



**EASA**  
European Aviation Safety Agency

# **Product Certification and Design Organisation Approval Workshop**

**22<sup>nd</sup> -23<sup>rd</sup> November 2016**

**Your safety is our mission.**

An agency of the European Union 

TE.GEN.00409-001



**EASA**  
European Aviation Safety Agency

# Level of Involvement

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**22 November 2016**

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# Level of Involvement

## ➤ Session purpose

- Inform participants about Agency proposal to amend Part-21 (Opinion 7/2016)
- Inform participants about expected timeline of compliance / applicability
- Inform participants about Agency's intention to apply the new Part-21 provisions (guidance material under development)
- Discuss guidance material and of practical aspects of preparation for applicability



# Level of Involvement - 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 in the coming weeks
- Applicability foreseen for February 2018

... we have 15 months left to prepare



# Level of Involvement - Opinion

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

Risks related to the non-exhaustiveness of Agency's compliances verification (Level of Involvement)

Inconsistencies related to TC basis

Inconsistencies related to the structure

Other aspects

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



# Level of Involvement – What is it?

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





# Level of Involvement - Context

## ➤ Phases of a certification project

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

## ➤ 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 determination



# Level of Involvement - Context

- 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 - Context

## APPLICANT

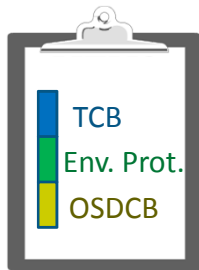
Files it

(complemented with a first draft of the certification programme)



Application

Makes a proposal

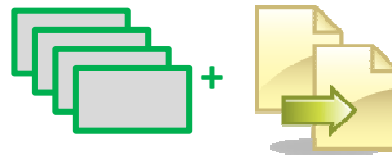


TC basis  
Env. Prot.  
OSD CB

Provides



Certification programme



CDI

LOI  
(per CDI)

Makes a proposal  
(based on risk assessment)

Determines and notifies

Informs EASA in case of difficulty

Demonstrates compliance



Compliance demonstration and verification

Verifies compliance

Declares compliance



Compliance declaration

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

May adjust LOI





# Level of Involvement - Objectives

- 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
- Implementation of safety risk management standards of ICAO Annex 19
- Development of objective criteria and transparent processes



# Level of Involvement – The concept



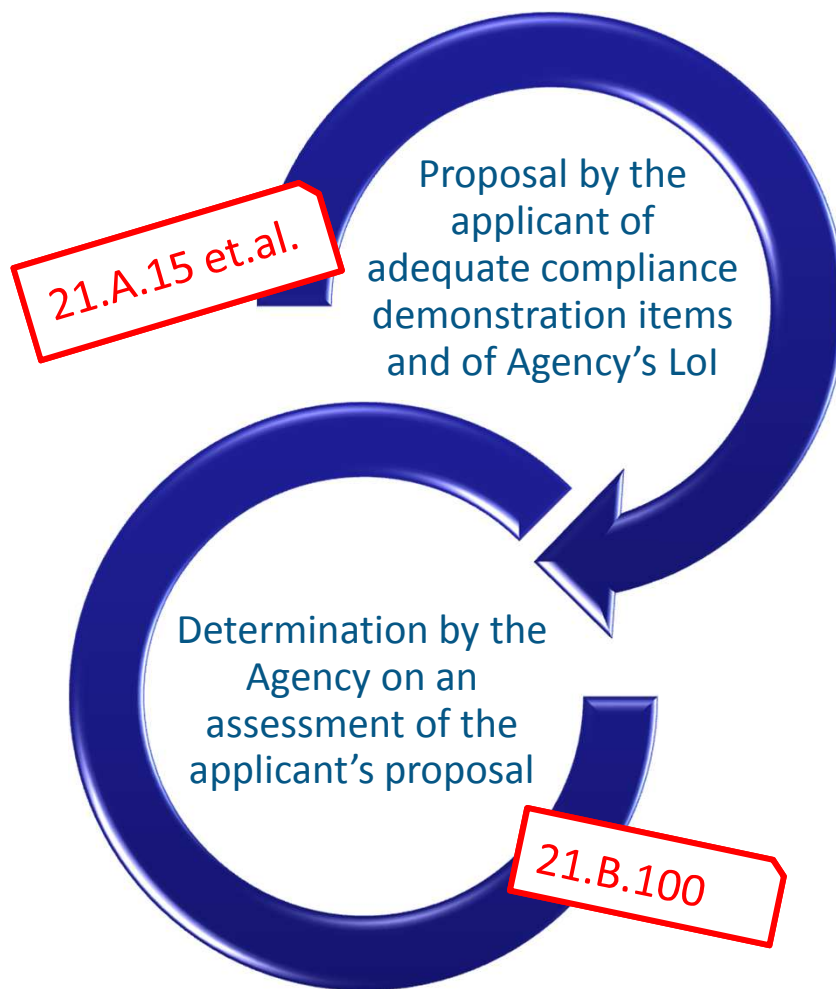
## Risk based compliance verification

- How likely is it that neither applicant (through compliance demonstration and verification) nor Agency (through compliance verification) identify a non-compliance with part of the certification basis?
- If so, what is the potential impact on product safety or associated with the environment?

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



# Level of Involvement – New Part-21



## Considering ..

21.B.100

... the likelihood that for a specific CDI the applicant does not comply with certification basis

... and its impact on the safety of the product or on the environment

... taking into account

- ❖ novelty
- ❖ complexity
- ❖ criticality
- ❖ DO performance



# Level of Involvement - Implementation

- How is this being applied in practice?
  - As part of RMT.0252 EASA has consulted and developed few basic AMC/GM, which will be published upon publication of the Part-21 amendment in the OJ
  - Phase 2 of RMT.0252 will develop further AMC/GM
  - Expected gap between adoption of AMC/GM and applicability of amended Part-21 will be bridged by providing guidance in form of Certification Memorandum (CM)
    - to be transposed later into AMC/GM



# Level of Involvement - Implementation

- CM will provide guidance on
  - the four criteria of 21.B.100 for LOI determination;
  - the relation and application of these criteria; and
  - the LOI determination

21.B.100

21.A.15 (b)(5)+(6)

- for
  - the applicant - in order to make its LOI proposal
  - the Agency - in order to determine LOI



# Level of Involvement - Novelty

## ➤ Ratings:

not novel

novel

## ➤ Novelty regarding

➤ Technology

➤ Operations

➤ Requirements

➤ Use of MOC

## ➤ Novel for applicant or for Agency

## ➤ Also considering time between last and current project





# Level of Involvement - Novelty

## ► Examples







# Level of Involvement - Complexity

## ➤ Ratings:

not complex

complex

## ➤ 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





# Level of Involvement - Complexity


## ► Examples

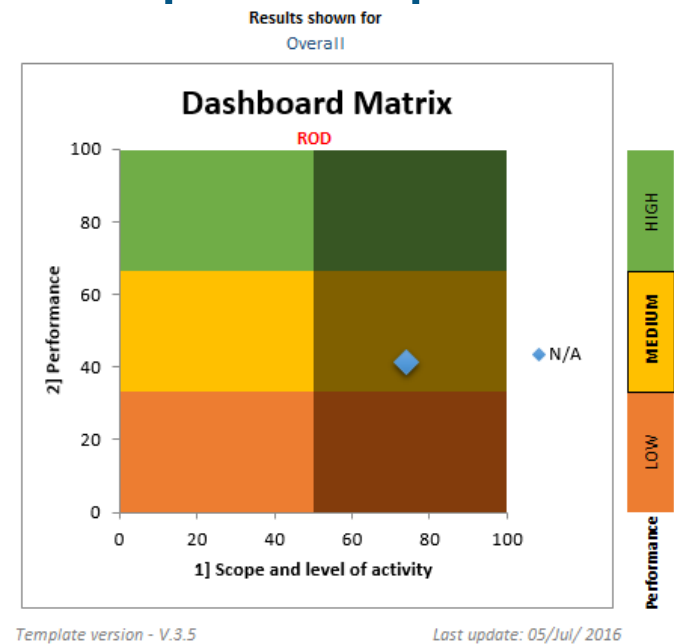


- Where complexity cannot be determined at early stage of the certification project, it shall be estimated conservatively; it can be adapted later



# Level of Involvement – Org. Performance

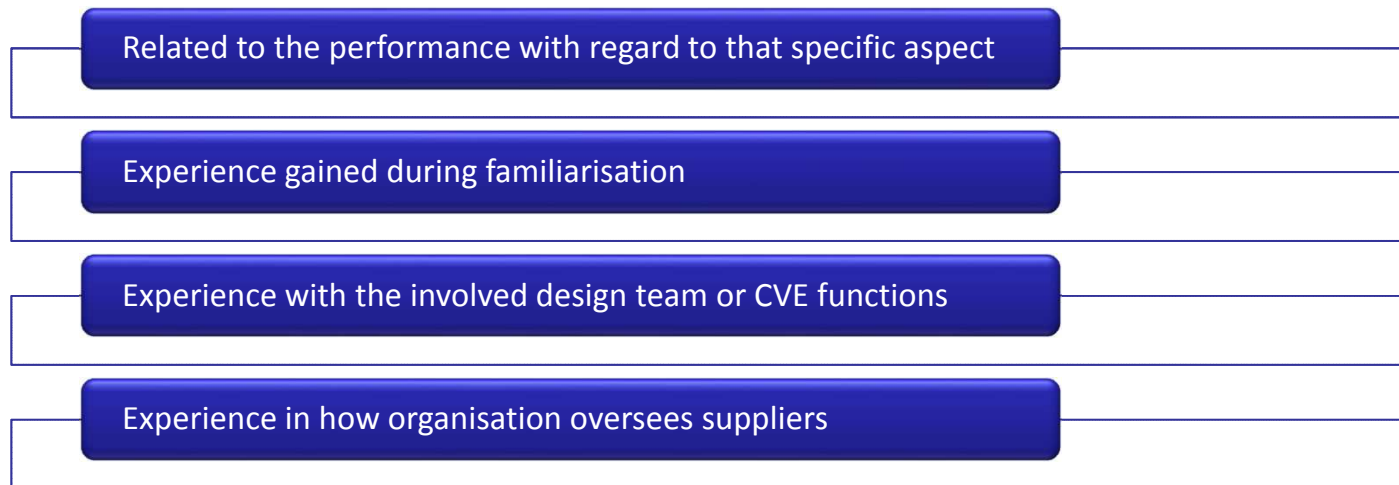
- Ratings: 
- Expected performance based on past experience
- Starting point
  - DOA dashboard
  - as available on (discipline), panel or organisation level
  - where dashboard is not available, applicant should propose “medium”
  - Agency will complete / adapt according to data available; or - where not sufficient data available - rate as “unknown”





# Level of Involvement – Org. Performance

- Deviations from dashboard possible where more specific or more recent information is available about the organisation, e.g.





# Level of Involvement - Severity

## ➤ Ratings:



## ➤ Possible criteria for “critical”, where

- failure effect classified as “hazardous” or “catastrophic” at a/c level (e.g. 2x.1309)
  - Human-Machine-Interface is affected
  - airworthiness limitations or operating limitations are altered
  - an AD is affected
- 
- ## ➤ Where severity cannot be determined at early stage of the certification project, it shall be estimated conservatively; it can be adapted later



# Level of Involvement – LOI Determination

## ➤ The CM applies those criteria as follows:

the likelihood that for a specific CDI the applicant does not comply with certification basis

- Novel aspects of the CDI
- Aspects of complexity of the CDI
- Performance of the Design Organisation

its impact on the safety of the product or on the environment

- Criticality

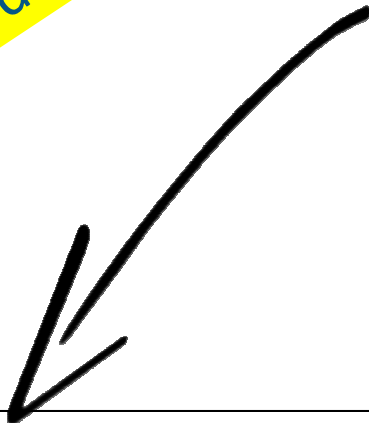
### Examples

- high performing DO + novel, but not complex = likelihood low  
if the impact on product safety is not critical that could mean low Lol
- Low performing DO + novel and complex = likelihood high  
if the impact on product safety is critical that could mean high Lol



# Level of Involvement – LOI Determination

Possible determination  
(still under discussion)



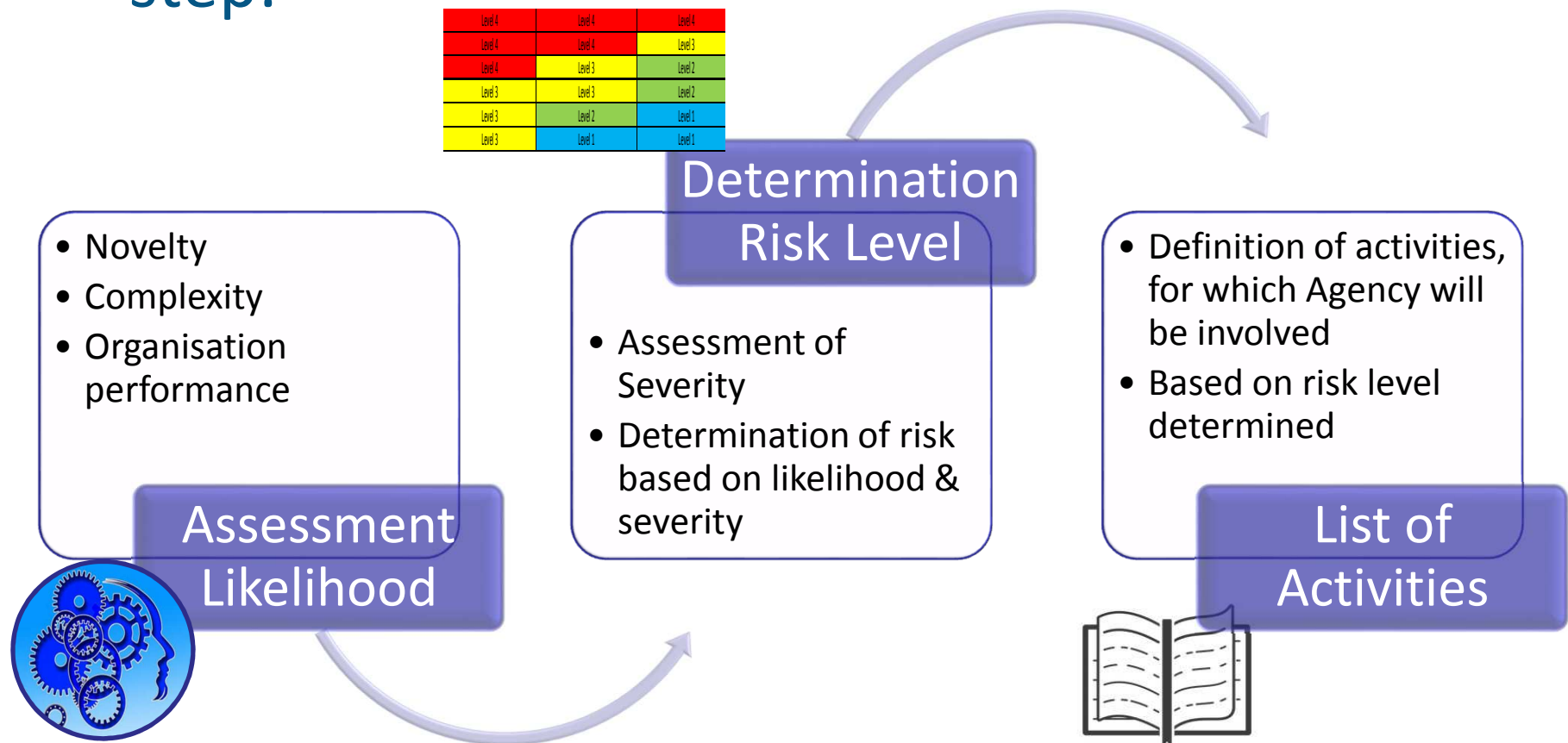
Step 1: Likelihood of an unidentified non-compliance			
CDI \ Organisation Performance	no novel or complex aspects	no novel, but complex aspects ; novel, but no complex aspects	novel and complex aspects
High	Very low	Low	Medium
Medium	Low	Medium	High
Low or unknown	High	High	High

Step 2: Determination of the Agency's level of involvement				
Likelihood \ Severity	Very low	Low	Medium	High
Non-Critical	Level 1	Level 1	Level 2	Level 3
Critical	Level 1	Level 2	Level 3	Level 4



# Level of Involvement – LOI Determination

➤ Determination of the risk level is not the last step:





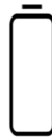


# Level of Involvement – LOI Determination

## Applicant's compliance demonstration activities

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

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



**Level 1: No further involvement**



**Level 2: Review of few documents; low participation to compliance activities (tests, audits, etc.)**



**Level 3: Level 2 “plus” more documents/participation**



**Level 4: Level 3 “plus” more documents/participation**



# Level of Involvement – What else?

- Update certification programme throughout the project
- Report difficulties and events encountered during compliance demonstration, which may necessitate to amend the Lol
- Agency can amend Lol at any time

**within certification project**

**outside certification project**

- Agency will sample project files and review Lol application during DOA surveillance process



# Level of Involvement – CM structure

- The above represent generic criteria applicable to all aspects of the certification project
- Panel specific criteria have been developed

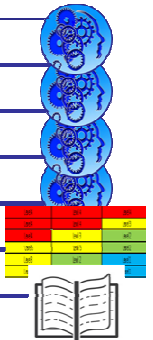
## ➤ CM Structure:

**Generic  
criteria for LoI  
determination  
applicable to  
all Panels**

**17 Attachments  
with Panel  
specific criteria  
& examples**

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





## Level of Involvement – CM establishment

- The draft CM will be publicly consulted beginning 2017
- Agency accepted proposals from some companies to
  - voluntarily apply with the proposed Part-21 changes in ongoing projects; and
  - test the guidance being developed so far



# Level of Involvement – Advanced application

## What is the advanced application of new LOI concept?

- A voluntary application of the initial guidance material for LOI determination developed by the Agency considering a risk-based approach
- The main scope is to test these guidelines in an operative environment identifying opportunities for their improvement, if needed
- 10 DOAs voluntarily accepted to participate. They represent large aircraft manufactures, General Aviation manufacturers and STCs holders:

<b>Airbus</b>	<b>Airbus Helicopter</b>	<b>ATR</b>	<b>Dassault Aviation</b>	<b>Diamond</b>
<b>Lufthansa Technik</b>	<b>Rolls Royce</b>	<b>Sabena Technics</b>	<b>Scandinavian Avionics</b>	<b>Tecnam</b>

- The advanced application started in mid Sept 2016



## Level of Involvement – Advanced application

### How is the advanced application of new LOI progressing?

- 2 DOAs has already launched its first certification process under the new LOI concept. LOI has been determined without specific difficulties.
- 1 DOAs made an application in October 2016 for certification processes under the new LOI concept. LOI determination is currently still ongoing.
- 2 DOAs have identified the first processes to be managed under the new LOI concept. LOI determination is not started yet.
- 2 DOAs are still selecting the more suitable processes to be first managed under the new LOI concept. The relevant applications are expected within the end of 2016.

**No major problems have been encountered so far on LOI determination**





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**End slide**

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