



EASA

European Aviation Safety Agency

LOI – update on roadmap and current activities

Leonardo Capacci

CT.7.1 Regulations & Certification Policy Section

Issue 1

STC WORKSHOP

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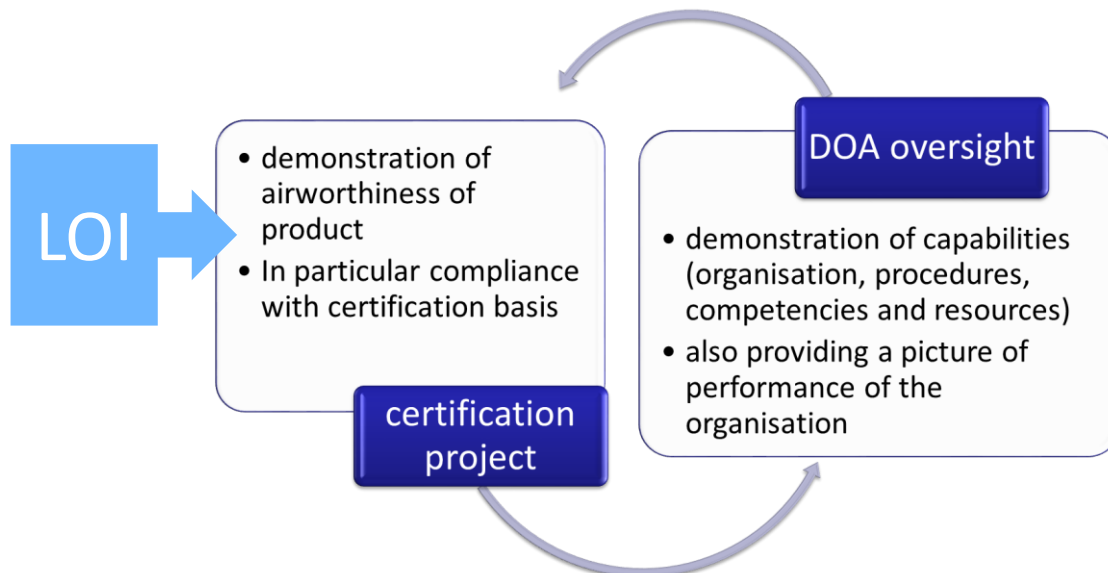
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Level of Involvement – What is it?

<< selection of the compliance demonstration activities and data that the Agency will investigate and the depth of these investigations during the certification process >>





LOI – The current situation

- Today, LOI is applied in all certification projects
- However,
 - no criteria set forth in Part-21;
 - limited guidance is available; and
 - application of LOI is not necessarily consistent
- Proposal in Opinion 7/2016 aims at improving this



Level of Involvement – What is changing?

➔ ~~LOI~~ is new approach towards LOI

- ✓ standardising the way we determine our LOI
- ✓ focussing our involvement in high risk areas



***Risk based, systematic approach
on Lol determination***



What is the risk based approach?

Dictionary meaning:

RISK = the probability of occurrence of an unwanted event multiplied by the consequence of the event.

Impact	5. Extreme					
	4. Very High					
	3. Medium					
	2. Low					
	1. Negligible					
		1. Rare	2. Unlikely	3. Moderate	4. Likely	5. Almost Certain
		Likelihood				

Application in product certification:

- Applicant demonstrates compliance (21.A.21) [and independently checks it (21.A.239)]
- EASA, before issuing the TC, needs to be convinced that compliance has been demonstrated and verified (21.A.21): i.e. involvement
- Where to be involved will have to be decided on a risk-based approach

RISK = the prediction of how likely a non-compliance with a part of the certification basis is, in combination with the potential impact of it on product safety or associated with the environment



Why we are changing approach to LOI?

- Introduction into Part-21 of a **risk-based approach** to Agency's compliance verification
- **Focus of resources** to aspects of certification projects posing higher risk
- Initiate the implementation of safety risk management standards of **ICAO Annex 19**
- Development of **objective criteria and transparent processes** and information of the Agency's involvement to the applicant





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Background

- RMT.0262 Level of Involvement
- EASA issued its opinion with a proposal for amendment of Part-21 in May 2016
- European Commission is preparing the legislative proposal for adoption
- Adoption expected soon
- Applicability currently foreseen for February 2018



Overall Roadmap

Sep 16	Oct 16	Nov 16	Dec 16	Jan 17	Feb 17	Mar 17	Apr 17	May 17	Jun 17	Jul 17	Aug 17	Sep 17	Oct 17	Nov 17	Dec 17	Jan 18	Feb 18	..
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Part-21
Amendment as per Op 07/2016

EASA Committee

Written procedure @ EASA Committee

Part-21 adopted

Transition period up to 1 Feb 2018 **(tbc)**

Certification Memo on LOI

CM public consult.

CM adopted

AMC/GM to Part-21

RMT.0262 Phase II – drafting phase of AMC/GM

NPA Public consultation (3 months)

EDD

Advanced application of new LOI concept

Advanced application by 12 volunteering DOAs

application by everybody



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Available rule proposal: The Opinion

➤ Opinion 7/2016 proposes to the European Commission the changes necessary to introduce LOI into Part-21

- i.e. the – mandatory – regulatory provisions (rights and obligations)
- Currently under discussion within the European Commission and between European Commission and the Member States



European Aviation Safety Agency
Opinion No 07/2016

Embodiment of level of involvement requirements into Part-21

RELATED NPA/CRD 2015-03 — RMT.0262 (MDM.060) — 23.5.2016

EXECUTIVE SUMMARY

This Opinion addresses a systemic issue of introduction of safety management principles into the process of airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as changes and repairs thereto in accordance with Part-21 (Annex I to Regulation (EU) No 748/2012).

The Opinion is linked with the [European Plan for Aviation Safety \(EPAS\) 2016-2020](#) action RMT.0262.

The main specific objective is to further strengthen the Part-21 certification processes performance in general, and the verification part of these processes by the European Aviation Safety Agency (hereinafter referred to as 'the Agency') in particular, so that their safety and environmental goals are consistently met in an effective and efficient manner. This will be achieved by introducing into Part-21 the new rules accommodating a risk-based approach to compliance verification through embodiment of the concept of level of involvement (LoI) of the Agency in the certification process. The risk-based LoI concept is in line with the safety risk management standards of International Civil Aviation Organization (ICAO) Annex 19, and will enable the Agency to better identify the areas of product certification more prone than others to risk with regard to safety and environmental protection. This will allow the Agency to focus its certification resources primarily on these areas that need a direct and high LoI in order to thoroughly verify that compliance has been demonstrated by applicants. In other certification areas, where the risk to product safety or environmental protection is assessed lower, the Agency may, when justified by their adequate performance, rely on approved design organisations. Moreover, this proposal will further enhance the oversight system of design organisations to become 'performance-based'. Some design organisations may obtain new design organisation approval (DOA) privileges to certify certain major changes to type-certificates (TCs), supplemental type-certificates (STCs), and/or major repair designs without the Agency's involvement, but only in technical domains where they demonstrate to the Agency their satisfactory experience and performance in compliance assurance.

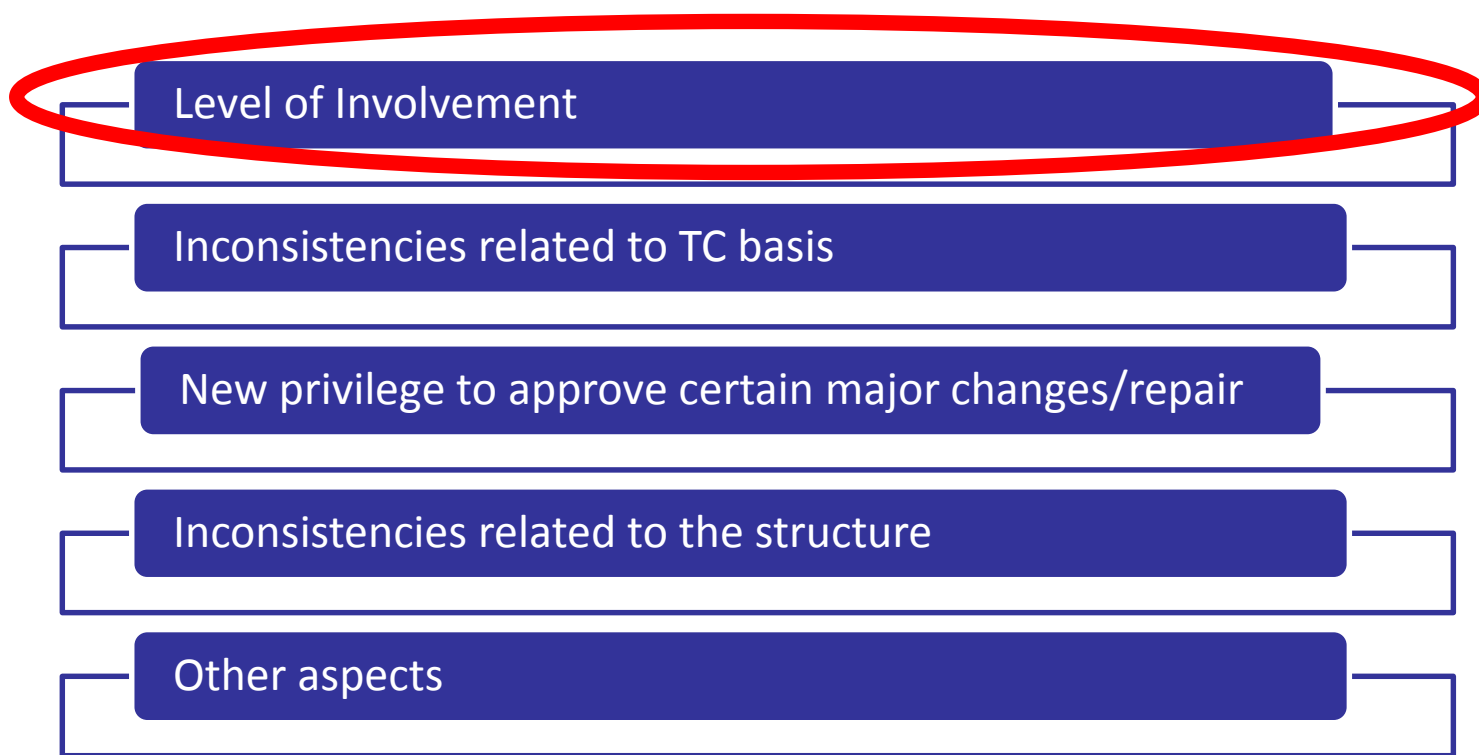
The present opinion is the first step towards transposing the ICAO Annex 19 'Safety Management' standards into Part-21. A further proposal to amend Part-21 in accordance with the ICAO safety management system (SMS) standards for design and production organisations, State Safety Programme (SSP) standards, and critical elements of a safety oversight system for the competent authorities (CAs), including the Agency, is being established by the Agency in a separate rulemaking task (RMT).

Applicability		Process map	
Affected regulations and decisions:	— Annex I to regulation (EU) No 748/2012 (Part-21)	Terms of reference (ToR), Issue 1:	27.8.2015
	— ED Decision 2012/020/R	Concept paper (CP):	Yes
Affected stakeholders:	Applicants for and holders of any certificate issued in accordance with Part-21; national aviation authorities (NAAs) contracted by the Agency to perform certain certification tasks on its behalf.	Rulemaking group (RMG):	No
		Regulatory impact assessment (RIA) type:	Full
		Technical consultation during notice of proposed amendment (NPA) drafting:	Yes
		NPA publication date:	23.5.2015
Driver/origin:	Safety, efficiency/proportionality, level playing field	NPA consultation duration:	3 months
		Review group (RG):	No
		Focused consultation:	Yes
Reference:	Please refer to Section 3.3	Decision expected publication date:	2017/Q2



Contents of the Opinion

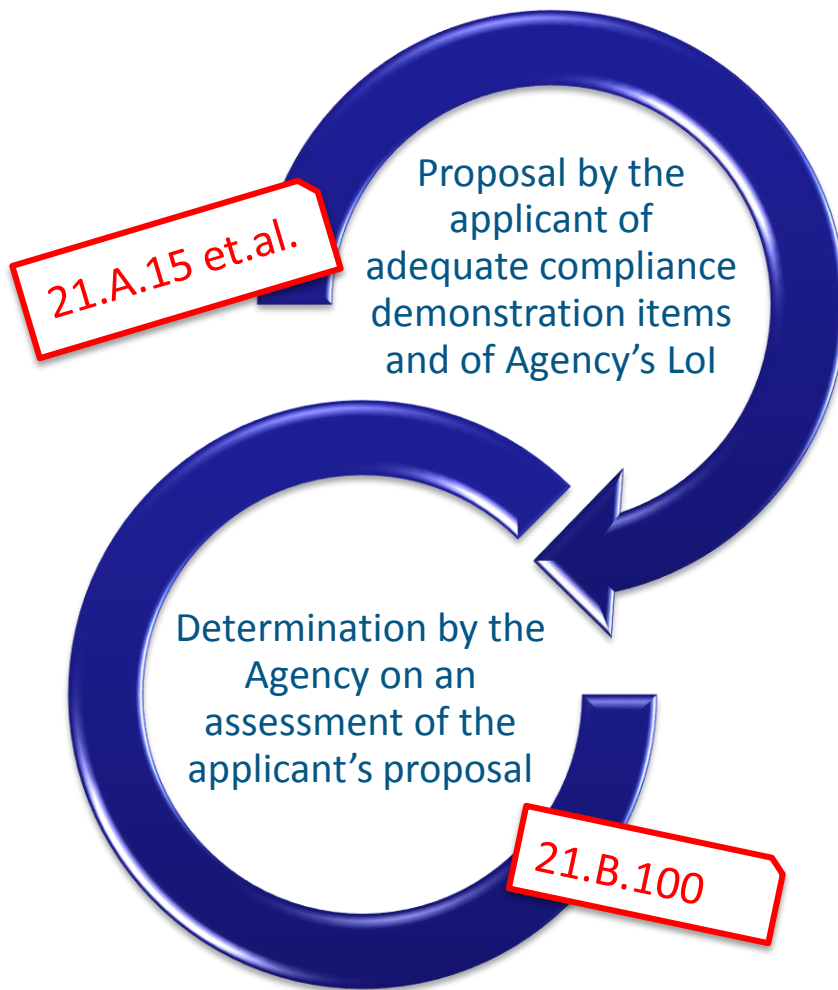
➤ Opinion 7/2016, proposal for amendment of Part-21



(proposals limited to Subparts B, D, E, J, M and O)



How is risk-based approach (LoI) introduced in Part-21?





Available guidance: The CM on LOI

- CM on LOI provides guidance on
 - the four criteria of 21.B.100 for LOI determination;
 - the relation and application of these criteria; and
 - the LOI determination
- for
 - the applicant - in order to make its LOI proposal
 - the Agency - in order to determine LOI



EASA Proposed CM No.: Proposed CM-21.A/21.B-001 Issue 01

Notification of a Proposal to issue a Certification Memorandum

Criteria for the determination of the Agency's level of involvement in product certification

EASA Proposed CM No.: Proposed CM-21.A/21.B-001 Issue 01 issued 23 January 2017

Regulatory requirement(s): 21.A.15 (b)(5) and (6), 21.A.93 (b)(3)(ii) and (iii), 21.A.113 (b), 21.B.100, 21.B.103 (a)(2), 21.B.107 (a)(2), 21.B.110 (a)(2), 21.B.115 (a)(2) and 21.B.117 (b)¹

In accordance with the EASA Certification Memorandum procedural guideline, the European Aviation Safety Agency proposes to issue an EASA Certification Memorandum (CM) on the subject identified above. All interested persons may send their comments, referencing the EASA Proposed CM Number above, to the e-mail address specified in the "Remarks" section, prior to the indicated closing date for consultation.

About Certification Memoranda

EASA Certification Memoranda clarify the Agency's general course of action on specific certification aspects. They are intended to provide guidance on a particular subject and, as non-binding material, may provide complementary information and guidance. Certification Memoranda are provided for information purposes only and must not be misconstrued as formally adopted Acceptable Means of Compliance (AMC) or Guidance Material (GM). Certification Memoranda are not intended to introduce new requirements or to modify existing requirements and do not constitute any legal obligation. Applicants may use the guidance provided in this CM in order to comply with the above mentioned regulatory requirements, but they may also propose to comply differently.

EASA Certification Memoranda are living documents into which either additional criteria or additional issues can be incorporated as soon as a need is identified by EASA.

¹ As proposed per EASA Opinion 07-2016.





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The 'new' Certification Process

Changes in green

APPLICANT

Files it
(complemented
with a first draft
of the
certification
programme)

Makes a
proposal

Provides

Makes a
proposal
(based on
risk
assessment)

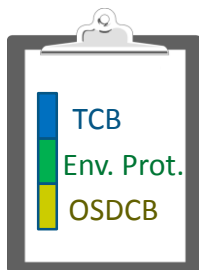
Informs EASA in
case of difficulty

Demonstrates
compliance

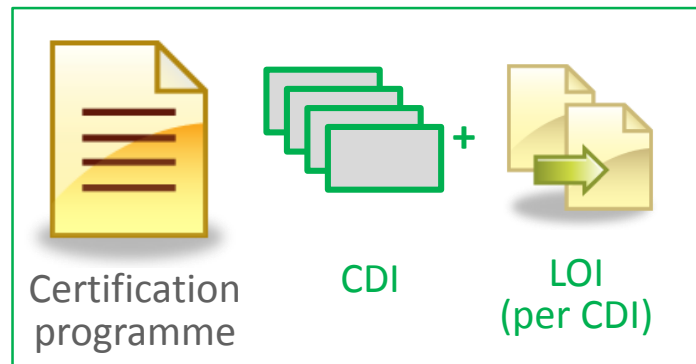
Declares
compliance



Application



TC basis
Env. Prot.
OSD CB



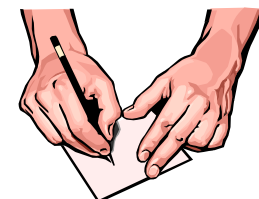
Certification
programme

CDI

LOI
(per CDI)



Compliance
demonstration
and
verification



Compliance
declaration

Accepts

Establishes
and notifies

Accepts

Determines
and notifies

Verifies
compliance

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

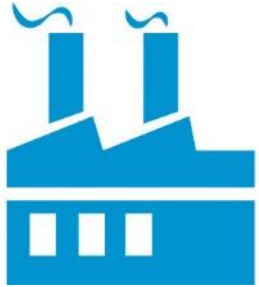
May adjust LOI





Overview on CDI

- The **Certification Program** proposed by the applicant during Tech Fam and establishment of TC basis should:
 - ✓ Identify all the CDIs
 - ✓ Identify the affected panels for each CDI
 - ✓ justify the proposed classification of CDI
 - ✓ include a proposal of LOI for each CDI



What is CDI (compliance demonstration item)?

! New Term but no new concept !

CDI is a meaningful group of compliance demonstration activities and data taken from the certification programme, which can be considered in isolation for the purpose of demonstrating compliance.



LOI proposal – the concept

The applicant proposal shall be made using the **Risk-Based** approach introduced in the Part-21 and further explained in the CM on LOI, it considers the following criteria:

- 1**
 - ❖ Novelty
 - ❖ Complexity
 - ❖ DOA performance

Likelihood of unidentified non compliance
- 2**
 - ❖ Severity

Potential impact on product safety or environment
- 3** The last step of the proposal is the identification of the activities and/or data which should be retained by EASA.

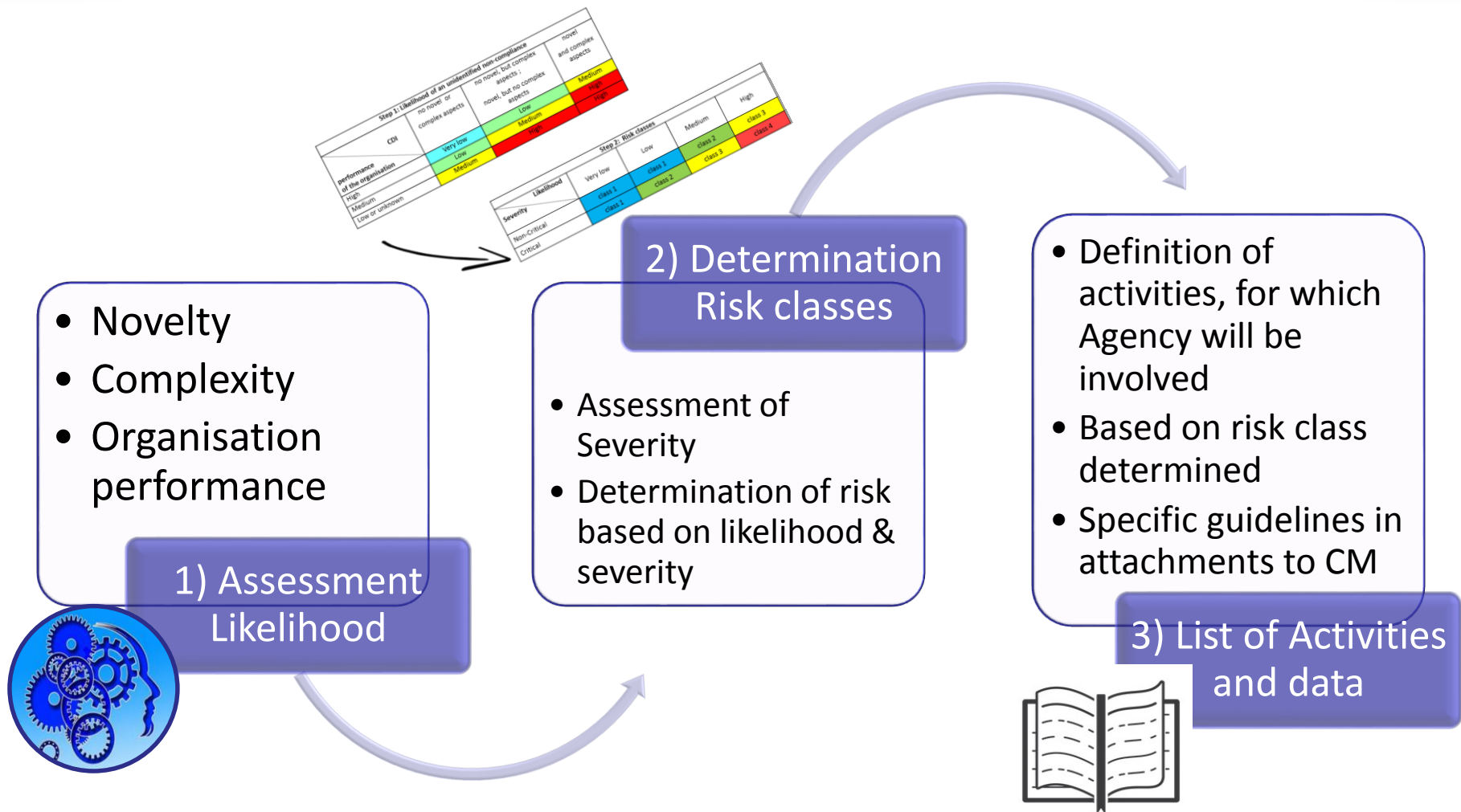
Step 1: Likelihood of an unidentified non-compliance			
	no novel or complex aspects	no novel, but complex aspects or novel, but no complex aspects	novel and complex aspects
High	Very low	Low	Medium
Medium	Low	Medium	High
Low / unknown	Medium	High	High



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



LOI proposal – the concept



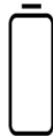


LOI proposal – list of activities

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



Class 1: no further involvement after C.P. agreement



Class 2: review of few documents; low participation to compliance activities (tests, audits, etc)



Class 3: class 2 “plus” more documents/participation



Class 4: class 3 “plus” more documents/participation



To be noted!

- Lol is proposed as part of the cert. programme
- Agency determines Lol
 - after familiarisation
 - on the basis of the accepted certification programme
 - sufficiently detailed means and methods of compliance
 - before applicant starts compliance demonstration

Phase I – Technical Familiarisation and establishment of the Initial Type Certification Basis
Phase II – Acceptance of the Certification Programme and determination Level of Involvement
Phase III – Applicants compliance demonstration
Phase IV – Final Report and issue of the Certificate



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BACK-UP SLIDES

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Consequences on Design Assurance System



TC/STC holders



- Application for significant changes in the DAS to be submitted and accepted before a new certification project is launched after the transition period
- The application shall cover the implementation of the new elements introduced by 21.A.15 and 21.A.20.



Minor repair/changes



- Application for significant changes in the DAS is **NOT needed**.
- DOA procedures may be adapted to incorporate the new LOI concept

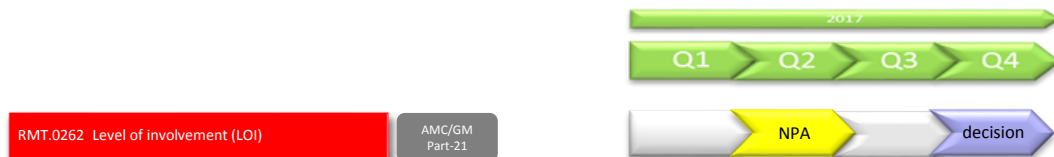


Exceptions may be done for DOAs already having LOI in their procedures



Implementation of Lol

- AMC/GM will be developed in Phase 2 of this RMT



- In the meantime, a CM will provide guidance in order to support industry in preparing for the application of Lol, namely on
 - the four criteria of 21.B.100 for LOI determination;
 - the relation and application of these criteria; and
 - the LOI determination
- Guidance will be tested while being developed (via advanced application projects)



- Draft CM was published on 23 January 2017
- Consultation period ended 6 March 2017
- 87 comments received from 9 commentators
- EASA is reviewing the comments and finalising the CM for adoption
- CM planned to be adopted upon publication / entry into force of the Part-21 amendment