EASA
European Aviation Safety Agency

The new LOI concept, description and updates

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STC WORKSHOP
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Your safety is our mission.

An agency of the European Union

Our journey through the new LOI…

- The main principles of LOI
- Why a new LOI concept?
- Practical changes in the certification process
- CDI, a new-entry in Part-21
- The Risk assessment
  - Novelty
  - Complexity
  - DOA holder performance
  - Criticality
- 4 Risk classes
- Overall Roadmap
- The advanced application
  - Some statistics
  - Lessons learnt
- Other initiatives
- LOI for AP to DOA or CP
- Examples of LOI implementation
  - EAD Aerospace
  - LHT

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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 >>

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The issue

- The current Part-21 does not provide rules regarding how the Agency determines its involvement

  - it implicitly recognises that the Agency's verification activities are non-exhaustive
  - *but there are no criteria for determining an LoI*
  - *it does not reflect safety management principles (hazard identification and related risks to product safety)*

The objectives

- To include a risk-based approach to the Agency's compliance verification in Part-21
  - to focus resources on aspects of certification projects posing higher risk

- To develop objective criteria and transparent processes
  - controlled processes
  - a degree of predictability
  - equal treatment for applicants
- To initiate the implementation of the safety risk management standards of ICAO Annex 19 into Part-21

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The 'new' Certification Process

Changes in green..

APPLICANT

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

Makes a proposal

Provides

Makes a proposal (based on risk assessment)

Informs EASA in case of difficulty

Demonstrates and verifies 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 by sampling

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

May adjust LOI

EASA

To be noted!

- LoI is proposed as part of the cert. programme
- The Agency determines its LoI
  - after technical familiarisation
  - on the basis of the certification programme to be accepted
  - sufficiently detailed means and methods of compliance
  - before the applicant starts the 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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Compliance Demonstration Item

- Part-21 will require a risk assessment to be made at Compliance Demonstration Item level
- CDI is a new element – what is it?

CDI
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 performing the risk assessment

Risk assessment => CDI

- Why was it necessary to create this new element?

CDI: a tool to facilitate the risk assessment at a meaningful level !

- Otherwise – using existing elements – the risk assessments would need to be made at the level of each compliance demonstration activity / data, or at the level of the certification project: **<u>often impracticable!</u>**

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The risk assessment

What is the **risk-based** approach?

Dictionary meaning

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

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 using a risk-based approach

Opinion 07/2016:

RISK = likelihood of an unidentified non-compliance with a part of the certification basis in combination with its potential impact on product safety or environmental protection

How to determine the risk

According to the new point 21.B.100(a) the risk shall be assessed at CDI level taking into account (at least) the following elements :

- Novelty
- Complexity
- DOA performance
- Criticality

1.

Likelihood *of un-identified non compliance*

Potential ***impact*** *on product safety or environment*

2.

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Criteria 1: Novelty

- Ratings: not novel → novel
- Novelty regarding
  - Technology
  - Operations
  - Installation
  - Requirements
  - Use of MOC
- Novel for applicant or for Agency
- Also considering time between last and current project

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Criteria 2: 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

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Criteria 3: DOA holder performance

- Ratings: low / unknown → medium → high
- Expected performance based on past experience
- Starting point
  - DOA holder dashboard
  - as available on (discipline), panel or organisation level
- deviations possible where more specific or more recent information is available

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Criteria 4: Criticality

- Ratings: non-critical → critical
- Some criteria are derived from the GM 21.A.91
- Possible criteria for “critical”, where
  - failure effect classified as “hazardous” or “catastrophic” at aircraft / 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 Safety Information Bulletin.
- Where criticality cannot be determined at early stage of the certification project, it shall be estimated conservatively; it can be adapted later.

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Potential ***impact*** *on product safety or environment*

2.

The risk classes

According to the proposed AMC '21.B.100(a) and 21.A.15(b)(6)' the 4 criteria identified in point 21.B.100(a) shall be combined using the following matrices to determine the risk of each CDI:

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**

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**

From risk class to ”retained/non-retained”

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 further involvement
	Risk class 2: review of few documents; low participation to compliance activities (tests, audits, etc)
	Risk class 3: risk class 2 “plus” more documents/ participation
	Risk class 4: risk class 3 “plus” more documents/ participation

From risk class to “retained/non-retained”

Example (Panel 6 – Avionic System)

Class 1

No specificities.

Class 2

The involvement of the EASA experts on the project may comprise of:

- 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:

- the review of key certification data such as:
  - 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

- 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.

Extract from CM LOI, Attachment 6

The proposal of retained data and activities

LoI means the sum of retained compliance demonstration data or activities.
Retained means that EASA should provide feedback, i.e. comments or a statement of no technical objection

compliance data ≠ compliance document

<u>Consequence:</u> Parts of a document may be retained

This is in particular the case for “large” documents

LOI proposal process – the 3 STEPS

To summarise..

- 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 should be involved
- EASA determines its LOI on the basis of the proposal received

3) List of Retained Data & Activities

Specific guidelines to all 3 steps are in the AMC '21.B.100(a) and 21.A.15(b)(6)' and in the CM on LOI

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Background – proposed changes to Part-21

RMT.0262 Level of Involvement (LOI)

- August 2013
  ToR and Concept Paper
- June 2015
  Public consultation of a draft proposal (NPA 2015-03)
- May 2016
  EASA issued opinion 7/2016 with a proposal for amendment of Part-21

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) — ED Decision 2012/020/R	Terms of reference (ToR), Issue 1:	27.8.2013
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.	Concept paper (CP):	Yes
Driver/origin:	Safety, efficiency/proportionallity, level playing field	Rulemaking group (RMG):	No
Reference:	Please refer to Section 3.3	Regulatory impact assessment (RIA) type:	Full
		Technical consultation during notice of proposed amendment (NPA) drafting:	Yes
		NPA publication date:	2.3.2015
		NPA consultation duration:	3 months
		Review group (RG):	No
		Focused consultation:	Yes
		Decision expected publication date:	2017/Q2

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https://www.easa.europa.eu/document-library/opinions/opinion-072016

Background – proposed changes to guidance material

RMT.0262 Level of Involvement (LOI)

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

EASA

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)(1) and (6), 21.A.93 (b)(3)(ii) and (iii), 21.A.115 (b), 21.B.100, 21.B.105 (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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- January 2017

  Public consultation of CM on LOI

  https://www.easa.europa.eu/sites/default/files/dfu/%27proposed%27%20CM-21.A_21.B-001%20Issue%2001_Criteria%20for%20the%20determination%20of%20the%20Agency%27s%20level%20of%20involvement%20in%20product%20certification_PUBL.pdf

European Aviation Safety Agency

Notice of Proposed Amendment 2017-20

Embodiment of level of involvement acceptable means of compliance and guidance material to Part-21

RMT.0262 (MDM.060)

EXECUTIVE SUMMARY

The objective of this NPA is to support the embodiment of level of involvement (LoI) and other changes into Part 21 as proposed by European Aviation Safety Agency (EASA) Opinion No 07/2016 (Phase 1). The NPA (Phase 1) proposes to amend the related Acceptable Means of Compliance (AMC)/Guidance Material (GM) to Annex I (Part-21) to Regulation (EU) No 748/2012.

EASA Opinion No 07/2016 proposed to introduce in the product certification process the safety management principles contained in International Civil Aviation Organization (ICAO) Annex 19. With said Opinion, the first step for the embodiment of LoI into Part-21 has been completed. As a second step, this NPA proposes to reflect in the related AMC/GM the amendments proposed by the Opinion. Additionally, new AMC/GM have been created and included in this NPA to cover the new elements introduced by the Opinion.

This NPA proposes AMC to support an applicant's proposal for EASA's LoI in certification projects, as well as EASA's determination of its LoI. Furthermore, GM is proposed not only on the application of a risk-based approach for determining EASA's LoI, but also on the process used. Furthermore, the GM proposed in the NPA provides guidance on the application of the new privileges for certain major changes, major repairs, and supplemental type certificates (STCs). Finally, the NPA includes new or amended AMC/GM based on the amendments to Part-21, in particular, it proposes to also relocate the guidance on those Part-21 requirements that have been moved from Section A to Section B.

The proposed changes are expected to support the implementation of the amendments to Part-21 proposed by Opinion No 07/2016. This will improve the effectiveness, efficiency, transparency, and predictability of the certification process, allowing for a better planning of the process with fewer delays as well as for a better allocation of both EASA's and the applicant's certification staff resources. In addition, compliance with ICAO Annex 19 will be achieved through the introduction of safety management system (SMS) elements into the certification process.

Action area:	Safety management		
Affected rules:	AMC/GM to Part-21		
Affected stakeholders:	Design approval holders (DAHs), EASA		
Driver:	Safety	Rulemaking group:	No
Impact assessment:	Light (ref. NPA 2013-09)	Rulemaking procedure:	Standard

*EASA rulemaking process milestones

Start (Notice of Intention) 1 — Consultation (Notice of Proposed Amendment) 2 — Decision (Certification Specifications, Acceptable Means of Compliance, Guidance Material) 3

27.8.2013 — 31.12.2017 — 2018/Q3

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- December 2017

  Public consultation of NPA 2017/20 containing AMC/GM to Part -21

  https://www.easa.europa.eu/sites/default/files/dfu/NPA%202017-20.pdf

The Current LOI Roadmap

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Advanced application of LOI

The Agency and some volunteering companies (DOA holders) have already started end 2016 to **test** the new LOI concept, in particular the draft guidance material

This test is expected to:

- ✓ identify **areas of improvements** and elaborate proposals
- ✓ identify **areas** in which the guidance material proves to be **already mature**
- ✓ **facilitate** the final application of the new LOI concept
- ✓ allow volunteering companies to **prepare for the application** of LOI

Participating companies

- ✓ Airbus
- ✓ ATR

- ✓ Dassault

- ✓ ATL
- ✓ EAD
- ✓ Lufthansa T.
- ✓ Scandinavian Av.
- ✓ PMV Engineering
- ✓ Sabena T.
- ✓ NAT
- ✓ STC 21
- ✓ Specialist Av. Serv.
- ✓ SWS

- ✓ Phoenix Aer.
- ✓ REDAM

- ✓ Airbus H.
- ✓ Leonardo H.
- ✓ Airbus H. UK

- ✓ Tecnam
- ✓ Diamond
- ✓ Grob
- ✓ Vulcanair

- ✓ Rolls Royce
- ✓ Safran H.

any other company interested in joining is welcome…

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Lessons learnt - Statistics

- from the first 54 pilot projects (420 CDIs):

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CDI: a tool to facilitate the risk assessment at a meaningful level !

Lessons learnt - Statistics

- from the first 54 pilot projects (420 CDIs):

Lessons learnt - Statistics

- from the first 54 pilot projects (CDIs):

overall – we observed a slight decrease in Agency involvement in most of the advanced application projects

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Lessons learnt

- Advanced application phase proved to be extremely useful to improve & further strengthen the guidance material
- In parallel, a lot of EASA internal discussion with PCMs, experts and DOATL took place and provided lessons learnt
- LOI concept was presented to wide audience on various occasions, e.g. public consultation of the draft LOI CM, ASD Airworthiness Meetings, STC Workshop, EASA/NAA meetings: feedback has been taken into account, …
- LOI is also being discussed with bilateral partners

Significant Outcomes

- The new process proved to be practicable
- Risk classes coherent with expectations
- No significant delays in cert of pilot projects
- Valid CDI identifications proposed
- Testing phase is attracting many volunteer companies
- Many DOAs apply systematically the new concept
- Positive feedback from training on LOI

- Reservations regarding overall LOI (both sides)
- Impact on IT Tools used by some DOAs
- More clarity needed on LOI proposal *(text adjusted)*
- Additional guidance needed on certain elements
  - *Alleviations for GA (initial draft added to NPA)*
  - *Derivative / repetitive projects (initial draft added to NPA)*

Lessons learnt – Proportionality

Simpler, lighter, better rules for General Aviation

GENERAL AVIATION

Guidance already allows the use of proportionality when determining the LOI (mostly to differentiate between LA and GA)

More generic criteria have been extracted from the panel specific examples and added to the existing generic guidance. This will allow LOI to be defined for a broader range of products (which is the case for GA products)

Examples of LOI determination will be prepared by EASA for those GA projects with simple designs and for applicants with low experience (young DOA, AP DOA, CP). These will be provided through the existing GA guidance on the EASA website

Lessons learnt - Other

- First project(s) require more effort
- In some cases, risk classes have been reduced to better meet expectations
- Administrative burdens identified and reduced
- Complexity of the guidance reduced
- Sometimes request for more (detailed) guidance
- More guidance necessary on CDI
- CP breakdown into CDIs not always complete
- Reflection of repetitiveness of compliance demonstration
- Alleviations for derivative products
- Need for specific training / explanation
- …

Our journey through the new LOI…

- The main principles of LOI
- Why a new LOI concept?
- Practical changes in the certification process
- CDI, a new-entry in Part-21
- The Risk assessment
  - Novelty
  - Complexity
  - DOA holder performance
  - Criticality
- 4 Risk classes
- Overall Roadmap
- The advanced application
  - Some statistics
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- Examples of LOI implementation
  - EAD Aerospace
  - LHT

Initiatives to support LOI implementation

WHAT	START	IN DETAIL	
Advanced application of new LoI	Oct 2016	20+ volunteering DOAs	100+ cert. pilot projects

WHAT	START	IN DETAIL	
Training of EASA PCM, experts and DOATL	Dec 2016	24 sessions performed	250+ EASA colleagues
Training of NAA staff involved in EASA certification projects	Mid 2017	~90 colleagues trained so far	Further sessions on request

WHAT	START	IN DETAIL	
DOA/Cert Workshop	Nov 2016 Nov 2017	450 pax each	
STC workshop	Apr 2017 May 2018	+100 pax each	
Roadshows for the industry in EU	Q4/2018, 2019	5 sessions out of Koln + 1 in Koln	

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Organisations using AP to DOA or CP

- Applicants using alternative procedures to DOA (or presenting the certification programme only) to demonstrate their capability are also subject to the new LOI approach

  Note: a different process applies for ETSOA applicants

- The **only** difference is that, not having a DOA, their performance level is established as 'unknown'
- The risk matrix is therefore simplified as follows:

Risk-matrix for applicant using alternative procedures to DOA			
Likelihood / *Severity*	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**

Organisations using AP to DOA or CP

- So far, advanced application phase has been limited to DOA holders only
- now that guidance material is becoming available, this may also be tested in projects where capability is demonstrated using an AP to DOA

any company interested in volunteering to apply LOI is welcome to approach us…

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EASA
European Aviation Safety Agency

Thank you.

Questions ?

Your safety is our mission.

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BACK – UP SLIDES

The rulemaking project: The rule

RMT.0262 Level of Involvement (LOI)

- August 2013
  ToR and Concept Paper
- June 2015
  Public consultation of a draft proposal (NPA 2015-03)
- May 2016
  EASA issued opinion 7/2016 with a proposal for amendment of Part-21
- Commission currently prepares the proposal for the legislative process

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) — ED Decision 2012/020/R	Terms of reference (ToR), Issue 1:	27.8.2013
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.	Concept paper (CP):	Yes
Driver/origin:	Safety, efficiency/proportionallity, level playing field	Rulemaking group (RMG):	No
Reference:	Please refer to Section 3.3	Regulatory impact assessment (RIA) type:	Full
		Technical consultation during notice of proposed amendment (NPA) drafting:	Yes
		NPA publication date:	2.3.2015
		NPA consultation duration:	3 months
		Review group (RG):	No
		Focused consultation:	Yes
		Decision expected publication date:	2017/Q2

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The ETSO context

- ETSO applicant has no DOA (except if the article is an APU)
- ETSO applicant is not regularly assessed for its procedures & processes (no DOA audits)

- The data requirements are listed in point 21.A.605, means to demonstrate compliance to be set out by applicant

Part 21.A.605 → ETSO Data Package

- Different Part 21 requirements => 21.B.100 (b)
  → different approach for LoI determination process for ETSO projects

LOI → ETSO Projects

Part 21.B.100 (b)

The 'new' Certification Process for ETSO

Changes in green..

APPLICANT

Submits

Provides

(setting out means to demonstrate compliance)

Demonstrates and verifies compliance

Informs EASA in case of any difficulty, deviation, limitation

Declares compliance

Application

ETSO Cert. basis

Certification programme

Initial LOI

ETSO Data

+

Oversight/ Witnessing

DDP

Compliance declaration

Accepts

Examines vs Scope of Work of AP-DOA

Accepts

Determines and notifies

Verifies compliance by sampling

Adjusts LOI (if necessary)

Verifies DDP

+ issues ETSOA

EASA

In conclusion

- For ETSO applicants:

Certification Programme to be submitted,

and then continues with the usual process

- For EASA:
  - EASA determines its initial LoI and notifies the applicant
    - Initial LoI (depth of investigation) is defined consistently with EASA current practice
  - LoI is adapted (reduced/increased) using a risk-based approach, project data and project evolution on the basis of the criteria provided in Part-21

LoI determination principles

- Initial LoI determination is based on the following criteria:
  - Applicant's experience in ETSO compliance
    - New AP-DOA, new APDOA scope of work, organization/ procedures changes…

  - The ETSO applicant's level of performance in the ETSO scope of work/cert basis
    - Feedback from ETSO projects in the same scope of work, period since last EASA involvement…

  - The use of novelties in the technology/design or in the means of compliance
    - Including new ETSO standards, new deviation, new limitation, new methodology/unusual means of compliance
  - The complexity of the ETSO article
    - Design, architecture, technology….
  - The criticality of the design

Organisations applying for ETSOA

- So far, advanced application phase was limited to DOA holders
- now that guidance material will become available, this may also be tested in ETSOA projects

any company interested + volunteering to apply LOI is welcome to approach us…

The proposal: Opinion 07/2016

- The opinion proposes the following amendments to Part-21:

  - Level of Involvement
  - Inconsistencies related to TC basis
  - New privilege to approve certain major changes/repair
  - Inconsistencies related to the structure
  - Other aspects

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

Implementation: The guidance (CM)

- LOI specific guidance drafted in advance; vehicle used: Certification Memorandum (CM)

- January 2017

  Public consultation of a draft CM

  https://www.easa.europa.eu/document-library/product-certification-consultations/proposed-cm-21a21b-001

- July 2017

  Finalisation of draft 2 of the CM considering the results of the public consultation

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

EASA

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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Implementation: The guidance (AMC/GM)

- Draft AMC/GM for all subjects proposed in Opinion 7/2016 are being developed (phase 2 of RMT.0262) – main elements of a.m. CM are part of it

- Nov/Dec 2017

  Public Consultation of draft AMC/GM will start in few days

- approx. Q2/3 2018

  Public Consultation of few additional draft AMC/GM

- after entry into force of Part-21 Decision adopting AMC/GM

European Aviation Safety Agency

Notice of Proposed Amendment 2017-XX

Acceptable means of compliance and guidance material to Part-21 related to the embodiment of level of involvement and other changes into Part-21'

RMT.0262 (MDM.060) – XX.XX.2017

EXECUTIVE SUMMARY

The objective of this NPA is to provide new or amended Acceptable Means of Compliance (AMC) and Guidance Material (GM) to support the embodiment of level of involvement (LoI) and other changes into Part-21 (as proposed by EASA Opinion 07/2016[1]).

The AMC/GM provides means of compliance to support an applicant's proposal for EASA's level of involvement in certification projects, and for EASA's determination of their LoI. Guidance is proposed for the application of the criteria given by Part-21 to determine the EASA involvement in a risk-based manner, as well as for the process to determine EASA's involvement.

Furthermore, this AMC/GM provides guidance on the application of the new privileges for certain major changes, major repairs and STCs.

Finally, the AMC/GM provides new or amended means of compliance and guidance material necessitated by the changes introduced into Part-21, and in particular, it relocates the guidance for the points of Part-21 that have been moved from Section A to Section B.

The proposed changes are expected to support the application of the amendments to Part-21 proposed by Opinion 07/2016.

Action area:	Safety Management		
Affected rules:	ED Decision 2016/007/R.		
Affected stakeholders:	Design approval holders (DAHs), EASA		
Driver:	Safety	**Rulemaking group:**	No
Impact assessment:	No	**Rulemaking Procedure:**	Standard

EASA rulemaking process milestones

Start	Consultation	Decision
Terms of Reference	Notice of Proposed Amendment	Certification Specifications, Acceptable Means of Compliance, Guidance Material
1	2	3
27.08.2013	DD.MM.2017	20XX/QX

Today

[1] https://www.easa.europa.eu/document-library/opinions/opinion-072016

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Page 1 of 95

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Our journey this morning …

- What do we intend to change, and why?
- Main milestones (past and present)
- Reminder of the main principles of LOI
- LOI in projects applied for by DOA holders
  - DOA holder performance
  - Risk assessment
  - Design Assurance System
- Lessons learnt during advanced application projects with DOA holders
  - Advanced Application Projects
  - General lessons learnt
  - Administrative burden & complexity
  - Lessons learnt environment
  - Your experience so far?
- Risk assessment in projects where capability is demonstrated through AP to DOA or CP
- Risk assessment in ETSOA projects
- Future milestones

Definition of the “risk”

What is the **risk based** approach?

Dictionary meaning

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

Application in product certification

- Applicant demonstrates compliance (21.A.21) [and independently checks it (21.A.239)]
- EASA, before issuing the TC, needs be convinced that compliance has been demonstrated and verified (21.A.21): i.e. involvement
- Areas and depth of involvement is decided using a risk-based approach

RISK = likelihood of a non-compliance with a part of the certification basis, which is not identified through Agency involvement, in combination with its potential impact on product safety or environmental protection

Level of Involvement in the new Part-21

21.B.100

Considering ..

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

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

... taking into account

- novelty
- complexity
- criticality
- DO performance

Defining the risk class

- To define the risk class, the ratings of the 4 criteria will be combined
- Depending on the way how the applicant demonstrates the capabilities of the organisation, the combination varies

Step 1: Likelihood of an unidentified non-compliance

Performance of the organisation \ CDI	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

Step 2: Risk classes

Severity \ Likelihood	Very low	Low	Medium	High
Non-Critical	class 1	class 1	class 2	class 3
Critical	class 1	class 2	class 3	class 4

Risk-matrix for applicant using alternative procedures to DOA

Severity \ Likelihood	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

- Details for each case are provided in the next slides

Consequences on Design Assurance System

TC/STC holders

- **<u>Application for significant changes</u>** in the Design Assurance System 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 points 21.A.15 / 20

Minor repair/changes

- **<u>Application for significant changes</u>** in the Design Assurance System is **<u>NOT needed</u>**
- DOA holders procedures may be adapted to incorporate the new LOI concept

Exceptions may be done for DOA holders already having LOI in their procedures

Lessons learnt - environment

- For a noise application the Attachment 9 was not taken into account and “correct” performance rating was not provided
  - “High” was assumed by the DO while “Medium” should have been applied
- The compliance demonstration for a major modification for an engine was based on an already existing certification report. However, a new requirement was in fact applicable
  - Correct application of the “novelty criteria” would have led to a higher risk class
  - Risk class was then revised

Lessons learnt - environment

For Environment (Panel 9) application of the above criteria is not always obvious, but works. Focus: What is the environmental risk?

Examples for Novelty: New procedures for the acquisition of data, analysis and/or adjustment of measured noise/emissions levels to reference conditions (including new or novel hardware and equivalent procedures)

Examples for Complexity: Equivalent procedures not referred to in the ICAO Environmental Technical Manual;

Use of aircraft noise "family plan" methodologies

Panel 9

Organisation performance: no specificities

Examples for Severity: commensurate with risk that a product might be certified with noise and/or emissions levels different to the levels that would have been certified if EASA had been fully involved;

Failure to manage this risk will lead to an uneven "playing field" in the context of operating restrictions and landing fees

Lessons learnt - environment

- EASA is working to continue and reinforce the exchange of information and experiences between DOA holder teams and Panel 9 Experts (Noise and/or Emissions) regarding DOA activities
  - Examples
    - Data communication and availability
    - Participation of CT5 experts in DOA audits
    - Dedicated audits on environmental activities

Criteria 3: DOA holder performance

- Ratings: low / unknown → medium → high
- Expected performance based on past experience
- Starting point
  - DOA holder dashboard
  - as available on (discipline), panel or organisation level
- deviations possible where more specific or more recent information is available

Criteria 3: DOA holder performance

Reading the DOA dashboard

Panel 9 - Noise, Fuel Venting and Emissions

Results shown for

Panel 9 - Noise, Fuel Venting and Emissions

Template version - V.5.1 *Last update: 16.12.2016*

Comments and analysis by the DOA Team

N/A

Panel 10 - Software and Airborne Electronic Hardware

Results shown for

Panel 10 - Software and Airborne Electronic Hardware

Template version - V.5.1 *Last update: 16.12.2016*

Comments and analysis by the DOA Team

N/A

Criteria 3: DOA holder performance

Reading the DOA dashboard

Panel 9 - Noise, Fuel Venting and Emissions

Results shown for

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Comments and analysis by the DOA Team

N/A

Panel 10 - Software and Airborne Electronic Hardware

Results shown for

Panel 10 - Software and Airborne Electronic Hardware

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Comments and analysis by the DOA Team

N/A

Establishing the organisation performance

Combined use of feedback from certification projects and DOA holder surveillance, incl. findings etc.

- For projects use of Technical Visa and Statement of Satisfaction
- Feedback provided by DOATL during annual meeting
- Detailed performance data for certification projects can be shared with DOA holders following signature of MoU to ensure “just culture”

Note: System currently under review to assess possible shortcomings and to address upcoming changes in Part-21

Lessons learnt – administrative burden

In particular

- No need to justify rating of criteria in obvious cases
- Full flexibility for documentation of LOI (proposal)
- Provision of template certification programmes and LOI proposal
- Simplification of the criteria ”novelty”, “complexity” and “severity”
- More explanation on CDI and the creation of those
- Further harmonisation of the panel specific examples and transfer of some of them into the generic guidance
- Even though a slight increase of workload is expected in the first project(s) in order to get used to the new concept, compliance demonstration and verification gets more efficient through early notification of Agency involvement and predictability

Level of Involvement – What is it?

- the compliance demonstration activities and data that EASA retains for verification during the certification process, and
- the depth of these verifications

Method:

Criteria 3: Performance of the organisation

- Ratings: low / unknown → medium → high
- Different approaches applied, depending on whether the organisation has demonstrated its capability by

holding a design organisation approval (DOA)	21. A.14 (a)	21. A.112B (a)
having received Agency's agreement for the use of procedures setting out design practices, resources … (AP to DOA)	21. A.14 (b)	21. A.112B (b)
receiving Agency approval of a certification programme only	21. A.14 (c)	21. A.112B (c)
[for ETSOA]: holding a POA or through compliance with Subpart F procedures AND holding a DOA (for APU) or by using procedures setting out design practices, resources … (all other articles)	21. A.602B	

- Details for each case are provided in the next slides