

New Part-21 amendment, what is changing for me?

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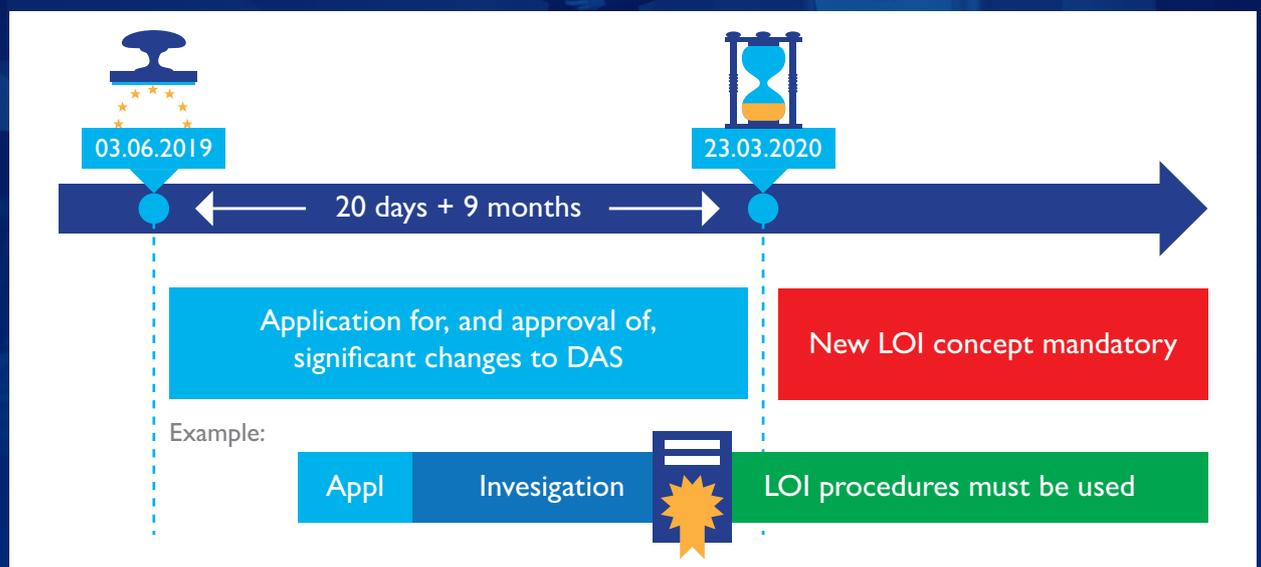
By Duane Kritzinger

Duane Kritzinger (Principal Consultant and Part 21 Subject Matter Expert) represented Baines Simmons at the information session at EASA entitled “New Part-21 amendment, what is changing for me?”

The objective of this session was to explore the changes brought into Part21 via Regulation (EU) 2019/897 (or Part 21 Issue 2 rev 5 for you and me)

Key aspects which require highlighting are:

- ▶ LOI is founded on a risk based approach, which has its basis in the safety oversight function in ICAO Annex 19.
- ▶ For TC/STC/major change/major repairs, LOI is determined at CDI level, and it makes sense to consider EASA Certification Panels in the approach to CDI allocation.
- ▶ Adoption of LOI (in the DOH and Procedures) is considered a Significant Change (refer Item 3 in J-News 2018/3] with target date at end of Q1 2020. Affected Design Organisations need to start the transition and contact their EASA Team Leader ASAP as no certification application will be progressed by EASA without it.



The following synopses/interpretation should be read in conjunction with the presentations, which can be accessed (in due course) on EASA’s website. EASA is evolving the presentation at each delivery, so the slide numbers referred to below refer to the presentations of 18-19 Sept 2019, which are available here.

I. Opening of the Workshop

by Michael Gerard (EASA Regulations & Certification Policy Section Manager)

Michael welcomed all attendees and introduce his colleagues (Stefano Fico, Ralf Bader, Leonardo Capacci and Robert Boersma) who participated in the creation of this amendment. This is the 3rd time that this session has been run with industry.

- ▶ Purpose of the event: Provide information of main changes brought to 2019/897 aimed at those who have not stayed abreast of its evolution. This entered “into force” on 23/6/19, but some parts become applicable on 23/6/19 and other on 23/3/20 (this is not in the Regulation, see the revised Corrigendum that was published with it).
- ▶ EU2019/897 at a glance: There are 5 new requirements, 46 requirements have been amended and 9 requirements have moved from Section A to Section B. A correlation table is provided to assist DOs in managing the change. The amendment introduces:
 - ▶ Opinion 07/2016 new LOI concept, new privileges to approve “certain” major changes or Repairs/STCs, new obligations
 - ▶ Opinion 01/2017 for permit to fly for certain maintenance check flights
 - ▶ Implementation of the CAEP/10 amendments on climate change, emissions and noise.
- ▶ The available material: Only EU2019/897 and its supporting AMC Iss2 Amm9 have been published (i.e. not yet any consolidated version or Part 21 or updated Easy Access Rules).
 - ▶ The Commission will publish consolidated version by March 2020.
 - ▶ EASA is working on updating Easy Access Rules some time in 2020. .

See also dedicated LOI webpage <https://www.easa.europa.eu/newsroom-and-events/news/new-easa-approach-definition-level-involvement-loi>

- ▶ Reminded of what Part 21 is about: It is all about the rights and obligations of organisations and competent authorities (i.e. who has to do what). To support this “hard law”, EASA develops supporting AMC and GMs which can be (not shall be) used to help with compliance (i.e. the how).
 - ▶ Using the AMC will lead to a “*presumption of compliance*” (i.e. EASA will not challenge/contest). If there are 2 AMCs then the organization can choose which to use (do not need to use both). No obligation to use the AMC, but you will then need to convince the competent authority.
 - ▶ GMs illustrate meaning of a Part 21 point (supports its understanding but, unlike an AMC, there is no “*presumption of compliance*” (currently some GM are written in AMC style and EASA is in process of cleaning this up in a future update).

2. Changes related to applications and compliance demonstration for a TC/STC/major change/major repair approvals

The intent is to introduce a risk based approach to determine EASA’s LOI. Applicant and EASA need to invest more time and effort in the beginning of a certification project:

- ▶ Submit an application i.a.w. 21.A.15,/93, 113, 432C
- ▶ Propose the Cert Basis consisting the TCB (21.B.80), OSD Cert Basis 21.B.82 and applicable Enviro protection requirements (21.B.85)
- ▶ Submit a Cert Programme proposing the LOI based on a Risk Assessment (this revision of the Cert Programme containing the latter can be submitted later):
 - ▶ Will require a breakdown of the certification project into meaningful groups of compliance demonstrating activities and data to facilitate risk assessment [e.g. 21.A.15, 21.A.93, 21.A.432, 21.A.113 and 21.A.604] (called CDIs in the AMC)
 - ▶ EASA will focus its attention on higher risk CDIs [21.B.100, note criteria of novelty, complexity, criticality and DO performance/experience].
- ▶ Inform EASA of any difficulties experienced during the program and EASA can elect to change its LOI [21.B.100(c)]

The key of LOI is the risk on which the LOI determination is based (i.e. the likelihood that a non-compliance with the Cert Basis remain unidentified and the potential impact of that on product safety.) Steps to be taken (see slides 25, 27, 75, 76):

- ▶ Define the Cert Basis and plan your MoCs
- ▶ Allocate your MoCs to meaningful CDIs [AMC21.A.15(b)(5)] (slide 30)
 - ▶ Slide 32 shows that EASA is flexible in how this is done (e.g. against panel, discipline, ATA chapter, MoCs, etc.)
 - ▶ Using EASA panels have distinct advantages (see slide 33) as it is the Panels that will exercise LOI.
 - ▶ Note (on slide 81) that, on 80 pilot LOI projects, that there was an average of 6 CDIs per STC project.
- ▶ For each CDI, propose the likelihood of unidentified (or unintended) non-compliance based on:
 - ▶ Novelty (see slides 37&38) (including the technology), noting that EASA panels will be looking at the matter from their perspective (and it could be novel to them)
 - ▶ Complexity (see slides 39 &40), noting it is independent of novelty
 - ▶ DO performance (see slides 41-45) based on past experience. Note that if you match your CDI to the EASA Panels, then you can use the Dashboard (slides 42 &44) to substantiate this for each CDI. Note also that EASA's emphasis here is Panel specific and a wider DOA performance measurement system (part of SMS) does not directly influence the criteria selection, although indirectly it will lead to a better Panel experience).
- ▶ For each CDI, propose the potential safety/environmental impact (at product level) of un-identified non-compliance (see slides 47-50), noting the choice is either "Critical" or "Non-critical" (slide 49).
- ▶ For each CDI, determine Risk Class 1 to 4 (see slides 29, 49, 52, 55, 56). On slide 52 note that there are exceptions, e.g. you might propose/determine Risk Class 1, but EASA will always want to review the AFM.
- ▶ For each CDI, propose EASA LOI (no format proposed by EASA) in the updated Certification Programme (and keep it current/updated) (see slides 53, 54, 60).

See slides 63-77 for some practical case studies (examples), noting these contain suggested (not prescribed) formats.

Slides 86-88 contains some best practice advice from EASA.

Additional information gleaned from questions asked during the presentation:

- ▶ Due to current fees and charges regulations, currently two applications are needed for STC and OSD changes (in due course EASA hope to combine into single application)
- ▶ No LOI activities required for Minor changes
- ▶ Each application is via a single DOA, so use your performance/experience in managing your sub-contractors (including when your sub-contractor provides CVEs) for each CDI.
- ▶ EASA will update the LOI CM as lessons are learned. Eventually the CM will disappear as its content is transferred to either AMC/GM or EASA webpages.

3. Changes related to applications for minor changes/repairs and ETSO

This only applies to organizations who do not have DOA (or appropriately scoped DOA). The idea/principals are the same as for major changes, but with a lighter approach. This is done by EASA determining LOI at the level of the entire certification project, not CDI level (see slide 4 and 21.B.100(b)).

- ▶ For minor changes/repairs see slides 7-10 for EASA actions upon receipt of a Certification Programme.
- ▶ For ETSO items (except APU) see slides 11-13 for EASA actions upon receipt of a Certification Programme.

So there is no additional LOI effort for the applicant (i.e. they do not need to propose LOI).

For application of a minor change see amendment to 21.A.93 around the Certification Programme (slides 15-16). For approval of such a change, see amendment to 21.A.95 (slides 17-18).

For minor changes a new 21.A.432(C) has been added. Similar to minor change but no Certification Programme required (see slides 19-20)

For ETSO approvals, 21.605 has been amended to include:

- ▶ the delivery of a Certification Programme (slides 22- 24)
- ▶ the reporting of any unexpected difficulties experienced during its execution (slide 25)
- ▶ Additional DDP declarations to be made (slides 26-28)

4. Changes related to DOA (i.e. Part 21 Subpart J)

Unless you only do minor changes/repairs, LOI impacts your Design Assurance System [21.A.239] and is predetermined by EASA to be a Significant Change [21.A.247]. This is because of a change in principle of certain procedures (see slide 6):

- ▶ DOA procedures should be updated to address the requirements on slide 7 (i.e. how to propose the LOI and agree and manage it with EASA via the Certification Programme)
- ▶ 21.A.263(b) has been deleted. EASA states that this is no longer needed (“as it is replaced by the LOI approach”), but the content of that requirement was never phrased very well and added little value.
- ▶ Privileges (21.A.263) have been extended to approve “certain” Major changes/repairs or STCs (i.e. low risk projects if you consider the LOI criteria). This means that these DO’s could, in future, issue their own Major Approval/STC (slides 11-16) if their privileges have been extended (slides 17-19, 21, 23). Note EASA desires a separate Form 82 for each Privilege (slide 20), after which discuss with your Team leader for any extension of an existing Privilege (slide 25).
- ▶ The AFM privilege in 21.A.263(c)(4) is deleted as addressed (slide 28) in 21.A.263(c)(1&2) and 21.A.265(h). This is an administrative change only (not a significant change).
- ▶ 21.A.263(c)(3) was deleted and turned into an obligation in 21.A.265(h). DOA procedures may need to be updated (and might be a significant change (see slides 30-32). The obliged statement is aimed at post certification documents you are providing to 3rd parties only (so includes release of “approved data” to the Production Organisation).
- ▶ Your Terms of Approval [21.A.251] may need updating [21.A.253] due to changes in 21.A.263 (see slide 34). This is an administrative change by EASA only (not a significant change). See new ToR template on slide 35).
- ▶ Slide 37 provides a summary (which is embedded in an internal EASA policy) on what is considered to be a Significant Change (SC) – and each needs to be applied for under individual Form 82’s.

Additional information gleaned from questions asked during the presentation:

- ▶ For these “certain Major changes”, there are no EASA application fees (hence a “privilege”).
- ▶ For FAA validation, you need to work through EASA again according with the current version of the BASA/TIP (i.e. will not automatically be accepted, yet).
- ▶ Note that EASA issues CS-25 as a complete revision, whilst FAA does each requirement at its own revision. This could have a big impact on your Cert Basis determination.
- ▶ These self-approved STCs will be made visible on the EASA STC list (hence why you need to provide it to EASA upon completion).
- ▶ Note error on slide 15 and the supporting AMC:
 - ▶ ALT-MoC should not be used in the context of ADO
 - ▶ AMOC is the term to be used in the context of an AD (via EASA Form 42)(see also FAQ n.19406)
- ▶ Note, ultimately EASA desire one change classification per project (i.e. if the DO elects to classify ICA/Manuals/OSD/Design separately, the overall classification of the project is the highest of the lot). EASA is updating applications forms (e.g. The AFM Minor change Application form will disappear).

5. Other Changes in Part I

The following are some highlights (not all inclusive):

- ▶ The addition of 21.A.33(c) is not linked to LOI, but more explicitly states the need to conform the test specimen, test set-up and test equipment (slides 4&5). Note from the Q&A:
 - ▶ 21.A.33(c) applies to the applicant (i.e. the DO), who can ask the PO to provide the Form I, but the DO needs to produce its own “Statement of Conformity”.
 - ▶ CVE should independently verify that this has been done (if he/she does it they are involved in the creation of the data)
 - ▶ If the DO uses historical test data it still needs to ensure itself of this conformity (and it may recognize any Form I). If not, the test will need to be repeated.
- ▶ Issuance of TC/STC: Part 21 Section B has been updated (see slide 7)
- ▶ Permit to Fly for Maintenance Check Flights: See the NPA for why these changes were made. See slide 9 for a definition of a “Maintenance Check Flight”, noting that Ptf is required for “(d) to assist with *fault isolation or troubleshooting*” (i.e. so only required if this is the objective of the Check Flight). Therefore, 21.A.710(a)(16) has been added to 21Subpart P (see slide 10). The Ops and Part M rules have also been updated (see slide 11, noting applicability and time-to-compliance dates).
- ▶ CAEP 10 Implementation: This regards ICAO Annex 16 changes (see slides 13-14) and impacts Part 21 requirements related to Noise and Engine Emissions, which now includes CO₂ (see slides 15-24). Each TC/STC application will thus need to also demonstrate compliance with the CO₂ emissions requirements. Note there is a new CS-CO₂.
- ▶ Overall Part 21 restructure is summarized in slide 26 (best shown in .ppt animation, so maybe rather refer to the Correlation Table in) 2019/897), showing
 - ▶ Changes in Section A
 - ▶ Where Section A requirements have been moved to Section B
 - ▶ New Section B requirements

6. Overview of Applicability Dates

Apart from CAEP/10 relation changes and 21.A.263, UR 2019/807 became applicable in June 2016 (see slides 5-8).

LOI becomes mandatory on 23 March 2020 (see slides 10). DO’s need to pro-actively evolve their DOH and ensure that EASA resources are available to support their Significant Change application(s) in time (see slide 11).

About Baines Simmons

We are specialists in aviation regulations, compliance and safety management and partner with the world's leading civil and defence aviation organisations to improve safety performance.

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Duane Kritzinger is an experienced Certification and Safety Engineering specialist. His distinguishing safety expertise lies in the ability to differentiate and integrate the Safety Assessments in the design phase with the Safety Management activities in the operational phase. His certification skills cover both the military and civil aviation domains, where he not only provides expertise in the certification of products/parts/appliance, but also assists with EASA/EMAR Part 21 Design Organisation Approvals (which includes the establishment of organisation processes and structures to move beyond minimum compliance towards organisational performance).

Since the publication of EMAR 21, Duane has been assisting both the military regulators (in their adoption of EMAR 21) and the regulated community (in demonstration of compliance in the most efficient manner with due consideration of other approvals held).