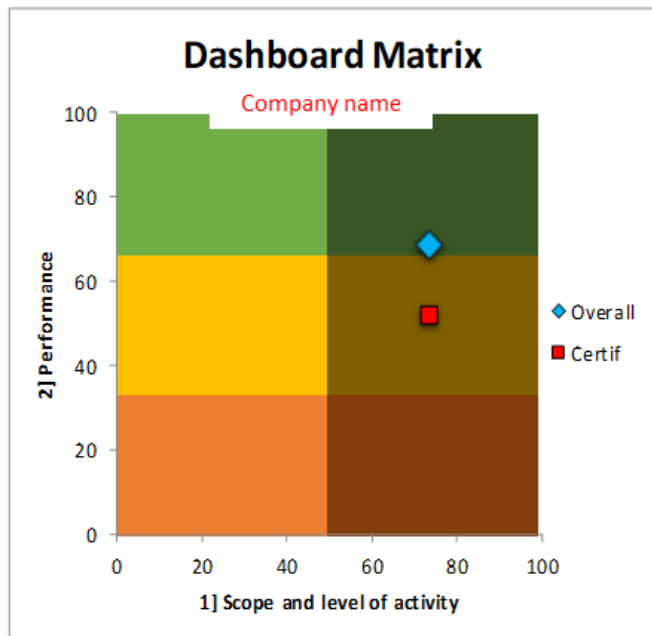
- The DOA dashboard – as communicated by EASA to the DOA holder – is the starting point for determining the performance of the organisation
- Performance data should be used as available on (discipline), panel or organisation level
- Performance data of the dashboard may be adjusted for the proposal if justified (e.g. more recent or more specific information available)

What does the DOA dashboard look like?

Panel 4 - Hydromechanical Systems

Results shown for

Panel 4 - Hydromechanical Systems



Row Labels	Planning / Com.	Requirements / MoC	Compliance dem.	Average
PCM	75	69	56	67
PE 1 - Flight	100	100	50	83
PE 3 - Structures	75	50	50	58
PE 5 - Electrical	100	50	100	83
PE 7 - Powerplant and fuel	83	83	83	83
PE 9 - Environment	50	50	50	50
PE 4 - Hydromechanical Systems	50	50	50	50
PE 1 - Flight Test and Human Factor	75	100	75	83
Grand Total	78	73	63	71

Performance of the organisation – other DOs

AMC 21.B.100(a)
and 21.A.15(b)(6)

LOI also applies to:

- applicants demonstrating design capabilities by using alternative procedures (AP) according to point 21.A.14(b), and
- applicants providing a certification programme according to point 21.A.14(c).

In principle*, same performance assessment as for DOAs, but due to the lack of an organisational approval, their performance level is established as:

‘unknown’



The 3 steps

Step 1: Likelihood of an unauthorised use (regardless of the number of complex aspects)				Step 2: Risk classes			
Performance of the organisation	Very low	Low	Medium	Very low	Low	Medium	High
High	Very low	Low	Medium	Very low	Low	Medium	High
Medium	Very low	Low	Medium	Very low	Low	Medium	High
Low or unknown	Very low	Low	Medium	Very low	Low	Medium	High

- Novelty
- Complexity
- Organisation performance

1) Assessment Likelihood

2) Determination Risk classes

- Assessment of Criticality
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- Definition of data and activities, for which Agency will be involved

3) List of Retained Data & Activities

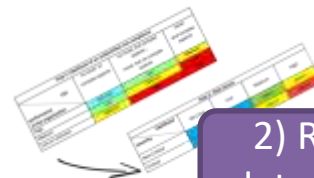
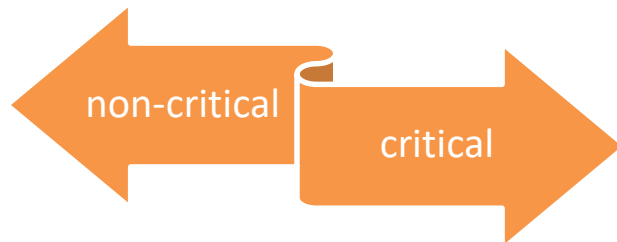


Assessment of the Criticality

CM on LOI,
attachments

AMC 21.B.100(a)
and 21.A.15(b)(6)

Ratings:



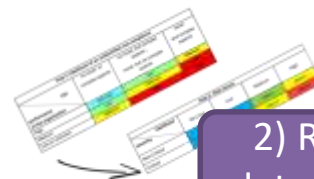
2) Risk class
determination

→ Possible criteria for “critical”:

- New or affected failure condition classified as “hazardous” or “catastrophic” at product level (e.g. 2x.1309)
- Appreciable effect on the Human-Machine-Interface
- Airworthiness limitations or operating limitations are established or potentially affected
- The CDI is affected by an AD or occurrence(s) potentially subject to AD or by a known in service issue or by a Safety Information Bulletin.

Assessment of the Criticality

AMC 21.B.100(a)
and 21.A.15(b)(6)



2) Risk class
determination

- *Where criticality cannot be determined at early stage of the certification project, it shall be estimated conservatively*
- *it can be adapted later*

Identification of the risk classes: DOA holders

AMC 21.B.100(a)
and 21.A.15(b)(6)

Step 1: Likelihood of an unidentified non-compliance			
CDI \ performance of the organisation	no novel and no 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

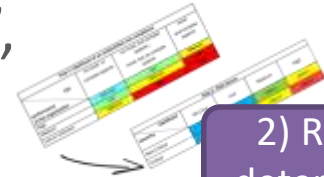
2) Risk class determination

Step 2: Risk classes				
Likelihood \ Criticality	Very low	Low	Medium	High
Non-Critical	class 1	class 1	class 2	class 3
Critical	class 1	class 2	class 3	class 4

Identification of the risk classes: other DOs

AMC 21.B.100(a)
and 21.A.15(b)(6)

→ Having rated the DOA performance as 'unknown', the risk matrix is simplified as follows:



2) Risk class determination

<i>Risk-matrix for applicant using alternative procedures to DOA</i>			
<i>Likelihood</i> <i>criticality</i>	no novel or complex aspects	no novel aspects, but with complex aspects ; with novel aspects, but no complex aspects	novel and complex aspects
Non-critical	Class 2	Class 3	Class 3
Critical	Class 3	Class 4	Class 4

The 3 steps

Step 1: Likelihood of an unauthorised use (regardless of the level of complexity)				Step 2: Risk classes			
Performance of the organisation	Very low	Low	Medium	Very low	Low	Medium	High
High	Very low	Low	Medium	Very low	Low	Medium	High
Medium	Very low	Low	Medium	Very low	Low	Medium	High
Low or unknown	Very low	Low	Medium	Very low	Low	Medium	High

- Novelty
- Complexity
- Organisation performance

1) Assessment Likelihood

2) Determination Risk classes

- Assessment of Criticality
- Determination of risk based on likelihood & criticality

- Definition of data and activities, for which Agency will be involved

3) List of Retained Data & Activities



Determining the retained data and activities

AMC 21.B.100(a)
and 21.A.15(b)(6)

3) List of
retained data



Applicant's compliance
demonstration activities and data

- ☐ Analysis
- ☐ Tests
- ☐ Audits
- ☐ Description
- ☐ Inspections
- ☐ Qualification
- ☐ etc.

Agency's compliance verification
activities as a consequence of the risk
class determined



Risk Class 1: no involvement in verification of compliance demonstration



Risk Class 2: review of some compliance data; usually no or low participation to compliance activities (tests, audits, etc.)



Risk Class 3: class 2 “plus” review of more compliance data / participation to compliance activities



Risk Class 4: class 3 “plus” review of more compliance data / participation to compliance activities

Determining the retained data and activities

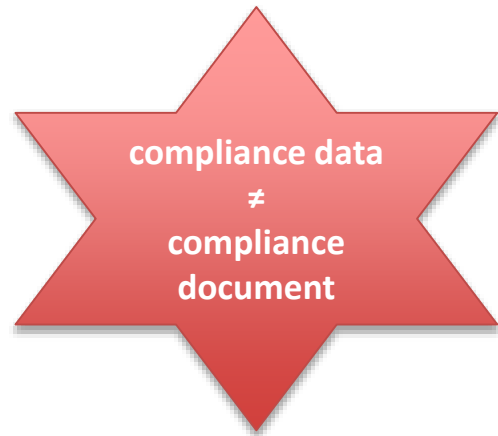


LOI means the sum of retained compliance demonstration data and activities.

(‘Retained’ means that EASA will provide feedback, i.e. comments or a statement of no technical objection)



Only parts of a document may be retained;
this will be stated in the LOI determination



Determining the retained data and activities

- Example of data and activities that are typically retained for Panel 6
- neither exhaustive nor mandatory; other data or activity may be retained as commensurable with the risk class

Class 1 No specifics.
Class 2 The involvement of the EASA experts on the project may comprise of: <ul style="list-style-type: none">• the review of the system certification plans, information summarising the main results of the compliance demonstration , and the AFM(S), and• the review of a low amount of compliance data (e.g. SFHA, compliance demonstration to CRIs or AMCs and other important compliance demonstrations). The expected number of certification meetings is likely to be limited and there should be no witnessing of test or inspections.
Class 3 In addition to risk class 2, the involvement of the EASA experts may comprise of: <ul style="list-style-type: none">• the review of key certification data such as:<ul style="list-style-type: none">• AFHA / (P)ASA / (P)SSA• Important analyses (PRA, ZSA, ...)• Important test plans and reports• The witnessing of few selected tests and inspections may be performed, and• Audits on the development assurance process may be conducted at one or two stages of the process.
Class 4 <ul style="list-style-type: none">• In addition to risk class 3, the involvement of the EASA experts comprises of the potential review of more compliance data.• The witnessing of large number of ground, simulator and/or bench certification tests and/or inspections may be performed, and• Audits on the development assurance process may be conducted at potentially all stages of the process.

3) List of
retained data



Simplified risk assessment for GA products

- For simple products, panel-specific criteria should only be considered for CDIs affecting Noise, Propulsion, DASA, OSD, Software and Airborne Electronic Hardware



simple products are those
other than CS-23 commuter
or CS-23 level 4 airplanes, CS-
25, CS-27 and CS-29 related
products

Proportionality: GA and SME



AMC allow the use of proportionality when determining the LOI (mostly to differentiate between Large Aeroplane and General Aviation)



Examples of LOI determination and templates are prepared by EASA for those GA projects with simple design and for applicants with low experience (young DOA, or DO demonstrating their design capability through acceptance of AP or provision of CP).

These examples will be provided in the EASA GA website.

Proposal of LOI (Certification Programme)

- If not obvious, the proposal of the applicant should be accompanied by a justification for each of the LOI determination criteria (novelty, complexity, criticality and DOA performance)



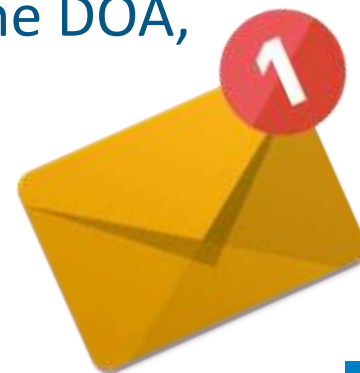
- If any of the elements required by point 21.A.15, or similar, are missing (e.g. risk assessment, LOI proposal etc.) the application will not be further processed by EASA
- EASA will request the applicant to provide the missing elements

Notification of LOI

EASA will notify the retained compliance demonstration data and activities via the acceptance of the Certification Programme.

This can be done through:

- ✓ SEPIAC,
- ✓ acceptance of specific forms proposed by the DOA,
- ✓ a specific Certification Action Item (CAI),
- ✓ a formal letter, or
- ✓ E-mail.

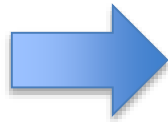


Notification of LOI



If the Agency disagrees with the applicant's LOI proposal and adjusts it, the notification of LOI will include a short explanation of those aspects where the Agency deviates from the proposal.

LOI determination is not a decision in the sense of Art 108 BR



No appeal is possible



Change / Update of LOI Determination

21.A.20(b), 21.B.100 (c)

GM 21.A.20(b)



- In case of difficulties or events encountered during compliance demonstration with an appreciable impact on the determined LOI, the Agency will re-assess the LOI determination
- The applicant shall inform the Agency of such difficulties or events (point 21.A.20 (b))
- At any stage of the project, the Agency is entitled to re-assess its LOI determination, if warranted
- This process should follow the same process as for the initial LOI determination

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Examples

→ The following are examples used by design organisations during the advanced application of LOI

Example 1 - Background

- This 'major non significant' change consists in the installation of a foldable galley with a water heater in the rear cargo area.
- This modification will allow to have another alternative configuration of the aircraft where the equipment will be unfolded to provide an inflight service of hot beverage.

Example 1 - CDIs

CDI#1. Structure and weight — General

CDI#2. Structure — Loads path

CDI#3. Electrical provisions

CDI#4. Electrical analysis

CDI#5. Cabin — General

CDI#6. Cabin — Cabin/Cargo area

CDI#7. Water circuit

Example 1 - Risk-assessment

6.2.2 CDl#2 Structure – Loads path

CDI	CDI#2 Structure – Loads path									
Content	This CDI addresses the compliance demonstration requirements regarding the potentially complex interaction of loads on the galley area.									
Concerned EASA Panel(s)	3									
Requirement(s)	25.303, 25.305, 25.307, 25.561, 25.613, 25.619, 25.625, 25.787(a)(b), 25.789(a)									
MOCs	0	1	2	3	4	5	6	7	8	9
	X		X							
Technical note(s)	EC-3935/17, EC-3959/17 and EC-5019/17									

Risk based analysis for EASA Lol proposal

CDI#2 Structure – Loads path					
	Criteria	Justification	Proposed classification		Risk
Likelihood	Novelty	Neither new material nor new demonstration methods will be used.	No	Low	Class 2
	Complexity	Interaction of loads on the area could prove to be of some complexity.	Yes		
	DOA Performance	As per DOA Dashboard (21/12/2017) for Panel 3	High		
Severity	Criticality	-	Yes		

Proposed EASA Level of involvement

Based on the obtained risk class according to the assessment shown in the previous table, and specific guidance provided by the EASA, the proposed Agency's level of involvement in this CDI is for Panel 3 to review technical notes: EC-3935/17, EC-3959/17 and EC-5019/17.

Example 1 - Risk-assessment

6.2.6 CDI#6 Cabin- Cabin/Cargo area

CDI	CDI#6 Cabin – Cabin/Cargo area										
Content	This CDI gathers all cabin/cargo area classification related compliance demonstration.										
Concerned EASA Panel(s)	11										
Requirement(s)	25.855 and 25.857(b)										
MOCs	0	1	2	3	4	5	6	7	8	9	
	X										
Technical note(s)	EC-1317/18										

Risk based analysis for EASA Lol proposal

CDI#6 Cabin – Cabin/Cargo area				
	Criteria	Justification	Proposed classification	Risk
Likelihood	Novelty	Cabin/Cargo area <u>classification</u> compliance demonstration is considered to be novel for the applicant.	Yes	Medium <u>Class 3</u>
	Complexity	[] compliance demonstration is based on already existing non-complex area demonstrations (Flammability and smoke detection tests already performed and certified).	No	
	DOA Performance	As per DOA Dashboard (21/12/2017) for Panel 11.	Medium	
Severity	Criticality	-	Yes	

Example 1 - LOI Proposal

6.3. TYPE DESIGN CHANGE Deliverables

Document Reference	Document title	Issue	MC	Linked CDIs	EASA Concerned Panels	Linked Risk Class ¹	Retained	Availability Date	EASA agreement date ²
EC-3566/17	Current Type Design Change Certification programme	3	-	-	3, 5, 8, 11	-	Yes	17/01/2018	TBD
EC-4053/17	Installation limitations note	1	0	4	5	2	Yes	04/2018	TBD
EC-1283/18	Pressurised cabin loads	1	0	5	11	1	No	04/2018	-
EC-1317/18	Statement Note for Cabin/Cargo area	1	0	6	11	3	Yes	04/2018	TBD
EC-3886/17	Description Note	1	1,0	1	3	1	No	04/2018	
				5	11	1	No		-
EC-3887/17	Statement Note	1	0	1	3	1	No	04/2018	-
				5	11	1	No		-
EC-3888/17	Statement Note	1	0	5	11	1	No	04/2018	-
EC-3889/17	Equipment Qualification for Flammability	1	9	5	11	1	No	04/2018	-
EC-3891/17	Design Inspection	3	7/5	1	3	1	No	04/2018	-
				3	5	1	No		-
				7	8	1	No		TBD

Example 1 - LOI Proposal

Document Reference	Document title	Issue	MC	Linked CDIs	EASA Concerned Panels	Linked Risk Class ¹	Retained	Availability Date	EASA agreement date ²
EC-3935/17	Toilet partition stress analysis	1	0	2	3	2	Yes	04/2018	TBD
				5	11	1	No		-
EC-3959/17	PNC partition stress analysis	1	2	2	3	2	Yes	04/2018	TBD
				5	11	1	No		-
EC-4017/17	Statement Note and equipment qualification for Water Circuit installation	3	0/9	1	3	1	No	04/2018	-
				7	8	1	No		TBD
EC-4018/17	Statement Note and equipment qualification for electrical installation	1	0/9	3	5	1	No	04/2018	-
EC-4561/17	Flammability Test	1	4	5	11	1	No	04/2018	-
EC-5019/17	Galley F3 load stress analysis	1	2	2	3	2	Yes	04/2018	TBD
				5	11	1	No		-
EFW-4999/17	Statement of Compliance	1	0	1	3	1	No	04/2018	-

Example 2 – background

- this ‘major not significant’ change consist of the installation of a new avionic suite based on digital instruments for primary flight information and analogue instruments for engine information.

Example 2 – Certification Programme

Paragraph	Title	ToR	MoC	Report	Compliance Demonstration Item
1321	Arrangement and visibility	6(P)	1	✓ Report No 2008/211 – Avionic System for MOD2008/037	✓ CDI2008/037_01 – Avionic System
		6(P)	1	✓ Report No 2008/212 – Avionics and Cockpit Layout, Design Criteria Validation and Verification for MOD2008/037	✓ CDI2008/037_01 – Avionic System
		1(P)	1	✓ Report No 2008/212 – Avionics and Cockpit Layout, Design Criteria Validation and Verification for MOD2008/037	✓ CDI2008/037_05 – Flight
1331	Instruments using a power supply	6(P)	1	✓ Report No 2008/211 – Avionic System for MOD2008/037	✓ CDI2008/037_01 – Avionic System
		5(P)	1	✓ Report No 2008/215 – Electric System for MOD2008/037	✓ CDI2008/037_02 – Electric System
1351 (a)(b)	General	5(P)	1	✓ Report No 2008/215 – Electric System for MOD2008/037	✓ CDI2008/037_02 – Electric System
		5(P)	2	✓ Report No 2008/216 – Electric Load Analysis for MOD2008/037	
		5(P)	5	✓ Report No 2008/221 – Ground Test Plan for MOD2008/037 ✓ Report No 2008/222 – Ground test Results for MOD2008/037	

[...]

Example 2 - Risk assessment

6.4.3. CDI2008/037_02 – Electric System

CDI No	CDI2008/037_02
CDI Title	Electric System
Primary Panel(s)	Panel 5 – Electric System
Secondary Panel(s)	-
Requirements	1301(d) 1331 1351(a)(b) 1357(c)(d) 1365(a) 1367(a) 1529 1581 CRI E-101 1351 CRI O-101 1351(b) CRI O-101 1431 CRI F-103
Approach	This CDI will focus on the electric system description, electric load analysis and ground tests.

Table 7 – CDI2008/037_02 – Electric System: likelihood of an unidentified non-compliance

Criteria	Classification	Justification	Likelihood ⁴
Novelty	No	<p>The philosophy of the electric system is unchanged, only small changes are made in order to allow the installation of the new avionic suite.</p> <p>MD302 instrument is equipped with a lithium battery despite this Tecnam proposes not to consider this as a novelty since it is already installed on other aircraft (P2010 and P2006T); moreover the instrument (and the battery) has a high qualification level.</p> <p>None of the "Specific aspects of novelty" from ref.[2.8] Attachment 5 is met.</p>	Very Low
Complexity	No	None of the "Specific aspects of complexity" from ref.[2.8] Attachment 5 is met.	
DOA performance	High	In accordance with DOA dashboard, ref.[2.9].	

Example 2 - LOI

Table 8 – CD12008/037_02 – Electric System: Determination of the Agency's level of involvement

Criteria	Classification	Justification	Risk ⁵
Criticality	No	None of the "Specific aspects of severity" from ref. [2.8] Attachment 5 is met.	<u>Class 1</u>
Likelihood	Very Low	In accordance with Table 8.	

Table 9 – CD12008/037_02 – Electric System: deliverables for showing of compliance

Report No	Title	Requirement	ToR	MoC	Ed.	Rev.	State	Date	EASA Review ⁶	EASA Witnessing
2008/100-S8	AFM supplement for MOD2008/037	1581	1, 5	1	1	0	Open	11/09/17	No	N.A.
2008/101-S6	AMM supplement for MOD2008/037	1529	5	1	1	0	Open	11/09/17	No	N.A.
2008/215	Electric System for MOD2008/037	1331, 1351(a)(b) 1357(c)(d) 1365(a) 1367(a) CRI E-101 1351 CRI O-101 1351(b)	5	0, 1, 2	1	0	Closed	-	No	N.A.
2008/216	Electric Load Analysis for MOD2008/037	1351(a)(b) 1357(c)(d) 1365(a)	5	2	1	0	Closed	-	No	N.A.
2008/221	Ground Test Plan for MOD2008/037	1301(d) 1351(a)(b) CRI O-101 1351(b) CRI O-101 1431	5	5	1	0	Closed	-	No	No
2008/222	Ground test Results for MOD2008/037	1301(d) 1351(a)(b) CRI O-101 1351(b) CRI O-101 1431	5	5	1	0	Open	31/07/17	No	No

Example 2 - LOI

Table 16 – CDI2008/037_05 – Flight: likelihood of an unidentified non-compliance

Criteria	Classification	Justification	Likelihood ¹³
Novelty	No	Avionic system is based on MD302 instrument which is already installed on P2010 and P2006T aircraft. G3X system is already installed on P2008JC: being its functions unchanged this CDI can be considered as not novel.	Low
Complexity	Yes	The showing of compliance will also focus on the HMI. In accordance with the "specific aspects of complexity" listed in ref.[2.8] Attachment 1 is met.	
DOA performance	High	In accordance with DOA dashboard, ref.[2.9].	

Table 17 – CDI2008/037_05 – Flight: Determination of the Agency's level of involvement

Criteria	Classification	Justification	Risk ¹⁴
Criticality	Yes	HMI is affected.	Class 2
Likelihood	Low	In accordance with Table 17	

Table 18 – CDI2008/037_05 – Flight: deliverables for showing of compliance

Report No	Title	Requirement	ToR	MoC	Ed.	Rev.	State	Expected	EASA Review ¹⁵	EASA Witnessing
2008/100-58	AFM supplement for MOD2008/037	1581 1589(a) 1303	1, 2, 5, 6	1	1	0	Open	11/09/17	Yes	N.A.
2008/212	Avionics and Cockpit Layout Design Criteria Validation and Verification for MOD2008/037	1321 CRI O-101 1321 CRI O-101 1381(a)(b)	1	1	1	0	Open	14/08/17	No	N.A.
2008/223	Weight and Balance for MOD2008/037	25(b) 29(a) 1301(d) 1431 CRI O-101 1381(a)(b) CRI O-101 773	2	2	1	0	Progr.	31/07/17	No	N.A.
2008/224	Flight Test Programme for MOD2008/037	1301(d) 1431 CRI O-101 1381(a)(b) CRI O-101 773	1, 5, 6	6	1	0	Progr.	31/07/17	Yes	No
2008/225	Flight Test Results for MOD2008/037	1301(d) 1431 CRI O-101 1381(a)(b) CRI O-101	1, 5, 6	6	1	0	Open	11/09/17	No	No

Other examples

→ Example from Tecnam at minute 54:00:

https://www.youtube.com/watch?v=K0D9aBJDEcl&list=PLTfS24aKkJn5BPBzeSpgl_R0kGED_2n4-&index=2

→ Example from EAD and Lufthansa Technik at 1:46:00:

<https://www.youtube.com/watch?v=gQ6mGeJMITQ>


Possible approaches

- It is possible to built the certification programme in many different ways, for example:
 - Top down approach (starting from the certification basis)
 - Bottom-up approach (starting from the compliance demonstration activities and data)
 - Mixed approach
 -

Top down approach

Paragraph	Title	MoC	Data / Activity	Document reference and issue	Affected EASA Panel	CDI	Risk Class	Retained verification of compliance demonstration
CS 25.xxxx		1	Compliance Report 2017/251 Electrical System ... for Mod XY		P5	A	2	Not retained
			Compliance Report 2017/167 Avionics System ... for Mod XY		P6	B	1	Not retained
CS 25.xxyy		6	Test Plan 2017/335		P1, P6	C	3/2	Retained P1/P6
			Test Performance		P1	C	3	Retained P1
			Test Report 2017/336		P1, P6	C	3/2	Not retained
CS 25.xxyx		1	Compliance Report 2017/123 Electrical System ... for Mod XY		P5	A	2	Not retained
CS 25.xxyy		9	Qualification Test Plan		P3, P5, P11	D	2/3/4	Retained P5/P11
			Qualification Test		P11	D	4	Retained P11
			Qualification Test Report		P3, P5, P11	D	2/3/4	Retained P11
CS 25.xyyx		1	Compliance Report 2017/166		P6			Not retained

plus separate Risk Assessments per CDIs A, B, C and D based on the criteria Novelty, Complexity, Severity, DOAH Performance



CDI	Title/Description	EASA Panel	Novelty	Complexity	DOAH Performance	Criticality	Risk Class
A		P5	No	No	medium	critical	2
B		P6	No	No	high	critical	1
C		P1, P6	Yes	Yes	medium/high	non-critical	3/2
D		P3/P5/P11	Yes	Yes	high/medium/low	non-critical	2/3/4

plus Justifications to Novelty, Complexity, Criticality, DOAH Performance if not obvious

Bottom-up approach

Proposed EASA involvement per EASA Panels											
Paragraph	Title	MoC	Data / Activity	Document reference and issue	Affected EASA Panel	Novelty	Complexity	DOAH Performance	Severity	Risk Class	Retained verification of compliance demonstration
CS 25.xxxx		1	Compliance Report 2017/251 Electrical System ... for Mod XY		P5	No	No	medium	non-critical	1	Not retained
			Compliance Report 2017/167 Avionics System ... for Mod XY		P6	No	No	high	critical	1	Not retained
CS 25.xxyy		6	Test Plan 2017/335		P1, P6	Yes	Yes	medium/high	non-critical	3/2	Retained P1/P6
			Test execution		P1	Yes	Yes	medium	non-critical	3	Retained P1
			Test Report 2017/336		P1, P6	Yes	Yes	medium/high	non-critical	3/2	Not retained
CS 25.xxyx		1	Compliance Report 2017/123 Electrical System ... for Mod XY		P5	No	No	medium	critical	2	Not retained
CS 25.xxyy		9	Qualification Test Plan		P3, P5, P11	No	Yes	high/medium/low	critical	2/3/4	Retained P5/P11
			Qualification Test execution		P11	No	Yes	low	critical	2/3/4	Retained P11
			Qualification Test Report		P3, P5, P11	No	Yes	high/medium/low	critical	2/3/4	Retained P11
CS 25.xyxx		1	Compliance Report 2017/166		P6	No	No	high	non-critical	1	Not retained
plus Justifications to Novelty, Complexity, Criticality, DOAH Performance if not obvious											

Questions & answers



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The advanced application of LOI

- Testing phase between Q3/2016 and Q4/2018
- A number of companies volunteered to already apply draft rule / draft guidance material in their certification projects
- 250+ certification projects included a risk-based determination of the Agency's involvement
 - Generally: companies had no major concerns working with draft rules

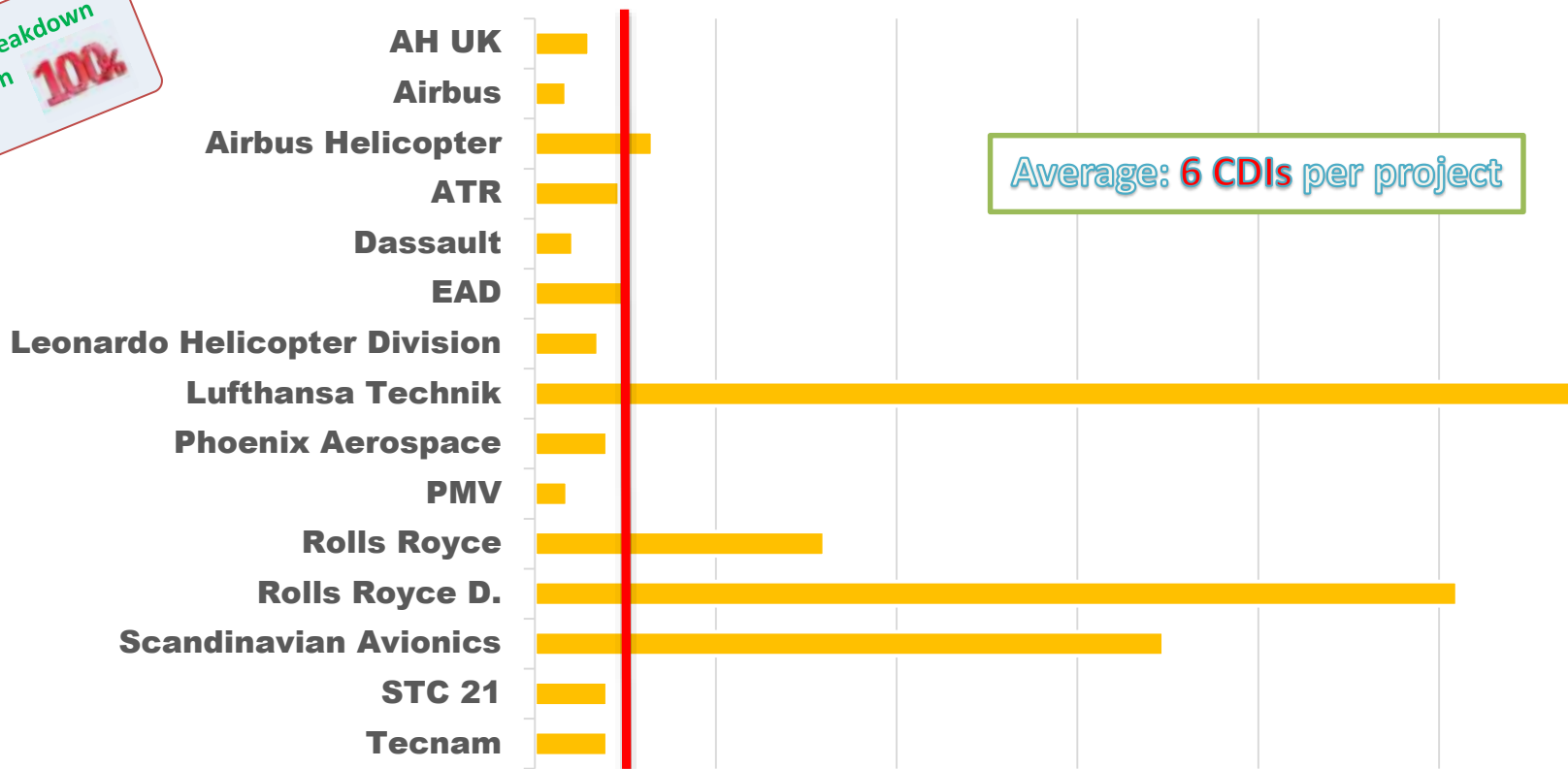


Statistics from the first 80 pilot projects

All proposed CPs breakdown
into CDIs have been
accepted..!

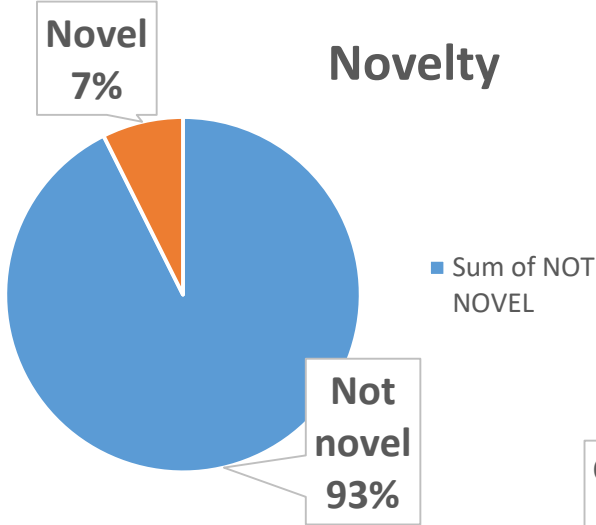
100%

of CDIs per project: 0 10 20 30 40 50

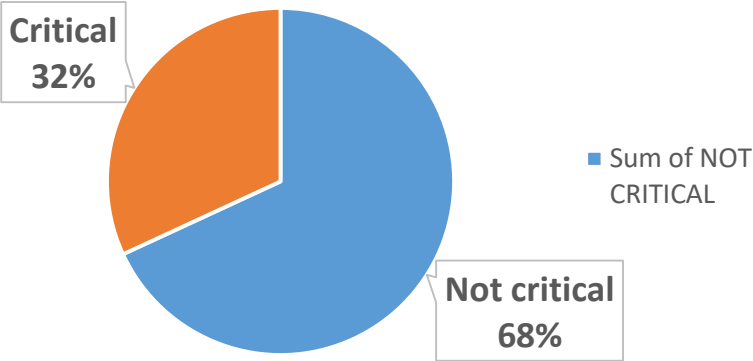


Statistics from the first 80 pilot projects

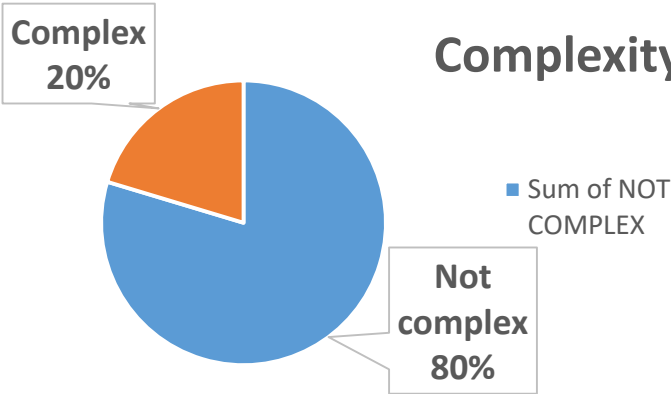
Novelty



Criticality



Complexity



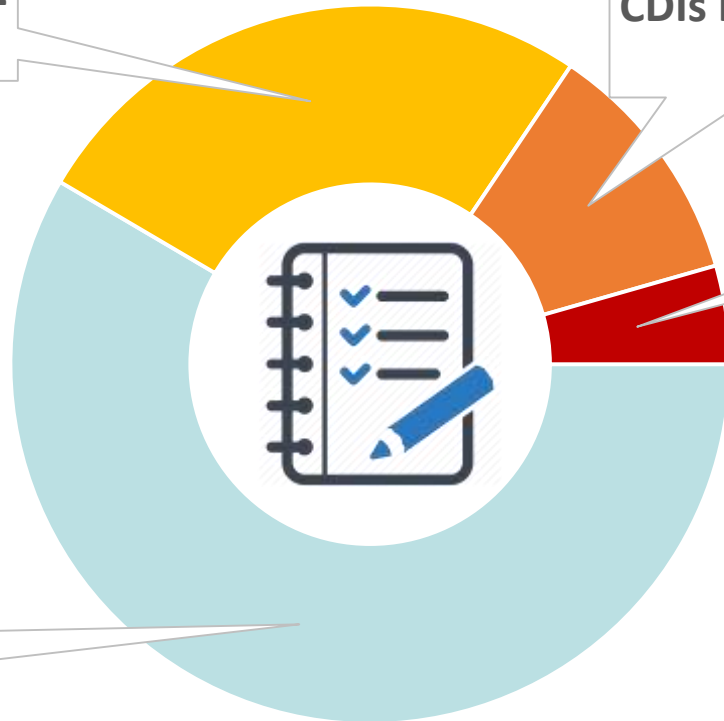
Statistics from the first 80 pilot projects

CDIs Risk class 2
26%

CDIs Risk class 3
11%

CDIs Risk class 4
4%

CDIs Risk class 1
59%

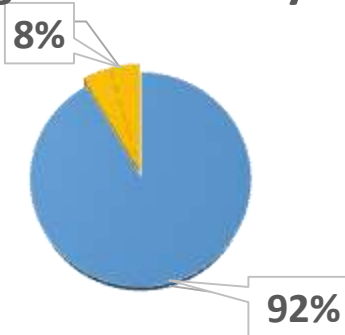


overall – after an initial increase necessary to get used to the new concept – we observed a slight decrease of Agency involvement in most of these pilot projects

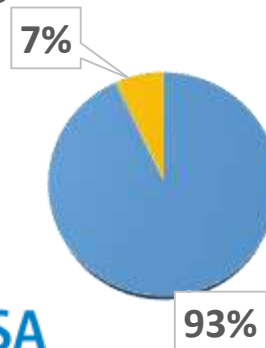


Changes during advanced application

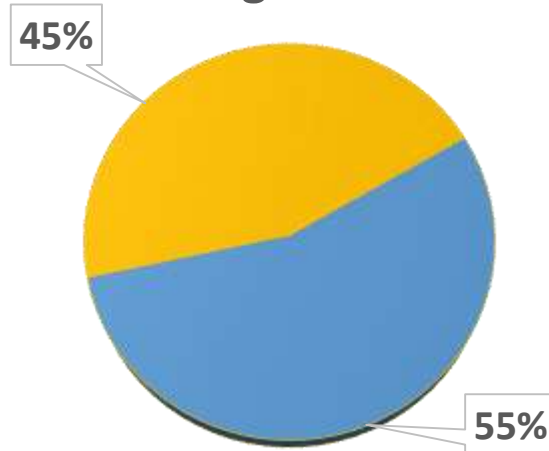
Changes on novelty



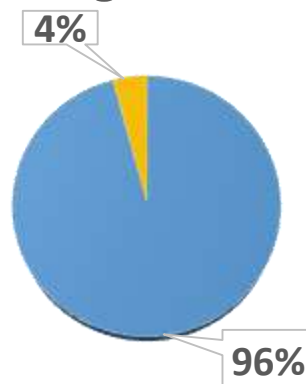
Changes on criticality



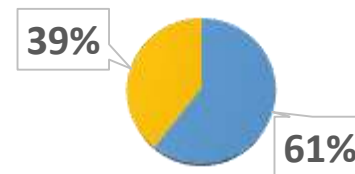
Changes at CDI level*



Changes on complexity



Changes on retained documents



**Changes at CDI level include any kind of change in the CDIs during the advanced application procedure*

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- Examples of LOI proposals
- The advanced application of new LOI concept
- Best practices and overall EASA considerations

Best practices and other hints



Grouping of elements into CDIs would facilitate the risk assessment

Case-by-case considerations should be made before deciding which CP breakdown process to follow

=> depending on the size and complexity of the project, different approaches may be beneficial.

Having the CDI reference in the table containing all the elements of the CP would automatically comply with the request to double check that each element is included in at least one CDI.

=> A template with a standard statement is not a best practice

More explanations about risk assessments would help EASA to carry out a timely assessment of the LOI proposal

=> classification of novelty-complexity and criticality is not always obvious

If a CDI affects more than one panel, consider whether the risk of unidentified non-compliance would be different per panel.

=> If yes, a split would be recommended.

Do not overcomplicate the concept

=> creation of additional intermediate steps may not be needed

Issues encountered



Mix-up of complexity
with novelty

=> demonstrations of
compliance remains complex
even if you have done it many
times

The LOI proposal does
not contain a list of
data/activities to be
retained

=> the risk-class proposal is
not the final step

If the initial LOI proposal is
modified, then following
EASA assessment/review,
the Certification Program
has to be amended
accordingly

If the CDIs are not listed in the
table of requirements and
corresponding MoC, some
elements of the CP might not
be included in any CDI => no
risk assessment!

Merging of risk classes is
not in line with the intent
of the risk-based
approach in Part 21

Other clarifications



The risk-based approach is introduced on the basis of ICAO Annex 19 to ensure a safety oversight function in accordance with established procedures in a standardised manner.

=> An increase or decrease in EASA involvement might be a side effect but is not the intent of the risk-based approach.

Risk classes are risk indicators only.
The higher the risk, the higher the involvement.

=> It is not and cannot be the intent of a risk class to have a pre-defined involvement for each possible kind of change or TC

The 4 criteria lead to 24 possible combinations. For simplification, these 24 combinations result in 4 risk classes that are of a continuous nature rather than consisting of discrete steps. Fewer than 4 risk classes would not any longer indicate the risk level in an appropriate way.

=> if a change in the criteria does not lead to a visible change in the risk class in many cases, the risk indicator would become meaningless.

A CDI is only a tool to perform the risk assessment on a meaningful level instead of performing it for each compliance document and activity

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