European Union Aviation Safety Agency

Comment-Response Document 2017-20

Appendix
to NPA 2019-03
Embodiment of the level of involvement acceptable means of compliance and guidance material in Part 21

RELATED NPA: 2017-20 — RMT.0262 (MDM.060) — 3.4.2019

Table of contents

1. Procedural information

1.1. The rule development procedure

The European Union Aviation Safety Agency (EASA) developed this Comment-Response Document (CRD) in line with Regulation (EU) 2018/1139[1] (the 'Basic Regulation') and the Rulemaking Procedure[2].

This rulemaking activity is included in the 2019–2023 European Plan for Aviation Safety (EPAS)[3], under RMT.0262 (MDM.060) (Phase II).

The draft amendments to the acceptable means of compliance (AMC) and guidance material (GM) to Part 21 have been developed by EASA. All interested parties were consulted through NPA 2017-20[4], which was published on 15 December 2017.

The text of this CRD has been developed by EASA.

1.2. The structure of this CRD and related documents

This CRD provides a summary of the comments and responses, as well as the full set of individual comments on NPA 2017-20 and the responses to them. The resulting text is provided in Annex I to this CRD.

1.3. The next steps in the procedure

This CRD is published in conjunction with NPA 2019-03, which complements NPA 2017-20.

At the time of publication of NPA 2017-20, the text of Opinion No 07/2016[5] was still under review by the European Commission. This phase has now been completed, and a draft text of the Part 21 amendment has been made available to EASA.

As a number of changes have been introduced to the text proposed by EASA in Opinion No 07/2016, some AMC/GM need to be amended in order to remain aligned with Part 21. NPA 2019-03 contains the proposed amendments to the affected AMC/GM.

After the public consultation of NPA 2019-03, EASA will issue a decision that contains amendments to the AMC/GM to Part 21.

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1 Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139).

2 EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by EASA for the issuing of opinions, certification specifications and guidance material (http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure).

3 https://www.easa.europa.eu/document-library/general-publications?publication_type%5B%5D=2467

4 https://www.easa.europa.eu/document-library/notices-of-proposed-amendment/npa-2017-20

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

2. Summary of the outcome of the consultation

217 comments were received from 22 stakeholders. The following Table 1 shows the number of comments received by each commentator:

Commentator	# of comments
AIRBUS	29
Antonio PARADIES	7
CAA CZ	5
CAA Denmark	1
CAA-NL	10
Christopher BERRY	4
cvjnvuld	1
Dassault-Aviation	25
DGAC France	1
EUROCONTROL	1
KID-Systeme GmbH	2
KLM engineering & maintenance	3
Laurent Lalaque	1
Leonardo Helicopters	5
LHT DO	18
Luftfahrt-Bundesamt	1
Rolls-Royce Deutschland / DOA Manager D. Stege	49
Safran Aircraft Engines	18
THALES AVIONICS	1
UK CAA	1
Yuksel Kenaroglu	13
Zodiac Aerospace - Sell GmbH DOA 21J.067	21
Total	*217*

Table 1

The following Table 2 shows the distribution of comments per topic:

Section	NPA page	Description	Comments
0	-	(General Comments)	8
1	1-2	EXECUTIVE SUMMARY	1
2	4-19	In summary — why and what	1
3	20-24	AMC 21.A.14(b)	11
4	24	AMC 21.A.15(a)	2
5	24-27	AMC 21.A.15(b)	29
6	27	Appendix A to AMC 21.A.15(b)	1
7	28-29	AMC 21.A.15(b)(5) and 21.B.100(a)	11
8	29-30	GM 21.A.15(c)	4
9	32	Appendix to AMC 21.A.20(b)	1
10	32	GM 21.A.20	2
11	32-33	GM 21.A.20(b)	1
12	33	AMC 21.A.20(c)	3
13	33-34	GM 21.A.20(d)	3
14	35	GM 21.A.33	3
15	35-37	AMC 21.A.33	6
16	37-38	GM to 21.A.90A	2
17	38-40	GM 21.A.91	10
18	41-42	Appendix A to GM 21.A.91	5
19	43	AMC 21.A.93(a)	1
20	43	GM 21.A.93(b)	2
21	44-47	AMC to 21.A.95	10
22	48	GM 21.A.101	1
23	49-51	GM No 1 to 21.A.103, 21.A.115 and 21.B.70	1
24	51	AMC 21.A.113(a)	2
25	51	AMC 21.A.115	1
26	52-53	GM No 1 to 21.A.239(a)	4
27	53	GM No 2 to 21.A.243(d)	3
28	53	GM 21.A.247	3
29	53-55	AMC No 1 to 21.A.263(c)(1)	1
30	56-57	AMC No 1 to 21.A.263(c)(2)	1
31	59-60	AMC No 3 to 21.A.263(c)(2)	2
32	60-61	AMC 21.A.263(c)(6)	4
33	61-63	AMC No 1 to 21.A.263(c)(5)(8)(9)	11
34	63-71	AMC No 2 to 21.A.263(c)(5)(8)(9)	8

Section	NPA page	Description	Comments
35	71-72	AMC No 3 to 21.A.263(c)(5)(8)(9)	7
36	72-73	GM 21.A.265(h)	6
37	73-74	GM 21.A.431(a)	1
38	75	AMC 21.A.432C(a)	1
39	75	AMC 21.A.432C(b)	1
40	76-78	GM 21.A.435(b)	1
41	78	AMC 21.A.605(a)(1)	3
42	79	GM 21.B.75	1
43	81	GM 21.B.82(a)	3
44	82-92	AMC 21.B.100(a) and 21.A.15(b)(6)	31
45	92-93	AMC 21.B.100(b)	3
46	93-98	AMC 21.B.100(b)	5
47	99	4. Impact assessment (IA)	1
48	100	5. Proposed actions to support implementation	1

Table 2

The nature of the comments received ranged from specific technical comments to observations aimed at improving the wording.

The majority of these misalignments have been corrected in line with the comments that were received, and in some cases the wording proposed by NPA 2017-20 has been improved for clarification purposes.

The majority of the comments submitted were either accepted or partially accepted, as shown in the following Table 3:

	ACCEPTED	PARTIALLY ACCEPTED	NOTED	NOT ACCEPTED	Σ
# of occurrences	49	44	62	62	*217*
percentage	23 %	20 %	28 %	28 %	*100*

Table 3

The individual comments and the responses to them are contained in Chapter 3 of this CRD.

2.1. Summary of the main changes made to the proposed AMC/GM to the Part 21 amendment

Hereafter is a summary of the main changes introduced as a result of the public consultation of the proposed amendments contained in NPA 2017-20.

It should be noted that the list below is not exhaustive.

Renumbering of the AMC/GM

A number of the proposed AMC/GM have been renumbered, and sometimes renamed, to better reflect their contents. Table 4 hereafter shows how these AMC/GM have been renumbered:

Name proposed in NPA 2017-20	New name
AMC 21.A.15(b)(5) and 21.B.100(a) Breakdown of the certification programme into compliance demonstration items (CDIs)	*AMC 21.A.15(b)(5) Breakdown of the certification programme into compliance demonstration items (CDIs)*
AMC No 1 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (CTC) or a supplemental type certificate (STC), and minor repairs	*AMC No 1 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (CTC) , APU ETSO or a supplemental type certificate (STC), and minor repairs*
AMC No 2 to 21.A.263(c)(2) Privileges — Organisations designing minor changes to a type certificate (TC) or a supplemental type certificate (STC) and minor repairs to products: procedure for the approval of minor changes to a TC or minor repairs	*AMC No 2 to 21.A.263(c)(2) Privileges — Organisations designing minor changes to a type certificate (TC) , APU ETSO or a supplemental type certificate (STC) and minor repairs to products: procedure for the approval of minor changes to a TC, APU ETSO or minor repairs*
AMC No 3 to 21.A.263(c)(5), (8) and (9) Numbering system for supplemental type certificates (STCs), major changes, and major repairs issued by design organisation approval (DOA) holders, and information to EASA	*GM 21.A.263(c)(5), (8) and (9) Numbering system for supplemental type certificates (STCs), major changes, and major repairs issued by design organisation approval (DOA) holders, and information to EASA*
AMC 21.B.100(b) Level of involvement (LoI) in projects for minor changes and minor repairs	*AMC No 1 to 21.B.100(b) Level of involvement (LoI) in projects for minor changes and minor repairs*
AMC 21.B.100(b) Level of involvement (LoI) in European technical standard order authorisation (ETSOA) projects	*AMC No 2 to 21.B.100(b) Level of involvement (LoI) in European technical standard order authorisation (ETSOA) projects*

AMC 21.A.15(b)(5) Breakdown of the certification programme into compliance demonstration items (CDIs)

The meaning of 'obvious cases' in relation to the classification of the CDIs has been clarified.

GM 21.A.33(d) Inspections and tests

This GM has been reworded to clarify that applicants should inform EASA sufficiently in advance about the execution of inspections and tests unless EASA has explicitly excluded its involvement in them according to 21.B.100 'Level of involvement'.

New GM 21.A.95(b) Requirements for approval of a minor change

This new GM has been created to ensure that the level of detail of the compliance documents that support the demonstration of compliance for a minor change is not affected by the approval process that is followed by the design organisation. This provision was initially included in AMC 21.A.95.

New GM 21.A.97(b) Requirements for approval of a major change

Similar to the new GM.21.A.95(b) but addressing major changes.

AMC No 3 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (TC) which affect the aircraft flight manual (AFM)

Paragraph 2.4 has been amended to clarify that the process followed to approve changes to the AFM should not necessarily be evident to the end users. This information shall, however, be traced in the configuration control system used by the design organisation.

Additionally, the concept of a 'data module' has been included as, in many cases, the AFM document is divided into several data modules.

GM 21.A.263(c)(5), (8) and (9) Numbering system for supplemental type certificates (STCs), major changes, and major repairs issued by design organisation approval (DOA) holders, and information to EASA

This guidance was initially proposed as AMC but, considering the comments received, EASA agreed to reclassify it as GM.

GM 21.A.432B(b) Alternative procedures

This new GM has been created to clarify that AMC 21.A.432C(a) should be considered for details of the alternative procedures.

AMC 21.B.100(a) and 21.A.15(b)(6) Level of Involvement (LoI) in a certification project for a type certificate (TC), a major change to a TC, a supplemental type certificate (STC) or a major repair design

As suggested by some commentators, the term 'criticality' has been replaced by the term 'severity' to prevent confusion.

Clarifications have been added on the possibility to 'clearly show' that all the elements of the certification basis are included in at least one CDI.

One sentence has been added to clarify the relation between novelty classification and knowledge management aspects.

AMC No 2 to 21.B.100(b) Level of involvement (LoI) in European technical standard order authorisation (ETSOA) projects

In paragraph 2, it has been clarified that the LoI assigned to each ETSO project is defined in the subsequent paragraph 2.1. This clarification is needed to prevent confusion with the LoI classes identified by EASA for other kinds of projects.

3. Individual comments and responses

In responding to comments, a set of standard terminology has been applied to show EASA's position. This terminology is as follows:

(a) **Accepted** — EASA agrees with the comment, and any proposed amendment is wholly transferred to the revised text.

(b) **Partially accepted** — EASA either agrees partially with the comment, or agrees with it but the proposed amendment is only partially transferred to the revised text.

(c) **Noted** — EASA acknowledges the comment but no change to the existing text is considered necessary.

(d) **Not accepted** — The comment or proposed amendment is not shared by EASA.

(General Comments)	-

comment *17* comment by: *THALES AVIONICS*

THALES would like to express some disappointment regarding the LoI process for ETSOA proposed by this NPA. The proposed process is considered very complicated and would induce additional workload to the EASA specialists for determination of the LoI and in discussions with Applicants. Moreover the proposed LoI determination is such that the resulting involvement of the EASA risks to be higher than the current situation.
Globally, THALES considers that this proposal is not consistent with the EASA strategic objectives to optimize its resources in certification in focusing them on safety risks and to increase the workforce for the preparation of the future (e.g. introduction of new technologies).
Finally, Industry regret that this proposal has never been discussed with Industry before publication as it has been done in the past for the LoI for TC/STC.

As illustration of this general comment, THALES would like to highlight the following measures:
1/ LoI process for ETSOA is not homogeneous with LoI process for TC, STC or major repair (meaning 2 different processes for Company doing both, but also for EASA specialists dealing both types of processes)

2/ Complexity of the LoI determination in several steps and moreover that minimizes the A-DOA experience. It should be easily simplified in a single step consistent with the first step of LoI TC (AMC 21.B.100 (a) paragraph. 3.2.5)

3/ The Top Down approach proposed for determining the ETSOA LoI with several criteria will have a great probability to lead to a higher EASA involvement than today. Why not a more pragmatic and realistic approach?

4/ Some criteria are consider too stringent:
- "*EASA has not conducted an ETSOA project assessment of the applicant in the same ETSO scope of work for a long period (2 or 3 years)"* - 2 or 3 years is the current time interval in a

	experimented company between 2 products with the same ETSO standards due to the development time. - *"New deviation requests are considered a novelty"* - not true 4/ LoI ETSOA classes (High, Highly reduced, Medium, Basic) are different from LoI TC classes (very low, Low, Medium, High): there are too many notions In conclusion, THALES considers that the current proposal has to be drastically simplified with pragmatism and would be volunteer in working with EASA to build a revised proposal.
response	Partially accepted. In the context of AP-DOA, the description reflects the process that is currently in use. The applicant has no DOA and is not regularly audited for its procedures and the application of its procedures. Based on the novelty, complexity, severity but also on applicant's performance in previous projects and experience in the ETSO scope of work, the EASA PCM is responsible for setting the level of involvement, and adapts it during the project, from the project data and compliance with the ETSO standard. The process is, by definition, different from that for a TC/STC, and the applicable sections of Part 21 are also different. 1/ Noted. It is true that a company that works on both TCs/STCs and ETSOs has to understand that they need to take no action for ETSO projects, but they need to propose the LoI on TC/STC projects. So it is not really two processes for the company. The EASA PCMs are responsible for setting the LoI of ETSO projects, and the process is known to them. The ETSO applicant is a kind of unknown DOA performance, and applying the same process would lead to an increase in the LoI compared with the current situation. This is clearly not the intention. The reason for different processes for TCs/STCs is highlighted in the words above. 2/ Noted. The LoI for a TC also has two steps. The ADOA applicant is not currently overseen regarding their application of procedures. It is all done through projects. The performance of the ADOA from previous recent projects in the same scope of work is taken into account. If the applicant is new in the scope of work, there is no previous experience to take into account. 3/ Noted. This process has been prepared with all the EASA PCMs to reflect the current involvement process. By definition, it is pragmatic and realistic. The only additional task is to provide feedback to the applicant, and this is not considered to be very complex. The process described lays down in a formal manner what the EASA ETSO PCMs currently do. EASA does not consider that there is a risk of increasing the overall LoI. 4/ Partially accepted. Regarding the 2-3 years without an EASA assessment: 2-3 years is indeed what can be regularly observed in an avionics ETSO project. EASA does not consider that there is an issue: if EASA finishes its year 3 assessment and a project restarts before the end of the 2-3 year period, the period is deemed to be adequate.

	We agree that a deviation 'request' might not result in a novelty. New deviations that are not published are generally considered to justify some LoI: EASA has to study the deviation, and this demands a quasi-systematic level of involvement. When the deviation is from a newer revision of a standard that is never or rarely used, this also justifies more involvement in general. Note that the criteria can only be general in a generic process description. 2nd bullet Thales 4/ Noted. The risk classes for TCs/STCs are risk classes 1, 2, 3, 4. The risk classes in ETSOs are High, High reduced, Medium, and Basic. The risk classes are intentionally defined differently, and the naming convention avoids any confusion. The Part 21 requirements, the responsibilities of the ADOA and the DOA holders, and the EASA involvement are pragmatically different. The LoI process is different. EASA suggests illustrating to the commentator with the applicant's concrete application cases that the process is pragmatic and that it realistically corresponds to what happened on the applicant's previous projects. EASA does not intend to have a higher LoI for ETSOs, and has now documented the process that EASA personnel follow.
comment	*34* comment by: *EUROCONTROL* The EUROCONTROL Agency welcomes the publication of EASA Notice of Proposed Amendment 2017-20 on the 'Embodiment of level of involvement acceptable means of compliance and guidance material to Part-21'. It also thanks EASA for the opportunity that has been given to submit comments. However, the subject of the amendment is considered outside the scope of activities of EUROCONTROL. In addition, despite the fact that it has no comments to make, the EUROCONTROL Agency would like to confirm that it will read with interest the comments on this NPA received from stakeholders and the responses given to them by EASA in its future comment-response document (CRD). Like for NPA 2017-20, EUROCONTROL staff will be given access to CRD 2017-20, for information.
response	Noted.
comment	*58* comment by: *LHT DO* Please grant us a transition period of two years for the implementation of this NPA. Implementation includes not only changing of processes but also changing of IT (incl. work flows), training of personnel, and updating of part 21 references. This is a time consuming task which we won't be able to complete within the usual 6 months.
response	Not accepted. The proposed transition period is 9 months. The proposal is based on the advice from the industry in the LoI Steering Group. The proposal considers that the draft text of the regulatory changes has already been known since the middle of 2016, and that of the draft guidance material since the beginning of 2017. It is to be noted that applicants who participate in the advanced application phase of the new LoI concept may start to adapt their internal procedures well before the adoption of the new Part 21. Additionally, applicants only need to have their processes and workflows adapted before they submit their first application after the amended rules become applicable.

comment	*102* comment by: *Luftfahrt-Bundesamt* LBA has no comments on NPA 2017-20.
response	Noted.

comment	*123* comment by: *CAA-NL* First of all the Netherlands agrees with the intent of this NPA, however we have some specific remarks. The AMC & GM of Part 21 was already very extensive and due to this NPA it will be even more extensive. For the short term the CAA-NL is of the opinion that this is inevitable, but we kindly request EASA to take the initiative to develop a more comprehensive and more effective Part 21 including AMC & GM that will also more align with the design and production processes within the industry (instead of the present alignment with EASA-processes). CAA-NL is of the opinion that the concept of LOI is difficult to understand and to implement. That means that especially for smaller organisations / general aviation LOI introduces an additional burden that is not proportionate. Therefore, EASA is requested to use the possibilities of the new Basic Regulation to introduce more proportionality for these smaller organisations / general aviation later on. Both the NPA for the introduction of the concept of LoI in the rule as this NPA also include a number of non-related regular update issues. This makes it even harder to follow the introduction of this new and complex concept. We would like to recommend to EASA in the future not to combine the introduction of such new concepts with regular update issues. Further comments will be made at specific points.
response	Noted. EASA appreciates that the new LoI concept may require additional effort for applicants. However, an overall effort has been made to reduce the workload. Additionally, EASA has promoted the voluntary advanced application of the new LoI concept to test and improve the guidance as necessary. Experience gathered in this phase demonstrated that once the volunteering organisation becomes familiar with the new LoI concept, the additional effort becomes marginal. Regarding proportionality, although the new concept already contains some elements of flexibility and proportionality, some simplifications have been added to address the specific case of 'simple products' (refer to AMC 21.B.100(a) and 21.A15(b)(6) paragraph 3). Regarding the combination of the new LoI and other unrelated changes, although EASA understands this comment, EASA is of the view that one large amendment to Part 21 is more (cost-) efficient than several small amendments.

comment	*178* comment by: *DGAC France* DGAC France has no specific comment on this NPA.
response	Noted.

comment	*180* comment by: *UK CAA*

	Thank you for the opportunity to comment on NPA 2017-20, Embodiment of LOI AMC and GM to Part-21. Please be advised that there are no comments from the UK Civil Aviation Authority.
response	Noted.

comment	*190* comment by: *CAA CZ* It is assumed that the complete LOI procedure, including analysis for each individual CDI item and the resulting EASA LOI must be done by the applicant. The proposed AMC/GM contains only the generally described procedure of this analysis, the result of which becomes part of the certification programme. In our opinion especially smaller DOA organizations will have considerable difficulties in analysing LOI and properly documenting it. Therefore, we consider necessary to prepare EASA's practical guidance for LOI whole process, including the appropriate forms, templates for the required documentation. This guidance should contain practical examples based on pilot projects from development stage of LOI.
response	Noted. EASA appreciates the potential difficulties to be faced by small organisations for the implementation of the new LoI concept. Several initiatives have already been launched to support this phase, and others will follow. These initiatives include the volunteer advanced application, training sessions, LoI presentations at several different forums, roadshows for the industry and the creation of a set of templates that may be used by small organisations. Additionally, a transition period should be established at the rule level to facilitate the adaptation. All these initiatives are expected to considerably reduce the difficulties. See also the response to comment #123.

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comment	*18* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* It should also be mentioned that the required workload (CDI creation, justifications, cert programme updates, LOI procedures, etc..) does impose additional burden on Design Approval Holders. The amount of AMC/GM details in and the volume of this NPA are indicating a high level of administration rather than 'easy to understand' Part-21 requirement implementation rules. Therefore, the wording 'will improve ... efficiency..' is not supported.
response	Noted. EASA appreciates the potential difficulties to be faced by small organisations for the implementation of the new LoI concept. Several initiatives have already been launched to support this phase, and others will follow. These initiatives include the volunteer advanced application, training sessions, LoI presentations at several different forums, roadshows for the industry and the creation of a set of templates which may be used by small organisations. Additionally, a transition period should be established at the rule level to facilitate the adaptation. All these initiatives are expected to considerably reduce the difficulties.

	See also the response to comment #123.

2. In summary — why and what p. 4-19

comment	*149* comment by: *Christopher BERRY* I suggest that deleting 'changes altering Airworthiness Limitations or Operating Limitations' was not erroneous , but made consciously to avoid contradiction with GM 21.A.263(c)(4) §2.1 (b), which has now been deleted by this NPA and replaced by GM 21.A.91 §3.6(b)(1). i.e. Changes to the AFM Operating Limitations that are achieved without altering or exceeding certification data (e.g. weight, structural, noise, etc.,) could be classified as minor. The following revised text is suggested. NPA TEXT: (e) where the change alters the airworthiness limitations or the operating limitations; PROPOSED TEXT: (e) where the change alters the airworthiness limitations; (f) where the change alters the operating limitations and has an appreciable effect on characteristics affecting the airworthiness of the product in accordance with 21.A.91;
response	Not accepted. The intent was to reinstate the previous existing text. This GM 21.A.91 paragraph e) is in line with the classification process chart in Appendix A to GM 21.A.91, and addresses operating limitations. For changes to the AFM only, the complementary guidance in 21.A.91 §3.6 provides additional details and explanations concerning AFM limitations or procedures. A comprehensive definition of operational limitations may be added during a future regular update of the AMC/GM to Part 21.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 1. AMC 21.A.14(b) p. 20-24

comment	*1* comment by: *Yuksel Kenaroglu* Paragraph 3.3.1 The statement, "Management of changes...", maybe stated as original statement. Using the word "Changes" before the explanation statement in pharenthesis seems too early !
response	Not accepted.

	The text has to be read in conjunction with Part 21 Subpart D. The text in parentheses only provides a shorthand version of 'changes to a type certificate or supplemental type certificate'.
comment	*2* comment by: *Yuksel Kenaroglu* Paragraph 3.3.2 In this NPA, before first usage of statement, "Operational Suitability Data Certification Basis", it may be better to define (or explain) the relationship between this data and the Type Certification Basis. Here, is the statement, "Operational ...", another certification base beside the Type Certification ? Is it in the definition of the Type Certification ? Additionally, using the word "data" in here seems to cause additional hardship for understanding !
response	Noted. The definition of a type certificate is provided under 21.A.41, and indeed, it contains the OSD certification basis and the type-certification basis. The term data has been used because of the nature of the OSD deliverables. This terminology was discussed at length in the rulemaking process for OSD. You may refer to Opinion No 07/2011 'Operational Suitability Data' for further details.
comment	*103* comment by: *AIRBUS* **Page 20/ Paragraph 3.1.1 related comments** **No 1** *"AMC 21.A.14(b) Alternative procedures"* : wording should be improved Airbus proposes: "The establishment of these alternative~~s~~ procedures to DOA may be seen as a starting phase for a Subpart J DOA, allowing at a later stage, ~~at the discretion of the applicant,~~ the applicant to move towards a full Subpart J DOA, at its own discretion, by the addition of the missing elements." Comment is an observation or is a suggestion Yes **Page 21/ Paragraph 3.2.1(topic1) related comments** **No 2** *"classification of the whole change and its individual components"*: the meaning of "individual components" shall be further explained/documented" For more clarity Airbus proposes to define the meaning of "individual components" (ie Change to type design and OSD) Comment is substantive or is an objection Yes

Page 21/ Paragraph 3.2.1(topic1) related comments

No 3
"the criteria used for classification must be in compliance with 21.A.91 and corresponding interpretations.": "must" cannot be used in AMC/GM"

Replace "must" by "should"

Comment is substantive or is an objection Yes

Page 21/ Paragraph 3.2.2(topic1) related comments

No 4
"The procedure must indicate how the following are identified:": "must" cannot be used in AMC/GM"

Replace "must" by "should"

Page 23/ Paragraph 4.2(topic1) related comments

No 5
"The design data and information (including instructions) may be issued in a format of a service bulletin as defined in ATA 100 system,": Not sure that ATA 100 is still the correct reference. Spec 2200 could be the correct one."

Airbus proposes to check the relevance of ATA 100 reference

Comment is an observation or is a suggestion Yes

Page 24/ Paragraph 6(topic1) related comments

No 6
"The applicant for alternative procedures to DOA should establish the necessary procedures to show to the EASA how it will control design sub-contractors and ensure acceptability of the parts or appliances designed or the design tasks performed." : Airbus proposes that the wording should be improved as not only design tasks but 1st of all certification tasks can be handled by subcontractors

"The applicant for alternative procedures to DOA should establish the necessary procedures to show to the EASA how it will control design sub-contractors and ensure acceptability of the **design data and/or ~~parts or appliances designed or the design~~** tasks **(e.g. certification)** performed **by such sub-contractors."**

Comment is substantive or is an objection Yes

response

Partially accepted.
No 1: Accepted with an additional improvement in the wording.
No 2: Accepted.

	Nos 3 and 4: Not accepted. When referring to the rule, the modal verb 'must' can be used in AMC. Indeed, the criteria have to be compliant with 21.A.91. No 5: Accepted. No 6: Not accepted: 'Design' is understood to cover both designing and certifying.

comment	*105* comment by: *AIRBUS* **PAGE 24 to 27 / PARAGRAPH 3 related comments** **No 9** *Within Airbus type Certification program of complex projects will be shared in Project/aircraft certification project and discipline (i.e. ATA) certification programs.* *The content of each will not addressed all points identified in 21A15 but all points of 21A15 will be addressed in at least one of the certification programs of the project.* Airbus proposes that the AMC 21.A15(b) should clearly indicate that modules proposed at bottom of page24 may not contain all the quoted elements provided that the some of the modules covers all of them.. Comment is substantive or is an objection Yes **PAGE 26/ PARAGRAPH 3 related comments** **No 10** *The following sentence is misleading and does not bring any additional clarification : " It is recommended to provide this information at the level of each EASA panel or discipline affected by a proposed CDI."* Airbus suggests to remove this text.
response	Not accepted. The proposal is already in the AMC: 'The certification programme may be based on modules that may be updated independently.' It is implicit that each module does not contain all the information, otherwise it would not be useful. The sentence on page 26 is, in the view of EASA, not misleading, and it is a useful recommendation at the CDI level to establish the LoI at the panel or discipline level.

comment	*124* comment by: *CAA-NL* Pages 20-23: AMC 21.A.14(b) Alternative Procedures. We understand that this AMC is located here, however it includes a lot of information related to 21.A.112B(b) and 21.A. 432B(b). We would like to suggest some limited AMC material with those paragraphs referring to this AMC and including some wording connecting it with those specific subjects.
response	Partially accepted. GM 21.A.112B already includes a reference to AMC 21.A.14(b). For better readability, the new GM 21.A.432B(b) has been introduced.

comment	*156* comment by: *Safran Aircraft Engines* Section3: Comment: To be consistent with §2.3, table 1 first summary, when the term “change to type design” is replaced, it should be “change to type certificate”. The term “change” alone introduce unclear context. Proposed Text: To replace “change to type design” by “change to type certificate”.
response	Accepted. The text has been amended accordingly.

comment	*157* comment by: *Safran Aircraft Engines* Section 3.1 AMC 21.A.14(b) §3.2 (page 21) Comment: Both paragraphs 3.2 and 3.2.3 have the same designation. Title of § 3.2.3 should be modify to clarify Proposed text: *§ 3.2.2* ***Scope***
response	Partially accepted. The subparagraph has been renamed ‘Considerations of effects of the change’.

comment	*158* comment by: *Safran Aircraft Engines* Section 3.1 AMC 21.A.14(b) §3.4 (page 23) Comment: Production deviations should be established following the principles of paragraphs 3.2 and 3.3. This means that unintentional deviations in production should be classified as per 21.A.91 criteria. For organisations holding a DOA per Subpart 21J, there is no such requirement in AMC No. 1 to 21.A.243(a) that only requests in 4.c) *The procedures for classifying and approving unintentional deviations from the approved design data occurring in production (concessions or non-conformance’s).* Proposed text!: To revise the AMC No. 1 to 21.A.243(a) to be consistent with the proposed AMC 21.A.14(b) §3.4 *The procedures for classifying and approving unintentional deviations from the approved design data occurring in production (concessions or non-conformance’s)* ***should be established in accordance with Part-21.A.91 criteria.***
response	Not accepted. This subject is outside the scope of the consulted NPA. However, EASA will consider this issue during future amendments of Part 21 and the AMC/GM to Part 21.

comment	*159* comment by: *Safran Aircraft Engines* Section 3.1 AMC 21.A.14(b) §5 (page 24)

	Comment: Obligations should apply to the ETSO Proposed text: *Obligations addressed in 21.A.44 (TC holder), 21.A.118A (STC holder),* ***21.A.609 (ETSO holder)*** *or 21.A.451 (major repair design approval holder)*
response	Not accepted. While alternative procedures to DOA also relate to ETSOs, this section in the AMC focuses on TC/STC approval and Subpart J. AP-DOA in the ETSO context refers to procedures that support compliance with Part 21 Subpart O.

comment	*205* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* To be consistent with 21.A.15(b) use "means of compliance" instead of "method ..."
response	Accepted. Text changed.

comment	*206* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Guidance is missing and should be added to clarify and appropriately specify conditions for "no further demonstrating of compliance".
response	Noted. The comment is noted and further guidance may be developed in the future if necessary. EASA believes that no further guidance is currently necessary: a compliance demonstration should be provided whenever the design change affects compliance with the requirements in the type-certification basis, the operational suitability data certification basis or the environmental protection requirements.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 2. New AMC 21.A.15(a) p. 24

comment	*19* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* Is it necessary to repeat what's in the completion instruction (i.e. 'The form should be completed in accordance with the completion instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website').
response	Noted. Formally this is not necessary; however, EASA believes that this sentence completes the first part of this AMC.

comment	*160* comment by: *Safran Aircraft Engines* Section 3.2 AMC 21.A.15(b) (page 24) Comment:

This AMC request the use of the web-based "EASA applicant Portal". It should be in the rule to enforce its implementation, otherwise the applicant should be allowed to use another mean.
AMC should be transferred in the regulation Section A § 21.A.15(a), to request to file an application using the web-based 'EASA Applicant Portal' *or the application form for a supplemental type certificate (STC) (FO.CERT.00033) which may be downloaded from the EASA website.*

Proposed text:
~~***AMC 21.A.15(ab) Form and manner***~~
~~*The applicant should file an application using the web-based 'EASA Applicant Portal'17 or the application form for a supplemental type certificate (STC) (FO.CERT.00033)18 which may be downloaded from the EASA website.*~~
~~*The form should be completed in accordance with the completion instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website19.*~~

response

Not accepted.
The rule describes that the application 'shall be made in a form and manner established by the Agency'. This AMC provides for that form and manner, which can be the applicant portal or a form. As this is an AMC, applicants can use different means. The intent is to not be prescriptive by mandating the use of the tool.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 3. New AMC 21.A.15(b) p. 24-27

comment

3 comment by: *Yuksel Kenaroglu*

For the statement, "EASA Panel", "EASA Type Certification Discipline" may be conside red more.

response

Noted.
The definitions of EASA panels and disciplines are provided as part of AMC 21.B.100(a) and 21.A.15(b)(6). This AMC is already mentioned in AMC 21.A.15(b); therefore, EASA considers that no additional clarifications are needed.

comment

20 comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

The word **'configuration'** on page 25 in the sentence '21.A.15(b)(1)... including all the configurations..' requires clarification against term like 'model' or 'variant' also used in AMC/GM. A definition and a consistent use would be of help.

response

Noted.
For the purpose of the application for a new TC, the AMC provides a list of items to be considered as part of the configuration of the product. Note that Part 21 does not introduce the terms 'model' or 'variant'.

comment	*21* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 26 the references in this AMC 21.A.15(b) to AMC/GM part of Section B 'Procedures for Competent Authorities' will create conflicts in compliance demonstration on Industry side. Proposed to move the content to GM not to stay as AMC.
response	Not accepted. The AMC refers to 21.B.80/82/85, requesting that the proposal should be made in consideration of these points; EASA does not see any potential conflict for the compliance demonstration. As a matter of fact, LoI is all about the interface between applicants and EASA, therefore sometimes referring from Section A to Section B is the most efficient way of explaining the rule. EASA considers that the rule drafted on AMC 21.A.15(b) indeed has the quality of an AMC and should not be GM.

comment	*22* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 26, the sentence 'The applicant should provide detailed information about novelty, complexity, and severity aspects...' might be revised to call 'The applicant should provide detailed information about **the likelihood of an unidentified non-compliance** and severity aspects...' That would include novelty, complexity as well as DOA Performance data in line with chapter 3.2.1 on page 84 of AMC 21.B.100(a) and 21.A.15(b)(6).
response	Not accepted. The likelihood of an unidentified non-compliance is the result of the process, and is not the starting point. EASA needs to know the novelty, complexity and severity aspects of a project that, combined with the DOA performance, give the likelihood of an unidentified non-compliance.

comment	*23* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 27 the list of industry standards should include ASD and ASD-STAN.
response	Accepted. The list is not intended to be exhaustive; however, the ASD reference has been included.

comment	*24* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 27, the detailed data required for testing should be limited to 'certification testing' only to be consistent with the explanation given on page 37 'Development versus certification tests'.
response	Not accepted. The testing referred to in AMC 21.A.15(b) is part of the compliance demonstration; therefore, in general it is ‘certification testing’.

comment	*25* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 27, the required details of software tools and methods with name and version/release are not realistic. Companies are using commercial software as well as special design software and going into the supply chain it's unlimited. Why is such information

	relevant in the Certification Programme? It is covered anyway by the Design Assurance System concept. It's **proposed to delete** this item or to reduce it to a justified level of necessity.
response	Not accepted. If the analysis/calculation is part of the compliance demonstration, the software that is used can be fundamental. The use of new software for an applicant can be also relevant for the determination of the LoI. Notwithstanding that, the applicant can also refer in the CP to a DOA document that addresses this information.

comment	*26* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 27, the requirement '... novel or unusual method... **for industry in general**' is unacceptable. A company can't assess 'industry in general'. That requirement must be deleted.
response	Accepted. It is an AMC and not a requirement. The 'for industry in general' part of the sentence is explanatory and not for assessment since each time an item is novel or unusual for the industry in general, it is necessarily novel or unusual for the applicant as well. Therefore, the addressed part can be deleted.

comment	*43* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* The word 'sufficient' on page 26 bottom text block is very subjective and should be deleted.
response	Partially accepted. The information should be sufficient for EASA to determine its LoI. So the information needs to include all the relevant details about the proposed means of compliance. The wording has been redrafted to provide more clarity.

comment	*59* comment by: *LHT DO* The requirement to provide sufficient detailed information about the proposed means of compliance, last two bullet points (page 27): This is not what we understood from our talks with EASA experts during the LOI pilot phase. We will provide a description of the proposed means of compliance, but not with all details required by this NPA. In our certification projects as a MRO DOA we do design, showing of compliance and installation at the same time. Often the required details will be defined only at the end of a project. We agreed with EASA during our LOI pilot that we will revise our descriptions and add further details in the course of the project and only when the CDI has EASA involvement (higher than risk class 1). Please rewrite this requirement more to the point to enable EASA purposes of defining LOI without causing extra work for industry for low-risk CDIs which will not have EASA involvement. Futhermore, it should be possible to add details in later revisions later in the project.
response	Not accepted.

	It is always possible to add details in later revisions later on in the project. This is foreseen in the process, and it will lead to an updated assessment if the EASA involvement is affected by such updates. It might be not necessary to provide all the described information directly in the certification programme if that information is included in referenced data packages. It should be considered that an update of a CDI may lead to a different risk class and a different level of involvement.

comment	*76* comment by: *Dassault-Aviation* Dassault-Aviation AMC to 21.A.15(b) page 26 Text: The Applicant should provide sufficient detailed information about the proposed means of compliance to the applicable requirements identified under 21.A.15(b)(4), to enable the Agency to determine its (initial) Level of Involvement. Comment: Only appreciable effect on proposed design change leading to addionnal CDI is to be discussed with EASA. If not affected, initial LOI determination vs existing CDI remains unchanged
response	Not accepted. Not agreed, since as well an appreciable effect on the compliance demonstration, procedures, etc., could lead to a change of CDIs and a change in the EASA LoI.

comment	*77* comment by: *Dassault-Aviation* Dassault-Aviation Amc to 21.A.15(b) page 27 **Text:** Identification of industry standards (Society of Automotive Engineers (SAE), American Society for Testing and Materials (ASTM), European Organisation for Civil Aviation Equipment (EUROCAE), etc.), methodology documents, handbooks, technical procedures, certification memoranda, policy statements, guidance material, etc., that should be followed in the demonstration of compliance; when the compliance demonstration involves testing, a description of the ground and flight test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; **Comment:** Such detailed information are not systematically provided by the TC Holder through the certification programme but should be provided in the test programs as part of the certification demonstration activities. Requested data are too exhaustive
response	Partially accepted.

EASA agrees that such details are not often provided in test programmes. References to those test programmes in the certification programme are a sufficient means to comply. It might then be necessary to provide the test programmes in such cases before the EASA LoI can be determined.
See also the response to comment #59.

comment *104* comment by: *AIRBUS*

PAGE 25/ PARAGRAPH 3 related comments

No 7

"General — Identification of the relevant personnel who make decisions affecting airworthiness, operational suitability and environmental protection and who will interface with EASA, unless otherwise identified to EASA.": example should be given for "otherwise identified to EASA"

Airbus proposes "General - Identification of the relevant personnel who make decisions affecting airworthiness, operational suitability and environmental protection and who will interface with EASA, unless otherwise identified in EASA **(e.g. within DOA procedures)."**

Comment is substantive or is an objection Yes

PAGE 25/ PARAGRAPH 3 related comments

No 8

"Subcontracting arrangements for design and/or production as well as design organisation approval (DOA) responsibility sharing.": wording should refer to cases where this can be documented elsewhere

Airbus proposes "Subcontracting arrangements for design and/or production as well as design organisation approval (DOA) responsibility sharing **unless otherwise identified to EASA (e.g. with DOA procedures)."**

Comment is substantive or is an objection Yes

response Partially accepted.
No 7: Accepted.
No 8: Not accepted.
A DOA could have more subcontractors identified in the DOA procedures, but they might not all necessarily be always involved in all the projects.

comment *106* comment by: *AIRBUS*

PAGE 27 / PARAGRAPH 3 related comments

No 11
Generally the following items are not addressed in the certification program but more in the test programs and analysis/calculation reports:
"when the compliance demonstration involves testing, a description of the ground and flight test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load) as well as of the intent/objective(s) of the testing; and - when the compliace demonstration involves analysis/ calculations, a description/identification of the tools (e.g. name and version/release of the software programmes) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose; furthermore, the validation and verification of such tools and methods should be addressed."

For complex project the level of detail requested is not realistic at time of initial submission to EASA. Such detail are usually included in compliance documnet referenced in the certification program. Airbus suggest the wording should be update to clearly cover the above condition.

Comment is substantive or is an objection.

PAGE 27 / PARAGRAPH 3 related comments

No 12
*"Identification of industry standards.... "**Certification memoranda, policy statements**, guidance material" - certify memo and policy statement does not pertain to this category*

Airbus proposes to remove "**Certification memoranda, policy statements**"

PAGE 27 / PARAGRAPH 3 related comments

No 13
*Last sentence chapter 3 **"this should include any deviation from published AMC/GM"** - if within the proposed certification basis, the special conditions , equivalent safety finding, or Deviations are made, there will be change in AMC/GM*

Airbus proposes to remove the sentence

PAGE 27 / PARAGRAPH 4 related comments

No 14
The introduction of this table in the AMC should be the opportunity to clarify the boundary between MC5 and 6 as well as define the limits of MC8 (equipment, system, aircraft)

Text to be proposed by the agency

Comment is substantive or is an objection. Yes

PAGE 27 / PARAGRAPH 4 related comments

No 15
A Test programme is not a compliance document, Even if signed by CVE , a test programme does not demonstrate the compliance, the test reports is making the demonstration.

Airbus proposes to change the tittle of the column by declaring "associated documents"

response

Partially accepted.
No 11 is not accepted: at the beginning of the paragraph, it states: 'This should include the following, as far as this information is available at the time of submission to EASA.' However, the more information (perhaps at the overview level) is included in the CP, the easier will be the determination of the LoI. Furthermore, if more information becomes available during the project, the LoI proposal can be updated and the LoI adapted.

No 12 is not accepted: certification memoranda and policy statements are not part of the industry standards list. They are separate examples.

No 13 is partially accepted: the reference to a deviation from the AMC is meant to cover 'real' deviations from the AMC; see Article 3 paragraph 2 of Management Board Decision 12/2007.

It is not meant to refer to the deviations from the CSs, which are part of the certification basis (as per point 21.B.80(a)3).

No 14: This table was not introduced by NPA 2017-20, it was merely moved from the Appendix to AMC 21.A.20(b).
The boundary between MC 5 and MC 6: the current practice is to allow the applicant to make their own definition and place it in the design organisation handbook. Factors to be considered would be:
— the necessity to have a permit to fly for the test;
— whether or not the flight test crew are required to be on station for the test;
— whether the subject of the tests involves a flight test crew evaluation or assessment, or any other person/function in the organisation gathering the test results.

It is to be noted that for rotorcraft, MC 6 should be considered as soon as the rotors are turning.
Limits of use of MC 8:
MC 8 typically is an aircraft-level test that is performed on a simulator with the pilot in the loop, and with the pilot making an evaluation or assessment. The human–machine interface and the aircraft behaviour need to be representative of the type design for the purpose of the test.
Tests on simulators and other devices that involve simulated functions without a pilot in the loop are typically MC 4. Tests that are related to equipment qualification are typically MC 9.
The explanations above are subject to the needs and peculiarities of each organisation, therefore EASA does not intend to publish such explanations in an AMC format.
No 15 is not accepted: if the content of the test programme (e.g. the test set-up, specimen configuration) is relevant to the demonstration of compliance, it becomes a compliance document.

comment

125 comment by: *CAA-NL*

Page 24: AMC 21.A.15(b) Content of the certification programme

	This paragraph mentions that "The certification programme is a document that allows the applicant and EASA to manage and control the evolving product type design, …" In our opinion it includes also the OSD and the environmental aspects and therefor 'type design' could be replaced by 'type certification' to include the complete process.
response	Partially accepted. The text of AMC 21.A.15(b) has been updated to change 'evolving product type design' to 'evolving product type design or OSD'. Referring to the type certificate may need a certification programme to be produced, for instance, when the TCDS is updated (as the TCDS is part of the type certificate as defined in 21.A.41).

comment	*126* comment by: *CAA-NL* Page 25: AMC 21.A.15(b) Content of the certification programme. Item max pax/crew is repeated in listings, see below: - 21.A.15(b)(1) 'a detailed description of the type design, including all the configurations to be certified' o maximum passenger seating capacity, minimum flight and cabin crew; - 21.A.15(b)(2) 'proposed operating characteristics and limitations': o Number of passengers, minimum crew, payload, range.
response	Not accepted. The maximum passenger seating capacity and the number of passengers could be different depending on the operations. The minimum crew also can be affected by the specific operation. 21.A.15(b)(1) refers to the design, and 21.A.15(b)(2) refers to the operations.

comment	*127* comment by: *CAA-NL* Page 26: The applicant is free to select CDIs, however EASA recommends to provide this information at the level of each EASA panel or discipline affected by a proposed CDI. This reduces the flexibility of the applicant. Especially operators as STC holders provide their substantive data often in relation to ATA subjects and not to EASA panel.
response	Noted. The breakdown of the certification programme into CDIs by panels or disciplines is one possible means to comply with point 21.A.15(b). Applicants can choose other means. EASA believes that the definition of the panels is a common practice in many projects. Breaking down the CP into CDIs using the panel or discipline criteria may therefore be performed with little additional effort in most projects, and can produce a presumption of compliance.

comment	*128* comment by: *CAA-NL* Page 26 etc: At various places within section A, a reference to AMC of section B of Part 21is made. We understand that EASA is the one who finally sets the certification base, but this makes it somewhat awkward that the applicant has to use AMC written for EASA to prepare its application with EASA. Two examples: - 21.A.15(b)(4) 'a proposal for the initial type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, considering the requirements and options specified in 21.B.80, 21.B.82 and 21.B.85'

	- 21.A.15(b)(6) … 'Further interpretative material on the necessary level of details is provided in AMC 21.B.100(a) and 21.A.15(b)(6).'
response	Not accepted. These comments are outside the scope of this NPA. The references to Part 21 Section B are included in the Part 21 regulation, and not just in the AMC and GM to Part 21. Please refer also to the response to comment #21.

comment	*145* comment by: *Antonio PARADIES* The wording used for Novelty, Complexity and DOA Performance criteria remain consistent through all the documents EASA has issued on LoI, but for some reason the wording used for criticality/severity criteria varies from one document to another or even in the same document like in this very NPA. We would like to understand the reason to do so, if there is one, even if we consider it to be misleading and would recommend being consistent with the wording and using just one of them.
response	Accepted. The AMC has been amended to delete the term 'severity'.

comment	*161* comment by: *Safran Aircraft Engines* Section 3.3 AMC 21.A.15(b) (page 27) Comment: It is requested to the applicant to identify any novel or unusual method for demonstration of compliance, either for the applicant or for industry in general. If the applicant has the clear knowledge of its methods and tools, it can't have such accurate and pertinent knowledge of its competitors. Request for identification of industry novel or unusual method should be removed Proposed text: *For every aspect mentioned above, the applicant should clearly identify whether the demonstration of compliance involves any novel or unusual method (analysis or test)* ~~*either*~~ ***for the applicant*** ~~***or for industry in general.***~~
response	Accepted. See the response to comment #26.

comment	*192* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 25 AMC 21.A.15(b): The detail in this section is very aircraft specific, it should be changed to cover all products. Sections should be generated that are not aircraft specific, APU, engine etc.
response	Partially accepted. The examples given do indeed focus on aircraft certification. However, some of these examples are also valid for assessments on other aeronautical products, e.g. architectures, functions, systems, materials, ratings, operating limitations, etc. The AMC will be revised to make it clear that in this paragraph examples are given, but the DO can address other items that are specific to their project.

comment	*193* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 29: The Panels should be defined. A definition of the panels should be provided or a reference to where they are located.
response	Noted. Refer to the response to comment #3.

comment	*207* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Please add "... and its verification by the applicant and if requested by EASA" as usually the verification is performed through the applicant DOA.
response	Partially accepted. The following change has been adopted: '…by EASA when required.'

comment	*208* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* For subcontracting arrangements add (1) "for design if decisions affecting airworthiness, operational suitability and environmental protection and interfaces to EASA are subcontracted", (2) "and maintenance" as per EASA Good Practices for Coordination between Design and Maintenance, ref. EASA_S21_GP001.
response	Partially accepted. (1) The text has been changed to the following: 'Subcontracting arrangements for design, operational suitability, environmental protection and/or production as well as design organisation approval (DOA) responsibility sharing.' (2) References to maintenance can create confusion. The EASA good practice EASA_S21_GP001 covers specific cases in which an MOAH can act as a POAH, as already mentioned in the text (regarding production).

comment	*209* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Add "all the configurations specified in the type certificate to be changed and certifed. For STCs refer to 21.A.115(c) for specific configurations in the TC to be certified."
response	Not accepted. The text refers not only to changes but also to new types. AMC 21.A.115(c) already contains this information.

comment	*210* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Delete "Number of passengers" and for clarity refer to appropriate wording from EASA TCDS: "Certified Maximum Passenger Seating Capacity"
response	Not accepted. The text 'Certified Maximum Passenger Seating Capacity' is used in the list referring to 21.A.15(b)(1)) 'a detailed description of the type design, including all the configurations to be

	certified'. 'Number of passengers' is used in the list referring to 21.A.15(b)(2) 'proposed operating characteristics and limitations' and can be affected by the type of operations.
comment	*211* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Please add a list of EASA panels and disciplines or reference to related EASA document and/or publication to have a clear and common view of panels and disciplines.
response	Noted. Refer to the response to comment #3. The list of EASA panels and disciplines can be found in the interpretative material, such as in the Certification Memorandum for LoI.
comment	*212* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* (1) For the sake of a clear and common understanding of an acceptable handbook or technical procedures add that these should be "approved by the applicant's DOA". (2) To maintain the level of safety as specified in the type certificate add "technical documents and specifications from the TC holder specified in the type-certificate data sheet."
response	Partially accepted. (1) Not accepted. The use of handbooks and technical procedures could also include those that are not approved by the applicant's DOA, but are recognised and accepted by EASA. (2) Accepted.
comment	*213* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* All elements listed form nearly the test plan and therefore should be limited to the necessary elements on the level of the certification programme: intent of the testing incl. test conditions, test location and test schedule.
response	Not accepted. In the certification plan, the applicant should provide sufficient detailed information to enable EASA to determine its initial LoI. The certification plan could also refer to the test plan or extrapolate from that the information that is required to determine the LoI.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 4. New Appendix A to AMC 21.A.15(b) p. 27

comment	*179* comment by: *Leonardo Helicopters* MoC table description is too generic and could lead to misinterpretation. It is recommended to include more details as follow MC 0: <u>Compliance Statement on Compliance Record</u> Reference to a general characteristic of the type design

Election of a method
Acknowledgement of a definition.

MC 1: Design Review
System Descriptive Notes
Airframe Certification Document (description)
Flight Manual
Maintenance Manual, MRB Document
Any other document describing materials, parts, processes, fabrication methods, rigging procedures, etc. ...

MC 2: Calculation/Analysis
Technical note with either:
Calculation for the evaluation of load, strength, performance, flying quality or other characteristic
Logical Analysis of a hypothetical scenario of event
Analysis of statistical experience
Analysis of a previous justification in view of extending it to a new type/model of A/C.

MC 3: Safety Assessment
Documents describing safety analysis philosophy and methods
Safety evaluation plans (software)
System safety assessments
Zonal safety assessment
FMEA.

MC 4: Laboratory Tests
Aerodynamic wind tunnel tests, including spin tests
Ditching model tests
Structural tests on representative parts, components, large pieces of airframe or complete airframe
Material tests
Functioning, endurance, or environmental testing on subsystems or complete systems.

MC 5: Ground Tests (without engine running)
Test performed on aircraft or exceptionally on a large component intended to be installed on a flyable aircraft.

MC 6: Flight Test (with engine running)
Test performed on aircraft
Under “flight testing” are included all tests written in the “Flight Test Program” and performed by a flight test crew, i.e.: all tests which require operation on either engines or APU, whether or not the airplane actually takes off the ground.

MC 7: Inspection
The means of compliance includes:
Conformity Inspection: determination that materials, parts, processes and fabrication procedures conform with type design
Aircraft Inspection: determination of compliance with requirement, which cannot be determined adequately from evaluation of technical data.

MC 8: Simulator Tests
When a test requires a flight crew in the lop, the simulator is used when:
It is established that the representativeness is adequate
The test outcome may have hazardous consequences.

MC 9: Equipment Qualification
The qualification process may include all previous means of compliance. The demonstration of compliance is conducted through a specific procedure including Technical Specifications and Declaration of Design and Performance (DDP).

response
Noted.
The MoC table is intended to provide adequate information to classify the means of compliance, while also allowing sufficient flexibility to fit into these categories the specific items of individual substantiation evidence, which may have a different designation depending on the design organisation, the associated design, etc.
A more detailed definition of the MoC, tailored to the specificities of the organisation, could be included in the approved procedures, if that is agreed with EASA.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 5. New AMC 21.A.15(b)(5) and 21.B.100(a) p. 28-29

comment *15* comment by: *cvjnvuld*

response
Noted.
No comment provided.

comment *27* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

The combination of AMC against Section A and B as proposed by **'AMC 21.A.15(b)(5) and 21.B.100(a)**', will lead to confusion when compliance is requested from Industry under DOA surveillance. Please avoid mix of Section A and Section B for AMC text! The AMC should therefore be split of revised to **become GM**.

response
Accepted.
The reference to 21.B.100 has been deleted from the title.

comment *28* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

The reference in this proposed '**AMC 21.A.15(b)(5) and 21.B.100(a)**' to another AMC called '**AMC 21.B.100(a) and 21.A15(b)(6)**' does indicate the high risk of confusion!! Is it really proposed to have two AMCs for 21.B.100(a) split and linked with two AMCs for 21.A.15(b)? That is not supported and should be re-structured.

response
Not accepted.
AMC 21.A15(b)(6) and 21.B.100(a) have been renamed to get rid of the reference to Section B. 'AMC 21.B.100(a) and 21.A15(b)(6)' is confirmed to be accurate, since the main elements of the rule (e.g. the four criteria for risk assessment) are contained in point 21.B.100.

	Once this material is approved, the applicant will easily find it through the EASA eRules publications, since this AMC will be linked to both Part 21 points.
comment	*29* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* References to Section B content in AMC of Section A should be avoided. Please convert into GM.
response	Partially accepted. The reference to 21.B.100 has been deleted from the title; however, the material cannot be considered to be GM as it actually describes an acceptable means to comply with point 21.A.15(5). See also the response to comment #28.
comment	*30* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 29, the CDIs shall require '- information on the novelty, complexity, and criticality...'. To be consistent with page 26 it should be revised to read 'novelty, complexity, and **severity'.** Additionally it is proposed to read **'likelihood of unidentified non-compliance and severity'**. If all the details are in the Certification Programme, the risk class determination could be done directly by EASA. It should be acceptable to record the likelihood as the outcome of a process coverd by the Design Assurance System.
response	Partially accepted. The term ‘severity’ has been removed from the AMC. See also the response to comment #145. Regarding the second part, EASA disagrees with the proposal to directly perform the risk assessment, as the applicant will have more detailed information regarding each project to be certified and about the characteristics of novelty, complexity, etc. Additionally, the applicant needs to identify the risk class in order to propose the EASA LoI.
comment	*79* comment by: *Dassault-Aviation* Dassault-Aviation AMC to 21.A.15(b) page 28 Text: However, there may be cases in which the risk assessment may also be performed at the level of the compliance demonstration activity or data, or at the level of the whole certification project Dassault-Aviation: It is understood that risk assessment level is to be done at MC level in addition to assessment at CDI level or as an alternative solution ?
response	Noted. It is an alternative solution. The intent of the proposed text is to identify different options for the grouping of compliance demonstration activities for which the risk assessment will be performed. The assessment can be done at any level between the lowest level of the

	individual compliance data (i.e. no grouping or a small grouping) and the highest level of the whole certification process (the largest grouping). The selected level may be more or less appropriate, depending on the applicant and also on the type of the project.

comment	*107* comment by: *AIRBUS* **Page 28 / Paragraph 5.1 related comment** **No. 16** *The Text "The chosen breakdown into CDIs may affect the resulting risk classes (please refer to AMC 21.B.100(a) and 21.A.15(b)(6)), but should not have any effect on the compliance demonstration itself or on **"EASA's overall LoI."*** – EASA overall LoI will depend of the granularity of the CDI and the associated compliance documentation – Airbus believes the statement is not true. Airbus proposes to remove last part of the sentence "or on EASA overall LoI" to read: " the chosen breakdown into CDIs may affect the resulting risk classes (please refer to AMC 21 B.100(a) and 21.A.15(b) (6)), but should not have any effect on the complaince demonstration itself." Comment is substantive or is an objection.
response	Not accepted. The size of the CDI may have an impact on the final risk class, but the EASA LoI for the individual activities will not be affected. The final EASA LoI (as defined in AMC 21.B.100(a) and 21.A.15(b)(6)) should not be affected by the size of the CDI, and the intent of the text is to clarify this point. The text will be changed to remove 'overall'.

comment	*108* comment by: *AIRBUS* **Page 29, paragraph 3 related comment** **Nr. 17** Airbus proposes to modify the following sentence, indeed the certification program content will not "determine" but "identify" the DOA performance: "*Additionally, it is recommended to identify the EASA panel(s)/discipline(s) affected by each CDI as this will support the determination of novelty, complexity, design organisation approval (DOA) performance, and criticality."* New sentence: "Additionally, it is recommended to identify the EASA panel(s) / discipline(s) affected by each CDI as this will support the determination of novelty, complexity and criticality and finally identify design organisation approval (DOA) performance.
response	Accepted. It is agreed to replace the word 'determination' with 'identification'. It is agreed to add the proposed sentence: 'Additionally, it is recommended to identify the EASA panel(s)/ discipline(s) affected by each CDI, as this will support the determination of novelty, complexity and criticality, and finally identify the performance of the design organisation approval (DOA) holder.'

comment	*140* comment by: *Antonio PARADIES* Please clarify and define what is to be understood by *"obvious cases"* in these paragraphs (p.29, 5. and p.92, 4.), so that applicants may use them properly if the conditions are met.
response	Partially accepted. Obvious cases are cases in which the classification is straightforward and does not require any additional clarifications. In general, applicant explanations/notes regarding the proposed classification should be provided, since this will also facilitate the acceptance of the LoI proposal. Nevertheless, to avoid unnecessary additional effort, these explanations can be omitted if they are obvious. The text has been slightly amended.

comment	*145* ❖ comment by: *Antonio PARADIES* The wording used for Novelty, Complexity and DOA Performance criteria remain consistent through all the documents EASA has issued on LoI, but for some reason the wording used for criticality/severity criteria varies from one document to another or even in the same document like in this very NPA. We would like to understand the reason to do so, if there is one, even if we consider it to be misleading and would recommend being consistent with the wording and using just one of them.
response	Accepted. The AMC has been amended to delete the term 'severity'.

comment	*181* comment by: *Leonardo Helicopters* Relevant Certification Memo is not mentioned. Will it be cancelled upon AMC publication? If that will be cancelled then it is necessary to assure that the last version of CM will be embodied.
response	Noted. The generic part of the CM is embodied in the (draft) AMC/GM. The panel-specific attachments, which are not part of the (draft) AMC/GM, will be kept in the CM and will be published as certification guidance.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 6. New GM 21.A.15(c) p. 29-30

comment	*80* comment by: *Dassault-Aviation* Dassault-Aviation AMC to 21.A.15(c) page 30 **Text:** any relevant change to the design organisation approval (DOA) holder's personnel (and design organisation (DO) suppliers) involved in the project; and...

Comment:
Not acceptable as LOI determination is not to be related to individual ressources

response

Not accepted.
The determination of the LoI is indeed not related to the identification of individual resources, but this point is not related to the determination of the LoI. It is related to the liaison between the applicant and EASA and to the responsibilities identified through the certification programme.

comment

109 comment by: *AIRBUS*

Page 30, paragraph 6 related comment

No. 18
"*Following each update to the certification programme as submitted by the applicant, EASA may update the determination of its LoI in accordance with 21.B.100(c*)." The point of reference to be used to proposed the EASA LOI should be pre-defined and agreed between applicant and EASA especially for the DOA performance.

Airbus proposes to add sentence:
The DOA performance used to determine the LOI should be the one at time of initial application.

Comment is substantive or is an objection

Page 30, paragraph 6 related comment

No. 19

"any relevant change to the design organisation approval (DOA) holder's personnel (and design organisation (DO) suppliers) involved in the project;": Changes to DOAH personnel are part of changes to the DOA which are not significant as per 21.A.247, thus not subject to EASA agreement. Therefore such information shall not be part of the certification programme but is managed by the DOAH and auditable by EASA.

Airbus proposes to remove this statement.

Comment is substantive or is an objection

response

Not accepted.
Comment #18: Not accepted.
In the case described, the LoI update is expected to be mainly driven by the updates introduced into the certification programme. In accordance with 21.B.100(c) and independently of a new submission of the certification programme, EASA shall update its LoI when this is warranted by the receipt of information which has an appreciable impact on the risk that was previously assessed.

Comment #19: Not accepted.

	EASA does not make any agreements on the nomination of personnel within the design organisation except for Form Four agreement or acceptance; see the response to comment #80.
comment	*214* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Not each and every change of personnel due to individual reasons, e.g. absence for vacations, illness etc., should trigger an update of the certification programme; such changes should be limited to "new personnel". For DO suppliers this should be limited to suppliers who make decisions affecting airworthiness, operational suitability and enveironmental protection.
response	Not accepted. The GM refers to a 'relevant change' to the design organisation approval (DOA) holder's personnel (and design organisation [DO] suppliers) who are involved in the project with the responsibilities identified through the certification programme. See also the response to comment #80.
comment	*215* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Add to changes to the schedule "if affecting EASA LOI", to prevent that changes of the applicant's internal schedule trigger an update of the certifcation programme.
response	Partially accepted. The GM refers to 'relevant changes to the schedule' only, and other changes are not expected to generate an update of the certification programme. The 'relevant' changes are those that impact EASA's involvement in the demonstration of compliance.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 12. Appendix to AMC 21.A.20(b) is deleted. p. 32

comment	*110* comment by: *AIRBUS* **Page 32 / paragraph 14 related comment** **No. 20** *Text "the certification programme to be followed, including the certification basis and the detailed means of compliance, should be almost identical to the one accepted by EASA for a major change or an STC when approved for the scope of the privilege as per point 21.A.263(c)(8) or (9); it may differ in some aspects (e.g. the detailed description of the changes), but it should be shown to remain in the frame of the corresponding justification document;"*: Additional examples should be provided. Airbus proposes the certification programme to be followed, including the certification basis and the detailed means of compliance, should be almost identical to the one accepted by EASA for a major change or an STC when approved for the scope of the privilege as per point 21.A.263(c)(8) or (9); it may differ in some aspects (e.g. the detailed description of the

	changes, Airbus believes there **is no need for CDI, no need for LOI justification, …),** but it should be shown to remain in the frame of the corresponding justification document;" Comment is an observation / suggestion. **Page 32 / paragraph 14 related comment** **No. 21** "*Applicants for a TC (or an RTC) should apply point 21.A.20 in full. Applicants for a major change to a TC or an STC are required (see points 21.A.97(b)(3) and 21.A.115(b)(4)) to apply point 21.A.20.*"**??**- reference is incomplete Airbus proposes to EASA to complement the reference. Comment is substantive or is an objection **Page 32 / paragraph 14 related comment** **No. 22** "the certification programme to be followed, including the certification basis and the detailed means of compliance, should be **almost** identical to the one accepted by EASA for a major change or an STC when approved for the scope of the privilege as per point 21.A.263(c)(8) or (9); it may differ in some aspects (e.g. the detailed description of the changes), but it should be shown to remain in the frame of the corresponding justification document; and" Airbus proposes EASA to define the term "almost". Comment is substantive or is an objection
response	Partially accepted. Comment #20: Noted. The GM explains that, if the DOA holds the privilege to approve certain major repairs/changes/STCs, then there is no application, and therefore no EASA LoI. This means that the risk assessment requested by 21.A.15 is covered by the justification document, and it is not necessary to repeat it. This concept is covered by the indication provided in the GM that the certification programme should be 'almost' identical. Comment #21: Accepted. The text has been completed. Comment #22: Noted. The GM already provides a clarification regarding acceptable differences, which should, in any case, remain in the frame of the corresponding justification document.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 14. New GM 21.A.20 p. 32

comment	*216* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* For clarity use "compliance" instead of "justification" to be in line with 21.A.20(c).
response	Not accepted. 'Justification' is the right word in this context, since it refers to the document described in AMC2 21.A.263(5)(8)(9).

comment	*217* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Correct wording should be "compliance documentation" instead of "justification document" to be in line with 21.A.20(c).
response	Not accepted. Refer to the response to comment #216.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 15. New GM 21.A.20(b) p. 32-33

comment	*194* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 33: The following is stated "If so agreed by the EASA, some compliance documentation may be produced after the issuance of the final statement of compliance required by 21.A.20(d)." what is the criteria for what can be produced after final statement of compliance?
response	Noted. This provision is intended to allow for a certain amount of flexibility, which may be needed in specific cases, but it is not intended to establish general criteria that are applicable to all projects.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 16. AMC 21.A.20(c) p. 33

comment	*31* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* The text'(except test or inspection programmes/plans)' should be added to the third item as well ' a satement by the applicant declaring... **(except test or inspection programmes/plans)**'; No substantiation data, no compliance declaration.
response	Noted. EASA considers that proof of compliance is provided by the combination of the test plan and the test report. The test report does not mandatorily repeat all information already contained in the test plan. Therefore, the test plan completes the understanding of the validity of the reported results.

comment	*73* comment by: *LHT DO* We appreciate that the requirement that every compliance document has an adequate link with the corresponding certification programme was deleted. No change proposed, only a thanks for the deletion.
response	Noted.

comment	*111* comment by: *AIRBUS* **Page 33 / paragraph 15 related comment** **No 23** *" - any significant failure or finding resulting from the tests performed as per points 21.A.33 or 21.A.35.":* this statement should be focussing on failures/findings where the design is at stake. When the test only is at stake (.g uncontrolled test conditions) the test has to be renewed but this is not a criterion for reporting to the EASA. Therefore Airbus suggest "any significant failure or finding resulting from the tests performed as per points 21.A.33 or 21.A.35 **where the design subject to certification is at stake"** Comment is substantive / objection **Page 33 / paragraph 16.1 related comment** **No 24** *1. "Compliance documentation comprises of one or more test or inspection programmes/plans, reports, drawings, specifications, calculations, analysis etc.":* drawings is now out dated considering that design data are mostly 3D data. Airbus text proposal: Compliance documentation comprises of one or more test or inspection programmes/plans, reports**, ~~drawings~~, design data (2D or 3D)**, specifications, calculations, analysis etc.": comment is an observation / suggestion. **Page 33 / paragraph 16.2 related comment** **No 25** *"Each compliance document should have a number and issue date. The various issues of a document should be controlled and comply with point 21.A.55.":* Number is not sufficient, unitity is needed. Only the validated issues and not the draft issues shall be subject to configuration control. Airbus suggest that each compliance document should have a **unique reference** and issue date. The various **validated (signed off)** issues of a document should be controlled and comply with point 21.A.55."

Page 33 / paragraph 16.2 related comment

No 26i

"*a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and*" – this sentence should remove test and inspections programmes/plans as the plan do not provide proof of compliance

Airbus proposes the following reading;
"a statement by the applicant declaring that the document provides the proof of compliance for which it has been created **(except test or inspection programmes/plans)**; and"

response

Partially accepted.

Comment #23 on GM 21.A.20(b): Noted.
EASA believes that the detail 'significant failure or finding' already provides the necessary flexibility for the organisation to determine when to report to EASA.
At the same time, EASA believes that this reporting should not only be done when the 'test failure or finding' leads the applicant to question the design under certification. There may be other considerations (e.g. the inadequacy of the test plan, the test set-up, the prototype, the test sequence, etc.) in the origin of a failure which, if significant enough, should be also reported and would lead to the involvement of EASA in the agreement of their necessary (i.e. significant enough) modifications. The introduction to the GM clearly states that the applicant should report to EASA any event or difficulty that invalidates or appreciably affects the assumptions that were previously made.

Comment #24 on GM 21.A.20(c): the comment is noted and this point may be modified in the future. At the same time, EASA believes that the inclusion of 'drawings' as compliance documentation is still appropriate today.

Comment #25 on GM 21.A.20(c): the comment is partially accepted. A compliance document should be unequivocally identified by its reference and issue date. The text has been amended to emphasise this point, while providing flexibility on how to manage the identification elements to account for the intended uniqueness.
EASA believes that drafts can never be construed as issues of a document, and does not deem it to be necessary to introduce any additional detail in this respect.

Comment #26 on GM 21.20(c): refer to the response to comment #31.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 17. GM 21.A.20(d) p. 33-34

comment

32 comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

The text '(including the function and reliability tests)' should <u>be deleted</u> as these tests are not listed in 21.A.35 itself.

response

Partially accepted.

The Flight Test is addressed by 21.A.35, and 21.A.20 refers to this paragraph when asking for the declaration. The text will be revised to be consistent, i.e. 21.A.35 is called 'Flight Test' while the GM makes reference to a 'Function and Reliability Test'. It will also be clarified that this test applies to aircraft only, and not to other aeronautical products.

comment

81 comment by: *Dassault-Aviation*

Dassault-Aviation

AMC to 21.A.15(c) page 33

Text:
No feature or characteristics' in point 21.A.20(d)(2) means the following: while every effort is made to address in the applicable certification basis all the risks to product safety or environment that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant has to declare that they have not identified any such features or characteristics

Comment:
What is the interest of such additional text ? 21.A.20(d)(2) does not exist in Part 21 ?

response

Noted.
The text of GM 21.A.20(d) serves as an explanation, and is intended to clarify what is meant by 'no feature or characteristics' of 21.A.20(d)(2). The typo will be corrected and reference will be made to 21.A.20(d)(2).

comment

141 comment by: *Antonio PARADIES*

Please clarify why the formal declaration in this paragraph is being asked by EASA from the applicant; and where, specifically, the declaration is going to be expected to be found.

response

Noted.
The formal declaration to be provided by the applicant is required under 21.A.20(d). The GM provides some explanation related to the wording used in 21.A.20(d) only.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 20. GM 21.A.33 p. 35

comment

4 comment by: *Yuksel Kenaroglu*

Paragraph "GM 21.A.33(d)":
First sentence of this paragraph is undestood that , generally, it will not require EASA to apply any inspection or test on the design before Applicant's "decleration of compliance". But, Aplicant

	may require a major design change that may need EASA Approval, before decleration of compliance. This statement may be reviewed.
response	Accepted. The first sentence has been deleted and the remaining text has been adjusted to provide more clarity.

comment	*112* comment by: *AIRBUS* **Page 35 / paragraph 21 related comment** **Nr. 26ii** This AMC should consider the ASD-STAN Standard prEN 9250 which has been already agreed by EASA. This comment is substantive or is an objection Yes **Page 35 / paragraph 20 related comment** **Nr. 27** *"The obligation of the applicant to allow EASA to witness or carry out any test or inspection as per point 21.A.33(d) applies generally once the applicant completes the compliance demonstration and issues the declaration of compliance as per point 21.A.20(d)." – this is not practical especially for destructive test (eg ultimate loads, crash test…)* Airbus proposes to remove the sentence as not feasible This comment is substantive or is an objection Yes **Page 35 / paragraph 20 related comment:** **Nr. 28** *"Moreover, for **extensive** certification projects"* –extensive should be defined Airbus propose to remove the sentence as linked to the previous one and do not add clarification. The proposed WoW just after is the practical one. This comment is substantive or is an objection Yes
response	Partially accepted. Comment #26ii: Noted. EASA will take into consideration the referenced standard as AMC as part of future regular updates of the AMC/GM to Part 21 following an assessment of the ASD standard and its public consultation. Comment #27: Accepted. This sentence has been deleted. Comment #28: Accepted. The sentence has been deleted.

comment	*162* comment by: *Safran Aircraft Engines* Section 3.21 AMC 21.A.33 (page 35) Comment: Obligations should apply to the ETSO Proposed text: *Use of the term 'applicant': point 21.A.33 is applicable to type certification, major changes, major repairs, ~~and~~ supplemental type certificates (STCs) **and ETSO**. Despite using the word 'applicant', it is also applicable to major changes, major repairs and STCs approved under DOA privileges (see point 21.A.263(c),(5),(8) or (9)).*
response	Partially accepted. Through 21.A.604, this point is also applicable to ETSOs for APUs; however, applicants for other types of ETSO are not subject to this point. The meaning of 'applicant' has been explained to also include the demonstration of compliance that is performed as part of a privilege.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 21. New AMC 21.A.33 p. 35-37

comment	*5* comment by: *Yuksel Kenaroglu* First sentence of GM 21.A.33 (d) (EASA involvement in the tests...) and sentence starting "Nevertheless, if aggreed...) is a little bit in contradiction when we consider EASA involvement. This last sentence also show that EASA involvement in the tests would be well before Applicant's decleration of conformity.
response	Accepted. The first sentence of GM 21.A.33(d) has been deleted.

comment	*33* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* The majority of this AMC content is explanatory information and should be converted into a GM.
response	Noted. Although part of this AMC contains information intended to facilitate the interpretation of the rule, this AMC also contains practical provisions to demonstrate compliance with 21.A.33. For readability purposes, EASA believes that keeping all the information in the same AMC would facilitate its use, therefore EASA does not concur with the proposal to turn it into GM.

comment	*82* comment by: *Dassault-Aviation* Dassault-Aviation AMC 21.A.33 page 37

Text:
Any planned test event should be declared in advance to be either a development test or a certification test

Comment:
Declaration to EASA of all development tests in advance is not relevant to compliance demonstration

response

Partially accepted.
Development tests are not meant to be declared to EASA.

comment

113 comment by: *AIRBUS*

Pages 35 & 36 / Paragraph 21 related comment

Nr. 29
Non-conformity between the design of the test specimen and the proposed type design.
These are typically defined in th early stage of the test planning, and should be addressed.

These deviation might not be known early in the planning as the type design definition is an iterative process – there is 2 subcase – the deviations known at the time of test and those identified after test due to type design evolution.

The comment is substantive / objection.

Pages 36 / Paragraph 21 related comment

Nr. 30

". It is recommended that the design organisation has a "solid" configuration management process to track the evolving type design." – definition of solid configuration management.

Airbus suggest to remove the adjective "solid"

The comment is substantive / objection

response

Partially accepted.
Added: '… proposed type design at the time of the test.'

Removed: 'solid'.

comment

163 comment by: *Safran Aircraft Engines*

Section 3.21 AMC 21.A.33 § Conformity of the test specimen
Comment:
This paragraph defines 2 different issues with regard to the conformity of the test specimen:
· The conformity of the actual design of the test specimen
· The statement that the test specimen is representatives with the intended type design
First is to record the actual tested design configuration, while the second is to state that the test specimen is representative of the type design.

Last point need to be assessed at the end of the test in the test compliance document, but will also need to be confirmed at the very end of the certification process, to ensure that no post-certification type design configuration change that may occurred during the certification process has invalidated the test compliance document.
Proposed text:
Statement of representativeness of the ~~*Conformity of the*~~ *test specimen* ***with the intended Type Design****: the statement of conformity required by point 21.A.33(c) is intended to ensure that the manufactured test specimen adequately represents the proposed type design. Possible types of non-conformity may be the following:*
— Non-conformity between the design of the test specimen and the proposed type design. These are typically defined in the early stage of the test planning, possible (e.g. in the test plan), ***defined in the test compliance document, and confirmed at the very end of the certification process.*** *There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.*

response
Not accepted.
We understand the proposal to rename the statement. However, since the name is defined in the rule, we have kept 'statement of conformity'.

comment
218 comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067*

References to (a) and (b) is not obvious, please provide complete references.

response
Accepted.
Added: '… the two types of non-conformities above'.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 22. GM to 21.A.90A p. 37-38

comment
35 comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

On page 38, the top sentence contains 'concept of TC'. What's the meaning of 'concept'? 21.A.41 defines the content of an EASA TC. Please delete this term.

response
Accepted.
The concept of a TC is defined by its elements in 21.A.41, and the sentence has been reworded for clarity.

comment
114 comment by: *AIRBUS*

Page 37 / paragraph 21 related comments

Nr. 31
Tests that are intended to be performed only once should be declared certification tests."
This is only relevant for test related to certification requirement

Airbus propose to reword the sentence to declare:

	*Tests **"supporting the compliance demonstration"** that are intended to be performed only once should be declared certification tests.* *Comment is substantive / objection* **Page 37 / paragraph 21 related comments** **Nr. 32** *"Point 21.A.33(d)(1) refers to any data or information related to compliance data; the scope of said requirement is therefore not limited to inspections and tests.* *In particular, point 21.A.33(d)(1) is not limited to data and information related to compliance demonstration items (CDIs) in which EASA is involved."-* if other data then this is linked to a different Part 21 requirements Airbus propose to remove the sentence as already covered by Part 21.A.257 (b) *Comment is substantive / objection*
response	Partially accepted. Comment #31: Accepted. We have added 'Tests supporting the compliance demonstration that are intended to be performed only once ...' Comment #32: Not accepted. Point 21.A.257 refers only to applicants who hold a DOA, while point 21.A.33(d)(1) is applicable to any applicant.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 23. GM 21.A.91	p. 38-40

comment	*6* comment by: *Yuksel Kenaroglu* Paragraph 3.4.(e): "...airworthiness limitations", "operational limitations"... This NPA may not be a good place to discuss this issue. Anyway, the question "Are operational limitations not a part of airworthiness ?" needs to be answered. The airworthiness may be assumed as a whole; "technical airworthines" and "operational airworthines"... **(Since, I have faced with some difficulties during savings of my comments; multiple savings, may be possible. Sorry for those !)**
response	Noted. Additional clarifications may be provided in the future. The current wording reinstates pre-existing text, the meaning of which is believed to be sufficiently clear.

comment	*36* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 39, at the end of new listing (f) is the last word 'and' exclusive or is it 'and/or'? Please ensure clarity.
response	Accepted. The introductory text specifies that 'a change [...] should be classified as major, in particular, but not only, when one or more of the following conditions are met:…' The 'and' that appeared as the last word in new item (f) has been deleted for clarity.

comment	*60* comment by: *LHT DO* Please reconsider the classification criteria for changes to CCD and FCD. Currently the classifaction of a change to CCD or FCD is part of / results from the showing of compliance. They should be two separate processes, since classification has to be done at the beginning of the project, while the showing of compliance takes place at the end of the project.
response	Noted. At the current stage, EASA is not in a position to redefine the classification for CCD and FCD changes due to the nature of these OSD constituents. However, the comment will be taken into consideration for future developments.

comment	*61* comment by: *LHT DO* Currently a change to type certifcate is defined as change to type design and change to OSD. The classifiction criteria are accordingly (figure 1 in GM No 1 to 21.A.103, 21.A15 and 21.B.70). Changes to AFM should follow the same logic of being one component of a change to type certificate. Please also consider this logic to changes to ICA (NPA 2018-01) which breaks the logic even more by being partly part design and partly not.
response	Noted. Changes to the AFM have been addressed in GM 21.A.91 paragraph 3.6. It is to be noted that the classification of changes to a type certificate is to be performed according to the new LoI concept. Therefore, the certification programme has to be broken down into CDIs and a risk assessment has to be performed for each CDI. If the risk class is 1, there will be no further EASA involvement.

comment	*115* comment by: *AIRBUS* **Page 39 / paragraph 23 related comment.** **Nr. 33** *"(e) where the change alters the airworthiness limitations or the operating limitations;":* changes to ALS could be minor as proposed in the NPA related to ICAs. Airbus propose to merge this change with new proposal in NPA related to ICAs Comment is substantive / objection
Response	Not accepted.

NPA 2018-01 'Instructions for continued airworthiness' has a different road map, and it is not possible to merge the changes that are proposed until they are definitive.

comment

150 comment by: *Christopher BERRY*

I suggest that deleting 'changes altering Airworthiness Limitations or Operating Limitations' was not erroneous , but made consciously to avoid contradiction with GM 21.A.263(c)(4) §2.1 (b), which has now been deleted by this NPA and replaced by GM 21.A.91 §3.6(b)(1).

i.e. Changes to the AFM Operating Limitations that are achieved without altering or exceeding certification data (e.g. weight, structural, noise, etc.,) could be classified as minor.

The following revised text is suggested.

NPA TEXT:

(e) where the change alters the airworthiness limitations or the operating limitations;

PROPOSED TEXT:

(e) where the change alters the airworthiness limitations;

(f) where the change alters the operating limitations and has an appreciable effect on characteristics affecting the airworthiness of the product in accordance with 21.A.91;

response

Not accepted.

Refer to response to comment #149.

comment

151 comment by: *Christopher BERRY*

As the term 'certification data' is a unique term without a clear definition it is suggested that a better description is provided. This will also ensure that 'certification data' is not confused with the 'certification data' provided as a 'certification data package', which is now defined in this NPA.

The following revised text is suggested.

NPA TEXT:

Changes to limitations or procedures that are made without altering or exceeding the certification data (e.g. weight, structural data, noise, etc.);

PROPOSED TEXT:

Changes to limitations or procedures that are made without an appreciable effect on characteristics affecting the airworthiness of the product in accordance with 21.A.91;

response

Partially accepted.

	The text of the NPA already includes examples to clarify the intended meaning. However, for clarity, the sentence has been amended, and the term ‘certification data’ has been deleted.

comment	*164* comment by: *Safran Aircraft Engines* Section 3.23 AMC 21.A.91 §3.2 Comment: It is referred to GM 21.B.107 ad 21.B.110 that doesn’t exist in the proposed NPA. To add GM or suppress reference to it. proposed text: N/A
response	Not accepted. GM 21.B.107 and 21.B.110 exist, see page 49 of the NPA.

comment	*177* comment by: *Christopher BERRY* Though it is not part of this NPA, the following text should be amended to identify if it is the 'Agency' or the 'DOA Holder' that can reclassify the change to minor. TEXT IS 'A simple design change planned to be mandated by an airworthiness directive may be re-classified minor due to the involvement of the Agency in the continued airworthiness process.' PROPOSED TEXT 'A simple design change planned to be mandated by an airworthiness directive may be re-classified minor by the DOA Holder due to the involvement of the Agency in the continued airworthiness process.'
response	Partially accepted. The intent of this text is that the reclassification to minor is to be agreed between EASA and the DOA holder. The text now reads: ‘A simple design change planned to be mandated by an airworthiness directive may be reclassified as minor due to the involvement of EASA in the continued airworthiness process when this is agreed between EASA and the DOA holder.’

comment	*183* comment by: *Leonardo Helicopters* It is not clear the meaning of terminating action. Is the action to be carried out for terminating the unsafe conditions (it is assumed that the AD provides an initial/preliminary solution and the change provides the final solution)? Or terminating the AD (e.g. fatigue life limit initially reduced by AD and finally included in ALS)? Or the item formally/explicitly reported in AD “solving a safety issue”?

response | Noted.
The terminating action of an airworthiness directive is the action that fully fulfils the requirement of the airworthiness directive without any further actions being necessary.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 24. Appendix A to GM 21.A.91 p. 41-42

comment | *7* comment by: *Yuksel Kenaroglu*

Page 42:
In this process flow, the statement, "appreciable", may need clarification.
Lets assume that, Designer accepted that the Change is not appreciable, and, didn't consult with EASA.
After a mishap, EASA determined that, that Chance was more than appreciable.
EASA may not available to carry out those applications, because of workload. Isn't it possible to use Design-Country Authority as first step for Applicants to take some workload of the EASA ?

response | Noted.
The term ‘appreciable’ stems directly from point 21.A.91 in Part 21.
The proposed guidance material provides explanation, in particular, refer to point 3.4 and Appendix A in GM 21.A.91.

comment | *37* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

The new chart on page 42 calls up 'For design changes (please refer to Section 3.4)' and 'For changes to OSD constituents...'. As the whole chart defines changes to a TC, please ensure clarity how to proceed with changes to other constituents on the TC (not design, not OSD). Ensure completeness against 21.A.41.

response | Noted.
The purpose of the chart is not to clarify or further define the elements of the type design as per 21.A.41, but to provide guidance concerning the classification of changes. In this respect, the guidance in GM 21.A.91 including this chart is complete and fully addresses the points in 21.A.91.

comment | *142* comment by: *Antonio PARADIES*

On this flow chart, the three dotted line boxes after Major box are considered to be too close to the boxes above them which could be leading to misinterpretations; as well as the OSD related box (“For changes to OSD […] examples in Section 3.5”) which is also too close to the surrounding boxes.

response | Accepted.
The flow chart has been improved.

comment | *186* comment by: *CAA CZ*

	Page 42: Diagram "Change to a type certificate TC": In the box with list of criteria of major change, in order to keep the logic of multiple criteria of major change, the word "and" should be replaced by "or". Meeting one of listed criteria means the change is major, i.e. the logical relation here is OR (not AND).
response	Accepted. The flow chart has been amended accordingly.

comment	*219* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* For clarity guidance should be added for "Any good reason".
response	Not accepted. There could be several different kinds of 'good reasons' identified by the applicant, and in each case, a dedicated evaluation has to be made by EASA. There are no 'predefined cases' that are universally valid, therefore EASA believes that the current flexibility should be kept.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 25. New AMC 21.A.93(a) p. 43

comment	*167* comment by: *Safran Aircraft Engines* Section 3.25 AMC 21.A.93(a) (page 43) Comment: This AMC request the use of the web-based "EASA applicant Portal". It should be in the rule to enforce its implementation, otherwise the applicant should be allowed to use another mean. AMC should be transferred in the regulation Section A § 21.A.93(a), to request to file an application using the web-based 'EASA Applicant Portal' *or the application form for a supplemental type certificate (STC) (FO.CERT.00033) which may be downloaded from the EASA website*. Proposed text: ~~***AMC 21.A.93(ab) Form and manner***~~ ~~*The applicant should file an application using the web-based 'EASA Applicant Portal'17 or the application form for a supplemental type certificate (STC) (FO.CERT.00033)18 which may be downloaded from the EASA website.*~~ ~~*The form should be completed in accordance with the completion instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website19.*~~
response	Not accepted. See the response to comment #160.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 26. GM 21.A.93(b) p. 43

comment	*38* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* The listing in the (already existing) bracket 'calculation, test or analysis' should be revised to be constent with Appendix A to AMC 21.A.15(b) to read **'(Engineering Evaluation, Tests, Inspections or Equipment Qualification)'**.
response	Not accepted. Engineering Evaluation, Tests, Inspections or Equipment Qualification are in accordance to the new Appendix A type of compliance, and not the means of compliance that we are referring to, which are expected to be more detailed.

comment	*116* comment by: *AIRBUS* **Page 43 / paragraph 26 related comment.** **Nr. 34** The 21.A.93 is related to application and the changes to a TC requiring an application. Thus the AMC21A93(b) should also be limited to this perimeter, as a consequence it should not contain any request related to changes performed under privilege for which no application is performed. Airbus propose to remove the sentence "*The level of detail should be the same regardless of whether the change is approved by EASA or under a design organization approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance."* Comment is substantive / objection
response	Accepted The sentence has been deleted. GM.21.A.95(b) and GM.21.A.97(b) have been created to clarify that the level of detail should remain the same regardless of whether the change is approved by EASA or under a DOA privilege.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 29. New AMC to 21.A.95 p. 44-47

comment	*8* comment by: *Yuksel Kenaroglu* Page 45; first sentence: "...to applicant (...?) to EASA" Need correction ? For minor changes, in-country Authority may play a role for reviewing those data that Designer produced, without giving harm to privileges.
response	Partially accepted. The first part of the comment is agreed, and the text will be corrected as follows: 'Point 21.A.95(d) only applies to projects where an application to EASA is in place.'

	The second part of the comment is noted. The review of data approved under the DOA privileges is done by EASA within the surveillance process of the DOA. Sometimes, indeed, EASA may subcontract this surveillance activity to an NAA. But it remains an EASA activity.
comment	*9* comment by: *Yuksel Kenaroglu* Page 46; (e) and (g): The statement "...change to the type design"...may be as "... change to the type certificate"...? Personally, I prefer using the statement "change to the type design", or, "change to t he **certified type design**" to "change to type certificate"... **(This proposal for every encounter in this NPA.)**
response	Partially accepted. The change to a type certificate is defined in GM to 21.A.90A, and it will be used in this AMC. The text will be changed accordingly. The text will be corrected as follows: (e) Definition of the change to the type certificate 'The change to the type certificate should be defined in accordance with GM 21.A.90A.'
comment	*56* comment by: *KID-Systeme GmbH* AMC 21.A.95 Item (g). Is it really intended to exlude other OSD constituents (except MMEL) from minor change approval? It was applicable e.g. for CCD at the time of OSD introduction and was reasonable; refer to Annex to ED Decision 2016/007/R? Please explain the reasons for limitations. If minor change approval is really limited to MMEL, the headline shall be changed to **'i.e.** [...] (MMEL)'; instead of '**e.g.** [...] (MMEL)')
response	Accepted. EASA concurs with this proposal and the text has been modified accordingly.
comment	*117* comment by: *AIRBUS* **Page 46 / pharagraph 29 related comment** **Nr. 35** *f) Embodiment/installation instructions* *The instructions for the embodiment/installation of the change (e.g. service bulletin, modification bulletin etc.) should be defined. This may include the installation procedure, the required material, etc.* The point of embodiment should be defined but the service bulletin is not relevant for change installed during production. Airbus propose to remove the notion of service bulletin comment is substantive / objection
response	Partially accepted.

	EASA agrees that for changes that are implemented during production, a service bulletin will not be used. A service bulletin is provided only as an example in the brackets. Another example is a 'modification bulletin'. In order to extend the scope, another example will be added as a 'production work order'.
comment	*129* comment by: *CAA-NL* Page 47, AMC 21.A.95(i)(1) is contrary to (previous) determination of the certification basis in 21.A.101, where the CB is i.a.w. 21.A.101(a) the CS at the day of application, and by way of derogation to 21.A.101(a) and i.a.w. 21.A.101(b) the CB might be referred to an earlier amendment of the CS, but it might not precede the CS incorporated in the TC. We could not find any substantiation for this change and see the arguments of the advantage it gives to industry with this difference on the certification base between major and minor.
response	Not accepted. Although the wording in the proposed new Part 21 has changed, the intent of the requirements provides the same options to the applicant, but in turn, gives a more appropriate starting point for a minor change. In fact, minor changes are, by definition, not significant, so also under the previous version of Part 21, this would always allow applicants to follow 21.A.101(b) or (c) (depending on the weight), and the applicant could select requirement amendments between the TCDS and the application date. In the new Part 21, the result is the same, but the starting point is always the certification basis in the TCDS (as in the bottom-up approach of 21.A.101(c)), but the applicant can still select later amendments.
comment	*136* comment by: *AIRBUS* **PAGE 46 / PARAGRAPH 29 (d)(3) related comment** **No 66** *"Aircaft manuals: where applicable, supplements to approved manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.":* AMM is not an approved manual as not required to be approved in the regulation (e.g. CS xx-1529, Part 21). *"Aircraft manuals: where applicable, supplements to approved manuals (e.g. aircraft flight manual (AFM),* airworthiness limitations section (ALS) ***~~aircraft maintenance manual (AMM)~~,*** *etc. may be issued."* Comment is substantive or is an objection Yes **PAGE 46 / PARAGRAPH 29(e) related comment** **No 67** *"(e) Design information The change to the type design is defined in terms of drawings, specifications, and any other information that captures the change to the type design on accordance with point 21.A.31.": the word "drawings" is now out dated considering that design data are mostly 3D data.*

	"(e) Design information The change to the type design is defined in terms of ***~~drawings~~****,* design data (2D or 3D), *specifications, and any other information that captures the change to the type design on accordance with point 21.A.31."*
response	Partially accepted. Regarding the first part of the comment, it is agreed that the AMM is not approved. The intent of the text is to highlight that, as part of a minor change, supplements to manuals can be issued. This does not refer only to the approved parts of the manuals. So the word 'approved' has been removed. Regarding the second part, the reference to the type design and 21.A.31 has been removed, so the word 'drawing' is no longer used. A reference to the type certificate and the corresponding GM to 21.A.90A has been added. See also the response to comment #9.

comment	*196* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 44: inconsistent structure. "AMC to 21.A.95" should be change to "AMC 21.A.95" to be consistent with the rest of the changes.
response	Accepted. The text has been amended accordingly.

comment	*197* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 46: Section d(3) "See also additional guidance below on embodiment/installation instructions." this should point at the section. Proposed change "See also additional guidance below on embodiment/installation instructions, item f."
response	Accepted. The text will be changed as proposed.

comment	*198* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 47: This is too aircraft specific it should be changed to product.
response	Accepted. 'Aircraft' has been replaced by 'product' in point (i)(1).

comment	*199* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 47: (i) (2) this states that application can elect to comply with a later amendment of the affect CS with out affecting the classification this is in contradiction to, this is inconsistent to the AMC 21.A.263 page 62 and GM 21.A.91 page 42.
response	Noted. The intent of the text is to explain that the applicant can elect to use later requirements with respect to those that would be acceptable for a minor change as explained in (i)(1): the certification basis incorporated by reference in the TCDS. This is not, strictly speaking, an elect to comply in the sense of 21.A.101(f), but EASA agrees that there are some commonalities. This is not in contradiction with 21.A.263 and 21.A.91, which describes cases where the

	certification basis needs to be changed because the proposed design requires an adjustment of the certification basis.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 31. GM 21.A.101 to be amended. p. 48

comment	*152* comment by: *KLM engineering & maintenance* Comment: NPA 2017-20 (page 48, par. 31) states that this GM is to be amended, but no amended text is included in the NPA. Recommendation: EASA is requested to include amended text to GM 21.A.101.
response	Noted. The amendment to GM 21.A.101 will be consulted through another NPA. The note here has only been added to anticipate that an amendment is needed to align the text of the GM with the contents of the related Part 21 point.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 33. GM No 1 to 21.A.103, 21.A.115 and 21.B.70 p. 49-51

comment	*83* comment by: *Dassault-Aviation* Dassault-Aviation GM N01 to 21.A.101(g) page 48 **Text:** In accordance with Article 7a(3) of Regulation (EU) No 69/2014, the Operational Evaluation Board (OEB) reports and Master Minimum Equipment Lists (MMEL) issued in accordance with the JAA procedures or by EASA before the entry into force of Regulation (EU) No 69/2014, are deemed to constitute the OSD approved in accordance with point 21.B.103(a)(2). **Comment:** Other OSD constituent need also to be considered (not only MMEL and OEB report)
response	Partially accepted. The grandfathering provisions of Article 7a(3) of Regulation (EU) No 69/2014 are no longer needed since previous OEB reports and MMELs have already been carried over in all the affected TCs. Therefore, to prevent future possible misinterpretations, EASA has decided to delete this paragraph from the GM, as the eligible grandfathered OSD, if any, should by now be listed in the EASA TCDS, together with the identification of the associated OSD certification basis.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 34. New AMC 21.A.113(a) p. 51

comment *168* comment by: *Safran Aircraft Engines*

Section 3.34 AMC 21.A.113(a) (page 51)
Comment:
This AMC request the use of the web-based "EASA applicant Portal". It should be in the rule to enforce its implementation, otherwise the applicant should be allowed to use another mean.

AMC should be transferred in the regulation Section A § 21.A.113(a), to request to file an application using the web-based 'EASA Applicant Portal' *or the application form for a supplemental type certificate (STC) (FO.CERT.00033) which may be downloaded from the EASA website.*

Proposed text:
~~AMC 21.A.113(ab) Form and manner~~
~~The applicant should file an application using the web-based 'EASA Applicant Portal'17 or the application form for a supplemental type certificate (STC) (FO.CERT.00033)18 which may be downloaded from the EASA website.~~
~~The form should be completed in accordance with the completion instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website19.~~

response Not accepted.
See the response to comment #160.

comment *195* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

RRplc comment on page 51: The second paragraph is only applicable to the forms out site the application portal as there is no completion instruction at the bottom of the application portal "completion instructions embedded at the bottom of the application forms". Proposed change: "..... downloaded from the EASA website. If forms are used out side the application portal these should be completed in accordance with the completion instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website16."

response Accepted.
The text has been adjusted as suggested.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 36. New AMC 21.A.115 p. 51

comment *191* comment by: *Leonardo Helicopters*

It is not specified how manage the definition of specific applicable configurations.

	It is recommended to include also the concept of kits compatibilities in order to ensure that the STC is properly verified and certified.
response	Partially accepted. The text has been reworded to address optional installations.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 37. GM No 1 to 21.A.239(a) p. 52-53

comment	*10* comment by: *Yuksel Kenaroglu* Page 52, point 3.1.5: "...all maintenance and operating instructions (including instructions for continued airworthiness..." This statement may be changed stating that: "... instructions for continued airworthiness including all maintenance and operating instructions, ..." Hierarchically, ICA is higher level (top of the family) than maintenance and operating instructions ! But, when doing this the title of the paragraph 3.1.5 may nedd to be changed as : "Instructions for Continued Airworthiness", or, in paragraph 3.1.5 (a), the statement for ICA in pharanthesis sholud be removed ! Finally, Maintenance data does not include ICA ! Reverse is correct !
response	Not accepted. Maintenance and operating instructions may contain ICA, not the other way round. ICA are those maintenance and operating instructions that are specifically required by the applicable CS.

comment	*39* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* Please consider NPA 2017-19 change to the title of chapter 3.1.5 to be newly called 'Instructions for Continued Airworthiness and Operating Instructions. It is even proposed to finally read: **'Instructions for Continued Airworthiness and Operating or Installation Instructions'**.
response	Accepted. EASA agrees, however, that the title of paragraph 3.1.5 will be amended in accordance with the results of NPA 2018-01 'Instructions for Continued Airworthiness'.

comment	*130* comment by: *CAA-NL*

	Page 52 item 37 GM No.1 to 21.A.239(a) changes the text of 3.1.5 Maintenance and Operating Instructions par. (a); in the proposal the wording is “Ensuring the preparation and updating of all maintenance and operating instructions (including instructions for continued airworthiness and Services Bulletins) needed to maintain airworthiness (continuing airworthiness)....” and reference is made to CS ().1529 Instructions for Continued Airworthiness (ICA). The CAA-NL finds this text very confusing. First of all ‘Operating’ should be deleted from the title of par. 3.1.5, because operating instructions have nothing to do with ICA. And with respect to maintenance instructions we can distinguish: - accomplishment instructions necessary for the incorporation of a change / repair on the component / aircraft; - instructions for continued airworthiness necessary for the maintenance of the components / product; Having said this, we proposes the following text for par. (a): “Ensuring the preparation and updating of all accomplishment instructions and instructions for continued airworthiness in accordance with relevant CS.”
response	Partially accepted. ‘Maintenance and operating instructions’ was part of the original text. Maintenance instructions (e.g. ICA) and operating instructions (e.g. AFMs) are indeed different, but both are intended to be captured here, and similar procedures can be used by the DOA for producing them. The text has been amended to also refer to CS 2X.1581. Refer also the response to comment #39.

comment	*137* comment by: *AIRBUS* **PAGE 52 / PARAGRAPH 37, 3.1.5 (a)** **No 68** *"establish a system to collect in-service experience to be used for the improvement of the instructions.":* the system to collect in service experience where there are potential issue is already required by 21.A.3A; therefore no need to re-state it specifically for instructions. 21.A.3A is valid for all kind of data/instructions released by the DOA holder. Airbus suggest to remove the sentence. Comment is substantive or is an objection: Yes
response	Not accepted. The sentence is not intended to identify ‘failures, malfunctions and defects’. It is meant that the DO should have a system in place to identify potential improvements to the instructions as published (e.g. a Part-145 organisation that reports errors or possible improvements in an AMM). This will also support the implementation of the new obligation as per 21.A.265(h).

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 38. GM No 2 to 21.A.243(d) to be amended. p. 53

comment	*62* comment by: *LHT DO* Please inform us about the content of the amendement.
response	Noted. The amendment to GM2 21.A.243(d) will be consulted through another NPA. The note here has only been added to anticipate that an amendment is needed to align the text of the GM with the contents of the related Part 21 point.

comment	*153* comment by: *KLM engineering & maintenance* Comment: NPA 2017-20 (page 53, par. 38) states that this GM is to be amended, but no amended text is included in the NPA. Recommendation: EASA is requested to include amended text to GM No. 2 to 21.A.243(d).
response	Noted. See the response to comment #62.

comment	*169* comment by: *Safran Aircraft Engines* Section 3.38 GM No2 to 21.A.243(d) Comment: It is referred to GM No2 to 21.A.243(d) that doesn't exist in the proposed NPA. To add GM or suppress reference to it. proposed text: N/A
response	Noted. See the response to comment #62.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 39. GM 21.A.247 to be amended. p. 53

comment	*63* comment by: *LHT DO* Please inform us about the content of the amendement.
response	Noted. The amendment to GM 21.A.247 will be consulted through another NPA. The note here has only been added to anticipate that an amendment is needed to align the text of the GM with the contents of the related Part 21 point.

comment	*154* comment by: *KLM engineering & maintenance* Comment:

	NPA 2017-20 (page 53, par. 39) states that this GM is to be amended, but no amended text is included in the NPA. Recommendation: EASA is requested to include amended text to GM 21.A.247.
response	Noted. See the response to comment #63.

comment	*170* comment by: *Safran Aircraft Engines* Section 3.39 GM No2 to 21.A.247 Comment: It is referred to GM No2 to 21.A.247 that doesn't exist in the proposed NPA. To add GM or suppress reference to it. proposed text: N/A
response	Noted. See the response to comment #63.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 42. AMC No 1 to 21.A.263(c)(1) p. 53-55

comment	*138* comment by: *AIRBUS* **PAGE 53 / Paragraph 42** **No 69** *"AMC No 1 for 21.A.263(c)(1) Procedure for the classification of changes to a type certificate (TC) or to a supplemental type certificate (STC) and of repairs designs as 'minor' or 'major'"* Add ETSO APU in the scope of this AMC.
response	Accepted. 'APU' has been added.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 44. AMC No 1 to 21.A.263(c)(2) p. 56-57

comment	*40* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 57, please revise in chapter 2.3.2 the wording 'engineering authority' by **'authority'** only to allow variations within DOAs.
response	Not accepted.

	Although it is recognised that this function might have different names in different DOAs, the dictionary meaning of 'engineering' is meant here, and as such, has validity in this context, as opposed to e.g. the financial authority.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 46. New AMC No 3 to 21.A.263(c)(2) p. 59-60

comment	*84* comment by: *Dassault-Aviation* Dassault-Aviation AMC N03 to 21.A.263(c)(2) **Text:** The procedure should explain the traceability of changes in order for any user of the AFM to understand who has approved what. Especially if a given page has been revised several times, it should be clear which part(s) of the page has/have been approved by EASA under which approval, and which part(s) has/have been approved under the privilege of a DOA holder **Comment:** The only relevant information for the AFM end user is to have the information about the AFM approval and updates. What is the AFM user supposed to do with more detailed information?
response	Accepted. The DOA should establish a means to trace which parts have been approved internally. However, this info should not necessarily be shared with any end user. The text has been amended accordingly.

comment	*139* comment by: *AIRBUS* **PAGE 60 / Paragraph 46 2.4** **No 70** *"Configuration control of the AFM The procedure should explain the traceability of changes in order for any user of the AFM to understand who has approved what. Especially of a given page has been revised several times, it should be clear which part(s) of the page has / have been approved by EASA under which approval, and which part(s) has/have been approved under the privilege of a DOA holder.":* This request is unpractical and unrealistic. Minor changes to the AFM made under DOA privilege could be only relevant to editorial changes (correction of typos). One or words are modified. Thus, no added value and no efficient way to identify and highlight in a revision record sheet that the DOA has approved these two typo corrections. Consider a more pragmatic wording for the configuration control of the AFM changes.
response	Accepted. See the response to comment #84.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 49. AMC 21.A.263(c)(6) p. 60-61

comment

11 comment by: *Yuksel Kenaroglu*

Page 61-62:
In here or at another place responsibilities of the Engine and Propeller Suppliers (Manufacturers) need to be defined more clearly and in more detail.
It is outside of this NPA, but, we well know that some (non-certified) small engine and propellers are used on the UAV's/RPAS.
When remembering this, in the scope of this NPA or in another way, some rules need to define, issue and apply to control and direct those Suppliers (Manufacturers) it may concern.

response

Noted.
The conditions and requirements for an application for a permit to fly are detailed in Subpart P of Part 21. The permit to fly will be issued for an aircraft, and not for an engine. The applicant has to specify the data and information that is related to the engine and is needed for that application, including the information related to the approval of the flight conditions. Therefore, an agreement with the engine/propeller manufacturer is envisaged. The final responsibility, in any case, remains at the aircraft level.

comment

147 comment by: *AIRBUS*

PAGE 60 / PARAGRAPH 49 related comment.

Nr. 71

In this context, the organisation responsible for the design of the engine/propeller acts as a supplier of the organisation responsible for the design of the aircraft. These conditions should be established and substantiated under the arrangement between the organisation responsible for the design of the aircraft and the organisation responsible for the design of the engine/propeller. The establishment and substantiation of these conditions is the ultimate responsibility of the organisation responsible for the design of the aircraft.":
This above new proposed statement is definitely unclear and not acceptable to an aircraft design organisation prospective. The arrangement called by this statement is not framed (purpose, scope ?) The last sentence in the statement shall be removed as putting all the responsibility for establishment and substantiation of engine/propeller flight conditions on the organisation responsible for the design of the aircraft. Eventualy, ...

PROPOSED TEXT:
Keep current content of published AMC 21.A.263(b)(1): "The establisment of flight conditions may include conditions related to engines/propellers without a type-certificate or with unapproved changes and fitted on the aircraft for which a permit to fly is requested. These conditions (i.e. installation, operating, maintenance conditions or limitations) are defined by the organisation responsible for the design of the engine/propeller and provided to the organisation responsible for the design of the aircraft.

When the organisation responsible for the design of the engine/propeller has a DOA, the establishment and substantiation of these conditions must be done under the relevant DOA procedures. For that purpose, the associated documentation must be processed like any other compliance document. It must be provided to the organisation responsible for the design of the aircraft that will use it for the establishment of the aircraft flight conditions."

comment is substantive or is an objection: Yes

response

Not accepted.
The contents of this AMC are in line with the current practice for establishing flight conditions, which should be done at the aircraft level. For the time being, EASA does not plan to change those provisions.
The new paragraphs have been added to explain that the establishment and substantiation of flight conditions for the aircraft, including its engine(s), is the ultimate responsibility of the organisation that is responsible for the design of the aircraft. To achieve this, an agreement has to be reached with the engine TCH.

comment

185 comment by: *Laurent Lalaque*

The process of establishing and substantiating the flight conditions related to engines without TC is very similar to the type certification according to Part 21 Section A Subpart B. The substantiation of flight conditions for engines actually consists in showing at least partial compliance with the certification specifications for engines CS-E or with equivalent requirements. The process of engine type certification is under the full responsibility of the engine manufacturer, under the monitoring and control of the EASA. Why should nearly the same process, applied to the establishment of flight conditions for engines, be the ultimate responsibility of the organisation responsible for the design of the aircraft? In that case, these organisations should demonstrate their capability to design engines, the engine designer acting as a their design subcontractor, which is not the case up to now, and which is clearly not the intent of Part 21, and of all airworthiness regulations in general. This would be both very costly and useless. The process of establishing and substantiating the flight conditions related to engines without TC should remain under the full responsibility of the engine manufacturer, under the monitoring and control of the EASA, through DOA procedures regularly audited by the EASA.
In the proposed AMC 21.263(c) (6) modification, the paragraph "In this context, the organisation.....ultimate responsibility of the organisation responsible for the design of the aircraft" shall therefore be removed.

response

Not accepted.
See the response to comment #147.

comment

200 comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

RRplc comment on page 61: The statement on Certification Basis should also include CAI.

response

Not accepted.
Although a CAI may be used in establishing the certification basis, it is not part of the certification basis.
The current practice is that a CAI can trigger an issue which is later transferred into a CRI.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 50. New AMC No 1 to 21.A.263(c)(5)(8)(9) p. 61-63

comment	*16* comment by: *CAA Denmark* "21.A.263(c)(5)(8)(9)" is used several times but should be written as: "21.A.263(c)(5), (8), and (9)" or may be as "21.A.263(c)(5)/(8)/(9)" just to avoid possible misunderstandings
response	Accepted. The wording has been improved as proposed to improve the clarity.

comment	*42* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* The term 'continued-airworthiness process' on page 62 under listing (k) should be replaced by **'service experience',** which is already used in other AMC/GM.
response	Not accepted. The wording is intended to specifically address in-service experience which has a possible impact on safety, and this is managed through the 'continued airworthiness process'.

comment	*64* comment by: *LHT DO* Please make sure that we can approve a STC under the privilege "certain major changes" also on a cross-TC basis, e.g. for when we want to approve the same cabin design for which we have previously obtained a STC on another TC. --> Same design, different TCs.
response	Accepted. It is confirmed that, in principle, this is possible.

comment	*85* comment by: *Dassault-Aviation* Dassault-Aviation AMC No 1 to 21.A.263(c)(5)(8)(9) page 61 **Text:** An EASA approval may be required in cases of major repairs proposed by DOA holders which are the TC, STC or APU ETSO authorisation holders if the major repair is: (a) related to a new interpretation of any item of the certification basis as used for type certification (such as the certification specifications (CSs), certification review items (CRIs) for special conditions, equivalent safety findings, deviations or 'elect to comply'); and (b) related to the application of a CS that is different from the one used for type certification **Comment:** This represents a regression compared to current DOA privileges status. What is the justification for this change? NPA does not indicate clearly that current TC holders privilege to approve major repairs is not affected by this NPA

response | Accepted.
The intent is not to make a regression compared with the existing privilege that is applicable for TCHs. However, as a matter of principle, repairs that are addressed by this limitation have never been included in the privilege.

comment | *86* comment by: *Dassault-Aviation*

Dassault-Aviation

AMC No 1 to 21.A.263(c)(5)(8)(9) page 61

Text:
certain major changes' and 'certain supplemental type-certificates' for which privileges may be granted as per point 21.A.263(c)(8)(9) are changes similar to those that have been previously approved by EASA for the same DOA holder. The similarity of the changes is to be seen in terms of the design, the installation, and the operational characteristics, whereas their repetitiveness in terms of the applicable requirements and compliance demonstration. In this context, a 'requirement' means any element of the type certification basis as specified in point 21.B.80 or operational suitability data (OSD) certification basis as specified in point 21.B.82 or the environmental protection requirement as specified in point 21.B.85

Comment:
Selection of equivalent major change is related to too restrictive criteria: minor deviation to previoulsy approved major change should be considered

response | Accepted.
The wording chosen in the AMC is 'similar' and not 'identical' to provide the needed flexibility. Minor deviations from a previously approved major change could therefore be acceptable.

comment | *87* comment by: *Dassault-Aviation*

Dassault-Aviation

AMC No 1 to 21.A.263(c)(5)(8)(9) page 62

Text:
(i) changes that affect a part or system, a single failure of which may have a catastrophic effect upon the product, and for which critical characteristics have been identified which should be controlled to ensure the required level of integrity

Comment:
Wording proposal "changes that appreciably affect a part or system" Moreover as per 1309(b) no single event may lead to a catastrophic situation

response | Not accepted.
In certain products, a single failure of some parts and systems may lead to a catastrophic situation (e.g. in the case of rotorcraft). Any change to such parts or systems is deemed to be

	of such importance that it makes them ineligible to be approved under the privilege of point 21.A.263(c)(8)(9) without EASA being involved. Please note that 1309(b) is not identical in all certification specifications.
comment	*88* comment by: *Dassault-Aviation* Dassault-Aviation AMC No 1 to 21.A.263(c)(5)(8)(9) page 62 **Text:** (b) Repetitiveness of the certification process. The whole certification process is repetitive, i.e. identical to, or part of, an already approved referenced process. For a change or repair that is a part of the referenced 'certain major repairs', 'certain major changes' or 'certain supplemental type-certificates', the certification process is still identical to the one for the affected change. This is the case when each compliance demonstration is performed to the same extent in accordance with the same requirements, GM, and content of the interpretative material, as well as with the same means and method of compliance (not only the same means of compliance (MoC) code). **Comment:** same modification applied on various platform may have different reference certification basis
response	Partially accepted. The text has been adjusted to allow the consideration of 'less stringent' requirements.
comment	*89* comment by: *Dassault-Aviation* Dassault-Aviation AMC No 1 to 21.A.263(c)(5)(8)(9) page 63 **Text:** In addition, EASA should have classified as 'low' or 'very low' the likelihood of an unidentified non-compliance for all included compliance demonstration items (CDIs) identified in at least the latest project referenced, for demonstrating 'similarity' and 'repetitiveness' (applying the criteria for the determination of EASA's level of involvement in product certification, see AMC 21.B.100(a) and 21.A.15(b)(6)). **Comment:** Assuming this criteria lead to only deal with - No novel or complex aspects OR - No novel, but complex aspects; Novel, but no complex aspects Consequently no interest to apply such additional selection criteria as too severe Moreover, similarity demonstration is not to be related to a DOA performance criteria
response	Not accepted. The privilege is granted based on a risk-based consideration. As the performance of the DOA holder is one of the criteria to be considered for risk determination, it also has to be included in the considerations to grant the privilege.

comment

148 comment by: *AIRBUS*

PAGE 61 / PARAGRAPH 50.1 related text:

Nr. 72

Certain major repairs' for which privileges may be granted as per point 21.A.263(c)(5) are:
(a) major repairs to products or auxiliary power units (APUs) for which the design organisation approval (DOA) holder holds the type certificate (TC) or the supplemental type certificate (STC) or European technical standard order (ETSO) authorisation; or
1.2 Eligibility criteria
An EASA approval may be required in cases of major repairs proposed by DOA holders which are the TC, STC or APU ETSO authorisation holders if the major repair is:
(a) related to a new interpretation of any item of the certification basis as used for type certification (such as the certification specifications (CSs), certification review items (CRIs) for special conditions, equivalent safety findings, deviations or 'elect to comply'); and
(b) related to the application of a CS that is different from the one used for type certification.
Note: this should be established at the time of granting the privilege to the DOA holder or later through an EASA-agreed procedure.":

Current privilege within published Part 21 is for any major repair from design organisation approval (DOA) holder being as well the type certificate (TC) or the supplemental type certificate (STC) or European technical standard order (ETSO) authorisation. This should remain.

PROPOSED TEXT:
Certain major repairs' for which privileges may be granted as per point 21.A.263(c)(5) are:
(a) **any** major repairs to products or auxiliary power units (APUs) for which the design organisation approval (DOA) holder holds the type certificate (TC) or the supplemental type certificate (STC) or European technical standard order (ETSO) authorisation; or
1.2 ~~**Eligibility criteria**~~ **limitation**
An EASA approval may be required in cases of major repairs proposed by DOA holders which are the TC, STC or APU ETSO authorisation holders if the major repair is:
(a) related to a new interpretation of any item of the certification basis as used for type certification (such as the certification specifications (CSs), certification review items (CRIs) for special conditions, equivalent safety findings, deviations or 'elect to comply'); and
(b) related to the application of a CS that is different from the one used for type certification.
Note: this should be established at the time of granting the privilege to the DOA holder or later through ~~an EASA-agreed~~ a procedure agreed by EASA.

comment is substantive or is an objection: Yes

response

Not accepted.
The proposed rewording does not seem to improve the overall readability.
Refer also to the response to comment #85.

comment

204 comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

RRplc comment on page 61: i, This wording should be made consistent with existing certification specification definitions as used in FMECA. A single failure with a catastrophic

	consequence is understood, and the lack of LOI privilege for such components is also understood. However, the current text excludes components for which a single failure 'could have a catastrophic consequence' suggests that failures with a 'hazardous' consequence (or lower) are also excluded from LOI, as this is part of the definition of 'hazardous'. This would exclude for example, engine critical parts, where the privilege would be highly beneficial, and there is a clear justification for its use by the relevant TC holders. We suggest the language is clarified to limit the exclusion.
response	Not accepted. The text refers only to catastrophic failure conditions, and not to hazardous failure conditions, so the interpretation made by the commentator is not aligned with the AMC text. However, there is also a subparagraph (j) which addresses the eligibility for engine/propeller critical parts hazard cases. According to the provisions of this paragraph, the privilege may be used in non-critical areas of such parts if the critical characteristics have been properly addressed by the DO.

comment	*220* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* For clarity and having a common understanding please add criteria for similarity, i.e. "similar changes". Similar should be e.g. comparable cabin installations independant from the product.
response	Not accepted. The AMC already contains some basic criteria to determine the similarity. More stringent criteria would limit the applicability of the privilege by reducing the flexibility.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 51. New AMC No 2 to 21.A.263(c)(5)(8)(9) p. 63-71

comment	*90* comment by: *Dassault-Aviation* Dassault-Aviation AMC No 2 to 21.A.263(c)(5)(8)(9) page 63 to 66 **Text:** Whole paragraph **Comment:** "Justification document" to be further explained as too ambigous, § to be reworded as difficult to understand
response	Not accepted. The contents of the 'justification document' are explained in AMC2 21.A.263(c)(5)(8)(9) par 1.(b)(2), which provides sufficient information.

comment	*91* comment by: *Dassault-Aviation* Dassault-Aviation

AMC No 2 to 21.A.263(c)(5)(8)(9) page 70

Text:
4.2 Forms for Approval Certificates
The DOA holders should use the following forms for the issuance of an approval under their privilege:
- EASA form XXX for a major repair;
- EASA form XXX for a major change; and
- EASA form XXX for a STC.
For the numbering of major changes to TCs, STCs, as well as of major repairs approved under the privilege, please refer to AMC No 3 to 21.A.263(c)(5)(8)(9)

Comment:
Not relevant / not applicable for DOA organisation already put in place (as specific DOA form already exist)

response

Accepted.
The text was changed to allow for the use of forms developed by the DOA holder, provided that they contain at least the same information as requested on the EASA forms.

comment

118 comment by: *AIRBUS*

Page 62 / paragraph 50(h) related coment

Nr 36
(h) changes that affect the noise and/or emissions characteristics of the changed product unless otherwise agreed with EASA;
Airbus proposes to use the definition of non-simple substantiation as indicated in TIP

Airbus proposes to read text as follows:
(h) non-simple substantiations of acoustic or emissions changes, whereas a simple substantiation is when the compliance demonstration with the EASA has involved standard means of compliance and procedures which were already regularly agreed by the EASA in previous projects
(using the same test organization).

Comment is substantive / objection

Page 62 / paragraph 50(h) related comment

Nr 37
The criteria (h) is seen too restrictive, indeed change that positively affect (reduce) the noise and/or emissions characteristics should be electable as “certain major changes”

Airbus propose to amend the wording of (h) as follow: “changes that “**negatively”** affect the noise and/or emissions characteristics of the changed product unless otherwise agreed with EASA”

Comment is substantive / objection

Page 62 / paragraph 50(k) related comment

Nr 38
The criteria (k) is seen too restrictive, indeed if the non compliance of the referenced change has correctly been addressed, there is no reason to forbid to elect similar changes as certain major changes

Airbus proposes to amend the wording of (h) as follow: "changes for which a non-compliance has been found in the referenced change during the continued-airworthiness process**" and not yet addressed"."**

Comment is substantive / objection

response

Not accepted.
Comments #36, 37: flexibility is already provided by the last part of h) 'unless otherwise agreed by EASA'.
Comment #38: the privilege is granted through a risk-based approach. When a continued airworthiness issue is discovered with the reference change, this risk is increased and has to be evaluated by EASA.

comment

119 comment by: *AIRBUS*

Page 62 / paragraph 50 section §2.2 related comment

Nr. 39
Repairs should be removed from §2.2 as §2 is related to changes and STCs. Airbus propose to remove "(5)" from 21.A.263(c)(5)

Airbus suggest that Title for 2.2 should be "criteria for major changes and STCs for which the privileges of point 21.A.263(c)(8)(9)

comment is substantive / objection: Yes

Page 62-63 / paragraph 50 section §2.2 related comment

Nr. 40

The criteria *2.2(b) Repetiviness of the certification process"* should be alleviate to certification process not identical but less constraining.

Airbus proposes to amend the wording as follow:
The whole certification process is repetitive, i.e. identical to **or less stringent than** , or part of, an already approved referenced process. For a change or repair that is a part of the referenced 'certain major repairs', 'certain major changes' or 'certain supplemental type-certificates', the certification process is still identical to the one for the affected change. This is the case when each compliance demonstration is performed to the same extent in accordance with the same **or less stringent** requirements, GM, and content of the interpretative material, as well as with the same means and method of compliance (not only the same means of compliance (MoC) code). "

comment is substantive / objection: Yes

Page 63 / paragraph 50 section §2.2 c related comment

Nr. 41
2.2c Performance and experience in previous projects.
The criteria 2.2(c) should be reworded indeed LOI should be risk based and the risk is linked to the combination of the likelihood of an unidentified non-compliance and its consequence on the product. Also the AMC should allow considering reference change performed before the implementation of LOI procedure.

Airbus proposes to amend the wording as follow: *"In addition, when using recent referenced project EASA should have classified as 'risk class1 or 2' the compliance demonstration items (CDIs) identified in at least the latest project referenced, for demonstrating 'similarity' and 'repetitiveness' (applying the criteria for the determination of EASA's level of involvement in product certification, see AMC 21.B.100(a) and 21.A.15(b)(6)). When using referenced project approved before implementation of the LOI project 'similarity and repetitiveness ' have to be judged based on the applicable requirements and the compliance method and documentation."*

comments is substantive / objection: Yes

response

Partially accepted.
#39: Accepted: the text is applicable to all 3 types. Para. 2.2 has been changed to para 3.

#40: Not accepted, as the less constraining criterion is already covered by the proposed wording (i.e. 'part of').

#41: Not accepted, as the scope of this paragraph is to assess the performance and experience of the DOA in similar projects. In this respect, the consideration of severity criteria does not bring in any additional information, since at least one CDI should be classified as critical.

comment

120 comment by: *AIRBUS*

Page 63 / paragraph 51 related comments

Nr. 42
The privileges for TC holder for major repairs should not necessitate to elaborate the list of " certain major repairs" - the privileges for major repair from TC holder should remain active.

Airbus propose to make the privileges for certain major repairs valid for all repairs.

Comment is substantive or is an objection

Page 66 / paragraph 51 figure 1 related comments

Nr. 43

The flow chart need to be adapted as the justification document creation should be generated after EASA agreed on the procedure.

	Airbus suppose to move box 4 & 5 of the flow chart after box 6 “EASA agreement of proposed procedures” Both comment are substantive / or objection
response	Partially accepted. #42: Accepted. AMC #1 already explains that the existing privilege is maintained (ref. to point 1a). Additionally, the applicability of AMC #2 has been corrected to refer to that point. #43: Not accepted. The justification documents and the lists need to be created before the EASA approval of the procedure to enable EASA to check the application of the procedure to real examples.

comment	*131* comment by: *CAA-NL* Page 63, item 51 New AMC No 2 to 21.A.263(c)(5)(8)(9) is inserted how to handle in case a DOA wants to obtain the privilege for the approval of major changes (and to use this privilege). Par. 1.(a) mentions that an application has to submitted according to 21.A.247. But applying for an additional privilege is an change to the terms of approval and as such reference should be made to 21.A.253 Changes to the terms of approval.
response	Accepted. The references are clarified in the AMC.

comment	*171* comment by: *Safran Aircraft Engines* Section 3.51 AMC No2 to 263(c)(5)(8)(9) §3(c) (page 70) Comment: This paragraph requires to the repair design applicant to make the assessment whether or not it is affected by any possible STC. The repair applicant has the clear knowledge of its design, it can’t have an accurate and pertinent knowledge of STC design that potentially affect the repair design. Proposed text: To remove the sentence 3(c) *“an assessment is made as to whether or not the repair design is affected by the presence of any STC”.*
response	Partially accepted. The text has been reworded to only apply to specific product serial numbers.

comment	*221* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* To be inline with 21.A.20(c) use "compliance documentation" instead of "justification document"
response	Not accepted. The intent of the justification document is to justify the use of the privilege, not to demonstrate compliance.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 52. New AMC No 3 to 21.A.263(c)(5)(8)(9) p. 71-72

comment	*44* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* Why the AMC title containing 21.A.263(c)(5) and (8) (**NOT STC Holder**), while the text refers to 21.A.263(c)(9) (**STC Holder**) only? Please ensure the numbering requirements is not applicable for TC Holder DOAs. Revise the title.
response	Partially accepted. The text has been adjusted to also include references to major changes and major repairs. The NPA is intended to provide an acceptable numbering system. This provision has been turned from AMC into GM, therefore DOAs who already hold the major repair privilege do not need to change their numbering systems.

comment	*57* comment by: *KID-Systeme GmbH* This is a very useful approach in terms of configuration management and standardization between the DOAs, but why is not applicable for minor change / repair approvals, too? This introduction is a very good chance to have one project identification standard applicable for any change or repair category. Considering the required IT system adaptation at DOAs, MOs, operators or CAMOs, they won't like to handle the identification of minor change / repair approval in other ways.
response	Noted. The proposed numbering system may also be applied to minor changes/minor repairs. See also the response to comment #44.

comment	*65* comment by: *LHT DO* We do not need the reference to month and day of approval in the STC number. Will EASA use the same system for their STCs? We would prefer if used the same system as the industry.
response	Accepted. The reference to month and day has been deleted, and additionally, the provision has been turned into GM. See also the response to comment #44. Each DOA holder will have the possibility to tailor the numbering system to their specific needs, provided that the duplication of numbers within the organisation is prevented.

comment	*92* comment by: *Dassault-Aviation* Dassault-Aviation AMC No 3 to 21.A.263(c)(5)(8)(9) page 71

Text:
STCs, major changes and major repairs issued by a DOA holder under their privilege of point 21.A.263(c)(9) should each be given a unique and consecutive reference number using the following numbering system

Comment:
Not acceptable, too complex, not relevant and not compatible with each TC Holder Management Configuration Process and not mixable with minor changes numbering which are not affected by this request. Moreover such numbering affectation is associated to the approval date which is unknown at the time the change is defined!

response

Accepted.
The numbering system has been simplified by removing the information about month and day. Additionally, this AMC has been turned into GM. See also the response to comment #44.

comment

121 comment by: *AIRBUS*

Page 71 / paragraph 52 AMC No 3 related comment

Nr. 44:
52 "STC, major changes and major repair issued by a DOA holder under their privileges....."

Numbering of major changes and major repairs are ensured by the TC holder under its own referential.
No need to add a supplemental numbering.
Airbus propose to remove AMC n°3 to 21.A.263(c)(5)(8)(9)

comment is substantive / or an objection

response

Accepted.
The AMC has been turned into GM and simplified, therefore the numbering system is left to the discretion of the DOA holder. See also the response to comment #44.

comment

172 comment by: *Safran Aircraft Engines*

Section 3.52 AMC No3 to 21.A.263(c)(5)(8)(9) (Page 71)

Comment:
This AMC defines a prescriptive numbering system. It should be in the regulation section B (Authorities) to be implemented.
Text of the AMC should be transferred in the regulation Section B (Authority) to give a unique and consecutive reference number using the numbering system provided by EASA.

Proposed text:
~~*STCs, major changes and major repairs issued by a DOA holder under their privilege of point 21.A.263(c)(9) should each be given a unique and consecutive reference number using the following numbering system: …*~~

response

Noted.

	The AMC has been turned into GM and simplified, therefore the numbering system is left to the discretion of the DOA holder. See also the response to comment #44.

comment	*201* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 71: The numbering system would not be able to be used by current DOA s with out a drastic overhaul of there systems, thus would also confuse the customer / airframe that are used to the current systems of how changes repairs are uniquely identified. The AMC should be rewritten to state what attributes should be documented e.g. unique identification, date of approval, version etc.
response	Accepted. See the response to comment #44.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 53. New GM 21.A.265(h) p. 72-73

comment	*12* comment by: *Yuksel Kenaroglu* In page 72, there are statements "**continuing airworthiness**" and "**continued-airworthiness**". ("**Continued airworthiness**, alson, is seen in some other documents.) (Also, CAP 722 (UK) defines those diferent terminology to some extent. They are used for related but different requirements.) It may be good to review usage of these diferent terminology, and, it may be good to clarify this issue whether to use one statement (such as "continued airworthines") or two different statements for different (design stage requirement and "in-service" stage requirement) purposes.
response	Noted. This comment may be considered for future rulemaking activities.

comment	*45* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* Please revise on page 72, chapter 2, the term 'mandatory continued-airworthiness measures' by **'AD'** for clarity.
response	Partially accepted. What is meant here are those measures which are normally referred to from ADs, such as service bulletins. Additionally, ADs are not issued by DOA holders, and therefore they cannot be listed here. The commented bullet has been reworded for better clarity.

comment	*46* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* The statement explained on page 73 is deemed to mean 'when those methods are implemented, the product should be in conformity with the approved design data'. Any use of product (a/c, engine, ...) will cause worn or other deviations to the Type Design data. Therefore, I assume the term 'approved design data' (from Subpart G) is used intentionally to

	reflect that difference, but it would nevertheless end up as an expectation. The following change is proposed:'**the information contains practical and well-defined installation or inspection methods to support the in-service operation of the product.**'
response	Partially accepted. EASA does not agree with the principle of the comment. The text is to explain the word 'approval' in the statement, which consists of two components: the underlying design approval and the correctness of the information/instructions. The latter, when applied correctly, should lead to the product being in conformity with the aforementioned approved design data. However, some improvements have been made to the wording: in the second dash, 'should be' has been changed to 'is'.

comment	*93* comment by: *Dassault-Aviation* Dassault-Aviation GM 21.A.265(h) page 72 **Text:** manuals required by Part-21 or applicable CS (such as aircraft flight manual (AFM), rotorcraft flight manual, operation suitability data (OSD), instructions for continuing airworthiness (ICA), etc.); Comment: OSD refers to the data included in a manual, not the manual itself. We propose to use OSM standing for Operational Suitability Manual begining of the sentence could start as follows: "data contained in any manual…"
response	Partially accepted. The OSD has been moved to a dedicated bullet in order to avoid the use of the word 'manual'. Indeed, the OSD Certification Specifications do not mention OSD as manuals.

comment	*94* comment by: *Dassault-Aviation* Dassault-Aviation GM 21.A.265(h) page 73 **Text:** The technical content of the statement is related to the design data and information. The approval included in the statement means that: — the design data have been appropriately approved ; and **Comment:** This text should not be restrictive to design data only, and should refer to Type Certificate data
response	Not accepted.

	In the context of 21.A.265(h), 'design' should be understood as the overall activity relating to type designs, OSD, AFMs, ICAs, manuals, and all other related data produced in support of a TC or a change to a TC.
comment	*132* comment by: *CAA-NL* Page 72, item GM 21.A.265(h) mentions that the approval statement is not to be used for data that is transferred to the POA (design data & concessions). The CAA-NL wants to express that it must be clear for all data generated by the design approval holder that gives information about the design, approved operating instructions and / or accomplishment instructions, the status of the data is clear above every suspicion. In order to establish this, a DOA could use the approval statements, e.g. on concessions and permit for alternatives.
response	Noted. The requirement to provide a visible statement of approved design data to a PO is addressed through 21.A.4 and the related AMC. In order not to create confusion, this is not reiterated under 21.A.265(h). A DOA could potentially use the same statement to comply with 21.A.4.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 54. GM 21.A.431(a) p. 73-74

comment	*122* comment by: *AIRBUS* **Page 73 / paragraph 54 flow chart related comment.** **Nr. 45** Dotted line in the proposed Flow chart figure is not understandable. Airbus proposes to remove dotted line. **Page 73 / paragraph 54 flow chart related comment.** **Nr. 46** The sketch GM 21.A.431A(a) is wrong: only a DOA holder (or thru alternative procedures) has the privilege to classify in EU regulation. It should be amended to reflect the regulation structure The reference to "the operator" in the flow chart should be deleted to find a better one. Comments are substantive / or an objection
response	Partially accepted. Comment #45: the dotted line has been clarified. Comment #46: the text has been amended to clarify that operators will only perform an initial assessment.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 56. New AMC 21.A.432C(a) p. 75

comment *174* comment by: *Safran Aircraft Engines*

Section 3.56 AMC 21.A.432C(a) (page 75)
Comment:
This AMC request the use of the web-based "EASA applicant Portal". It should be in the rule to enforce its implementation, otherwise the applicant should be allowed to use another mean.
AMC should be transferred in the regulation Section A § 21.A.432C(a), to request to file an application using the web-based 'EASA Applicant Portal' *or the application form for a supplemental type certificate (STC) (FO.CERT.00033) which may be downloaded from the EASA website.*

Proposed text:
~~***AMC 21.A.432(ab) Form and manner***~~
~~*The applicant should file an application using the web-based 'EASA Applicant Portal'17 or the application form for a supplemental type certificate (STC) (FO.CERT.00033)18 which may be downloaded from the EASA website.*~~
~~*The form should be completed in accordance with the completion instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website19.*~~

response Not accepted.
The rule states that the application 'shall be made in a form and manner established by the Agency'. This GM provides for that form and manner, which can be the applicant's portal, or a form.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 57. New AMC 21.A.432C(b) p. 75

comment *66* comment by: *LHT DO*

Please reconsider if you need this level of detail in a certification programme for major repairs.

In our experience the documentation for a major repairs is very simple and cannot be compared with the STC documentation. We therefore consider it overdone to produce an extra document for that. We once did it for a MRA on PCM request. The extra document we created for this case included neither extra information nor was is easier to read for the PCM than the repair documentation itself.

Please consider to only require a full certification programme for major repairs if the repair documentation is complex and a full certification programme is requested by the PCM.

response Not accepted.

	The comment applies to the rule, and not to the NPA for the AMC and GM. In any case, the intent of the AMC is not to request the same level of information as in a CP for a TC or an STC, but to provide a descriptive checklist to the applicant for a major repair to be included in the relatively simple CP.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 59. New GM 21.A.435(b) p. 76-78

comment	*175* comment by: *Safran Aircraft Engines* Section 3.59 GM 21.A.435(b) §(b)(3) (Page 77) Comment: It is not clear on what repair, the limited service period is applicable, whether the temporary repair or the permanent repair. Text need to be clarified. Proposed text: *These are life-limited repairs to be removed and replaced by permanent repairs after a limited service period. These repairs should be classified under point 21.A.435 and the service period should be defined when the **temporary** repair is approved.*
response	Accepted. The text has been amended accordingly.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 63. New AMC 21.A.605(a)(1) p. 78

comment	*67* comment by: *LHT DO* Please schedule the publication of this requirement to be on the same time as the requirement to design ETSO articles under the DOA. Otherwise we have to change our processes twice in a short time period.
response	Noted. According to the proposed amendments to Part 21 that were published in Opinion No 07/2016 'Embodiment of level of involvement requirements into Part-21', applicants for ETSO authorisations have to prepare a certification programme and submit it to EASA. This AMC has been prepared to clarify which contents should be included in the certification programme. For the time being, there are no requirements to hold a DOA in order to apply for an ETSO, with the single exception of APUs.
comment	*187* comment by: *CAA CZ* (a)2: Text „submit the plan to EASA; and" should be replaced by: „submit the certification programme to EASA; and"
response	Accepted.

	The text has been amended accordingly.

comment	*202* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* RRplc comment on page 78: number (4) calls out to a US standard. Shouldn't the EU equivalent be listed EUROCAE ED-14 or both EUROCAE ED-14/RTCA DO-160?
response	Accepted. The reference has been deleted and replaced by 'applicable standards'.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 66. New GM 21.B.75 p. 79

comment	*133* comment by: *AIRBUS* **Page 79 / paragraph 66 related comments** **Nr. 47** 66 GM 21.B.75 Special conditions: The term 'newly identified hazards' is intended to address new hazards that have been identified (e.g. during the certification process of a new product) which, "**if not addressed by a special condition, should be addressed by an airworthiness directive (AD)"** immediately after the issuance of the type certificate (TC)." Does this means that Airbus could have the choice between a special condition and an AD ? Airbus suggest the need to clarify. As it could be understood as an AD just after the issuance of the TC could replace a special condition. comment is substantive / an objection.
response	Accepted. EASA agreed to delete the commented text, since it could be misunderstood. The remaining text has been reconsidered, and since it does not provide significant clarifications compared with the rule, EASA decided to completely delete this GM.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 68. GM 21.B.82(a) to be developed. p. 81

comment	*47* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* Delete text.
response	Noted. The new GM 21.B.82 will be consulted through another NPA. The note here has only been added to anticipate that an amendment is needed to align the text of the GM with the contents of the related Part 21 point.

comment	*134* comment by: *AIRBUS* **Page 81 / paragraph 67.5 related comment** **Nr. 48** Guidance is missing for GM21.B.82(a) comment is substantive /or an objection
response	Noted. The new GM 21.B.82 will be consulted through another NPA. The note here has only been added to anticipate that an amendment is needed to align the text of the GM with the contents of the related Part 21 point.

comment	*176* comment by: *Safran Aircraft Engines* Section 3.68 GM 21.B.82(a) (Page 81) Comment: GM 21.B.82(a) is proposed to be developed but no text is available in the proposed NPA. . Proposed text: N/A
response	Noted. The new GM 21.B.82 will be consulted through another NPA. The note here has only been added to anticipate that an amendment is needed to align the text of the GM with the contents of the related Part 21 point.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 69. New AMC 21.B.100(a) and 21.A.15(b)(6) p. 82-92

comment	*13* comment by: *Yuksel Kenaroglu* The statement "EASA Certification Discipline" (or, EASA Type Certification Discipline) m ay be used for "EASA Panel". For "EASA Discipline" the statement, "EASA sub-discipline" may be used. The rason for this proposal is that the statement, "EASA Panel" does not give strong (formal) impression for a working group. EASA's level of involvement: This definition may be reviewed to show the role (and authority) of EASA more clearly.
response	Not accepted. The definitions proposed are consistent with the wording normally used by EASA during certification processes.

comment	*48* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

	Mix of AMC in Section A and Section B creates conflicting conditions for DOA evidence. Please split the content or convert into GM. The length of the text indicates GM rather than AMC condition.
response	Not accepted. The risk-based assessment is to be performed by the applicant (for the LoI proposal) and by EASA (for the LoI determination). In this context, it is evident that the criteria to be used should be identical. Although part of this AMC consists of information that is intended to facilitate the interpretation of the rule, this AMC also describes a process to demonstrate compliance with the new requirements in Part 21. When this process is followed, there is a presumption of compliance with 21.B.100 (for the competent authority) and 21.A.15 (for the organisation). EASA believes that keeping all the information in the same AMC facilitates its readability and implementation, therefore EASA does not concur with the proposal to turn it into GM.

comment	*49* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 82, the text under 'EASA Panel' refers to aircraft certification. What about the other products? Should be revised into '... **product** certification'.
response	Accepted. The text has been amended accordingly.

comment	*50* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 83, chapter 3, the listing contains 'knowledge management aspects' as a criteria to be used. That term requires more clarification as it could be used in various interpretations.
response	Accepted. Additional clarifications have been introduced into the AMC.

comment	*51* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* To use in the AMC text a foot note reference to an EASA CM, subject of changes outside Rulemaking controls, should not be accepted. If the panel-criteria are important to establish compliance with requirements of the Part-21, the CM content should have been part of this NPA and part of this public consultation. Please delete the reference to EASA CM.
response	Not accepted. The contents of the Certification Memorandum (CM) are considered to be essential at this stage; nevertheless, EASA believes that due to the amount of information and the level of detail, that material is not suitable for inclusion in the AMC. Additionally, EASA believes that this CM could be superseded once the industry becomes sufficiently familiar with the new LoI concept. Its contents may be transferred into other forms of data (e.g. FAQs). Regarding public consultation, it should be noted that this CM was publicly consulted in Q1/2017.

comment	*52* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 84, top text block, the term 'type certification basis' is used and the 'OSD certification basis' in addition. Make sure the term 'type certification basis' is consistently used to cover

	all aspects: airworthiness req, OSD, and environmental protection req.. Proposal to delete type certification basis in this text and replace it by 'airworthiness requirements'.
response	Not accepted. The type certification basis will be defined in 21.B.80 (refer to Opinion No 07/2016 'Embodiment of level of involvement requirements into Part-21').

comment	*53* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 87 it is said: 'should be conservatively proposed'. As this AMC is against Section A and B, is should be stated by whom it shall be 'proposed'. EASA or Industry.
response	Accepted. The proposal is expected by the applicant. EASA will evaluate the proposal and then decide. The text has been amended to clarify the process.

comment	*54* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* On page 88 under 3.3 Severity, the criteria 'affected by an **existing airworthiness directive** (AD) or affected by (an) occurrence(s) **potentially subject** to an AD, or by a **Safety Information Bulletin** (SIB)' **should be deleted**. These are operational tools and where applicable should be converted into a CRI to become part of the certification basis. Under ICAO each State of Registry could issue at any time above mentioned in-service data, that can't be managed in a Certification Programme by a DOA unless it becomes part of the formal certification basis.
response	Not accepted. EASA considers that this criterion is relevant for the determination of the impact on safety of non-identified non-compliances with the certification basis. The purpose is not to include them in the certification programme for compliance demonstration, but that they should be considered to be part of the LoI proposal.

comment	*68* comment by: *LHT DO* 3.2.2 Novelty Novelty is defined as novel to the EASA panel, the industry, the applicant or his sub-contractors. We understand sub-contractors in this context as sub-contractors under DO/DO arrangement (subcontracting of independent checking function) or under a 21.A.2 arrangement, but not subcontracting of tasks which are created under our DAS and for which we take full responsibility. Proposed changes (addition in red, ~~deletion strikethrough~~): *"Whether or not a CDI is novel is based on the extent to which the respective elements of the certification project, the related requirement or means of compliance are new /novel to either the industry as a whole, the applicant including sub-contractors of independent checking function tasks or from an EASA panel perspective."*
response	Not accepted. EASA believes that the criteria should be applied considering the actual arrangements independently from the type of contract stipulated. Additionally, the novelty criterion has to also be considered for the design office, and not only for the independent checking function.

comment	*69* comment by: *LHT DO* 3.2.3 Complexity We appreciate the clarification, that the complexity of the change should be taken into account rather than the complexity of the original system. No change proposed, only a thanks for the incorporation
response	Noted.

comment	*70* comment by: *LHT DO* 3.2.4 Performance of the design organisatin The possibilty to use the overall performance if no performance on a specific panel is available, is helpful. No change proposed, only a thanks for the incorporation
response	Noted.

comment	*71* comment by: *LHT DO* 3.5 Determination of EASA's LOI Re-use of CDIs: We have not yet incorporated this new possibility in our CDI/LOI concept, but it might be very helpful. No change proposed at the moment.
response	Noted.

comment	*72* comment by: *LHT DO* 3.5 Determination of EASA's LOI Please crosscheck this paragraph with the corresponding paragraph in the LOI CM. It might be a simple formatting error in the CM. CM on LOI - draft 3 3.5 Determination of the Agency's involvement Please clarify the listed cases. In our understanding the list only makes sense, when "performed through test" is part of the bullet "classification of failure cases…". If, however, you mean "performed through test" as a separate case for which EASA is involved by default, we would object to that. Proposed change (addition in red, ~~deletion strikethrough~~): *By default, the following activities require EASA's involvement in all cases:* *— Initial issues of, and changes to, a flight manual (for those parts requiring EASA approval and not falling under DOA holder's privilege);*

— Classification of failure cases affecting handling qualities and performance, when performed through test (in flight or simulator); and
— ~~performed through test (in flight or simulator); and~~
— Initial issues of, and non-editorial changes to, Airworthiness Limitations.

response

Accepted.
The text has been aligned with the proposal.

comment

74 comment by: *LHT DO*

3.2.4 Performance of the design organisation
"The determination of the performance of the design organisation may also take into consideration information that is more specific or more recent as compared to the DOA holder's dashboard, e.g. experience gained during technical familiarisation [...]"

This paragraph should not result in intransparency.

Proposed change (addition in red, deletion strikethrough):
In special cases the determination of the performance of the design organisation may also take into consideration information which is more specific or more recent as compared to the DOA dashboard, e.g. experience gained during technical familiarisation with the current certification project, the performance of compliance verification engineers and the design team functions, as well as the performance of the design organisation in overseeing system/equipment suppliers . If this results in a higher LOI the agency should justify its decision. Such a reevaluation of the design organisation's performance should be done in a timely matter in order to not delay the project.

response

Partially accepted.
The process described in this AMC is already in line with the text consulted through NPA 2017-20. According to paragraph 4, indeed, in principle, the DOA holder shall make a risk assessment on the basis of which an LoI will be proposed. Then EASA will assess the proposal and will notify the LoI to the applicant. Any deviation from the proposal, either an increase or a decrease in the LoI, will be recorded and notified to the applicant.

comment

75 comment by: *LHT DO*

LOI for minor changes to CCD or FCD (with a major change to type design):

The statement that the part of a major change which is classified as minor (e.g. major design change + minor OSD change) does not need EASA verification seems to contradict the risk classification which might result in a higher LOI for the minor part. This contradiction should be clarified.

Proposed change (addition in red, ~~deletion strikethrough~~):
In case one or more parts of the change is/are classified major, while the associated part(s) of the change is/are classified minor, the approved design organisation can propose to the Agency not to verify the classification and the part(s) of the change classified minor in accordance with its privilege under 21.A.263(b)2 or 3 as part of its proposal for the Level of Involvement by the Agency (see point 21.A.93(b)(3)(iii). The Agency should then accept the part(s) of the change classified minor without further verification irrespective of the result of

	the risk classification in accordance with AMC 21.B.100(a) and 21.A.15(b)(6). Once it is satisfied that compliance is has been demonstrated for the part(s) of the change classified major, the Agency can then issue the complete change approval or Supplemental Type Certificate (STC).
response	Not accepted. There should be one classification for a change. If parts of a change are to be accepted by EASA with no further verification, this is done through the LoI provisions and the associated CDI risk classification in accordance with AMC 21.B.100(a) and 21.A.15(b)(6). Consequently, the AMC content is proposed to be removed. To prevent any possible misunderstanding on the process to be followed, the commented paragraph has been deleted. The possibility for misinterpretation will also be removed at the Part 21 level.

comment	*95* comment by: *Dassault-Aviation* Dassault-Aviation AMC 21.B.100(a) and 21.A.15(b)(6) page 85 **Text:** Additional new guidance/interpretative material in the form of new certification memoranda (CMs) may be considered for the determination of novelty if its incorrect application/use may lead to an unidentified non-compliance. In the context of novelty, the time between the last similar project and the current project of the applicant should also be considered **Comment:** Not acceptable, except for voluntary elect to comply, significant changes or new TC Moreover by definition a CM cannot lead to a non compliance
response	Noted. EASA agrees that a CM cannot lead to a non-compliance. However, under some circumstances, consideration of a CM may provide further clarifications. Therefore, EASA considers that this sentence should be kept in the AMC.

comment	*96* comment by: *Dassault-Aviation* Dassault-Aviation AMC 21.B.100(a) and 21.A.15(b)(6) page 87 **text:** The ultimate objective is to define the organisations performance at the discipline level. **Comment:** Performance at discipline level is too complex
response	Noted. This is just the ultimate objective, and it may be achieved only under specific circumstances and for a small number of DOAs.

comment	*97* comment by: *Dassault-Aviation* Dassault-Aviation AMC to 21.B.100 (a) and 21.A.15(b)(6) page 86 and 87 **Text:** Performance **Comment:** Planning aspect could be excluded from the DOA Performance assessment by EASA and more focused on the compliance demonstration aspects
response	Noted. The details of DOA performance assessments are not part of NPA 2017-20 and may be subject to future adjustment.

comment	*98* comment by: *Dassault-Aviation* Dassault-Aviation AMC to 21.B.100 (a) and 21.A.15(b)(6) page 88 **Text:** The severity of a CDI should be classified as critical if, for example - a function, component or system is introduced or affected where a failure effect is classified as hazardous or catastrophic at the aircraft level, for instance for 'equipment, systems and installations', e.g. where applicable, as defined in 2X.1309 - a CDI has an appreciable effect on the HMI (displays, approved procedures, controls or alerts); - airworthiness limitations or operating limitations are established or potentially affected - a CDI is affected by an existing airworthiness directive (AD), or affected by (an) occurrence(s) potentially subject to an AD, or by a safety information bulletin (SIB); or - a CDI affect parts classified as critical as per CS 27.602/29.602, CS-E 515, or with a hazardous or catastrophic failure consequence (e.g. principal structural element as per CS 25.571 **Comment:** Using this definition most of CDI will be classified as critical. What is the meaning of appreciable effect ? CDI is critical whatever the impact on ALI or operation limitation OR only when the impact is more stringent than the approved data? PSE is already considered as a key element for major application, consider all PSE impact as critical is too conservative To summarise, applying such criteria is equivalent to Major Classification criteria, consequently each Major change will be considered with high LOI
response	Not accepted. Practical experience gathered during the advanced application phase of the new LoI concept showed that only a small number of CDIs have been considered to be critical. This is probably due to the fact that the assessment is to be made at the CDI level, and any major change/major repair contains several elements, which are not typically classified as critical.

comment	*99* comment by: *Dassault-Aviation* Dassault-Aviation AMC to 21.B.100 (a) and 21.A.15(b)(6) page 90 and 91 **Text:** If the risk assessment (Steps 1 and 2 above) is made on the level of a compliance demonstration activity or on the level of a document, the risk class provides an indication for the depth of the involvement, i.e. the verification may take place only for certain compliance data within a compliance document **Comment:** Not acceptable, selection of retained or not retained is to be done at MCs level and not at deeper stage which is not manageable
response	Not accepted. The commented provision is intended to be used under specific circumstances, for instance when a large compliance document only contains novel/complex elements in some isolated paragraphs. In such a case, the commented provision allows EASA to perform its verification on only a limited part of the document, and the LoI notification has to contain that information.

comment	*100* comment by: *Dassault-Aviation* Dassault-Aviation AMC to 21.B.100 (a) and 21.A.15(b)(6) page 89 **Text:** Class 1 **Comment:** Based on some DOA holder experience, assuming Medium DOA Performance, risk class 1 is too restrictive and seldomely be applied
response	Noted. During the advanced application phase of the new LoI concept, risk class 1 proved to be the more frequent one. Nevertheless, the proposed AMC already provides some flexibility to be used when required by the specific circumstances.

comment	*140* ❖ comment by: *Antonio PARADIES* Please clarify and define what is to be understood by *"obvious cases"* in these paragraphs (p.29, 5. and p.92, 4.), so that applicants may use them properly if the conditions are met.
response	Noted. Obvious cases are cases for which the classification is straightforward and does not require any additional clarifications. In general, applicant explanations/notes regarding the proposed classification should be provided, since this will also facilitate the acceptance of the LoI

	proposal. Nevertheless, to avoid unnecessary additional effort, these explanations can be omitted if they are obvious. For reasons of clarity, a note explaining the meaning of 'obvious cases' has been added in the AMC.
comment	*143* comment by: *Antonio PARADIES* Please clarify and define what is to be understood by *"clearly show"* in this paragraph (p.84), so that applicants may properly meet the specified conditions.
response	Accepted. There could be different ways to 'clearly show' that the all the elements of the certification basis are included in, at least, one CDI. For instance, this could be achieved by means of a 'CDI reference' column added in the table that lists all the elements of the certification basis. Since many possibilities exist, EASA considers that the proposed wording provides the needed flexibility. For reasons of clarity, a note explaining the meaning of 'clearly show' has been added in the AMC.
comment	*144* comment by: *Antonio PARADIES* In these paragraphs (p.86), some examples illustrating the complexity criteria could be leading to an overlap with the novelty criteria, namely: "[…] the means of compliance are not a common and accepted practice;" In comparison to the example for the novelty criteria: "new or unusual use;" (p.84 §3.2.2).
response	Noted. Both criteria are valid and should be considered.
comment	*145* ❖ comment by: *Antonio PARADIES* The wording used for Novelty, Complexity and DOA Performance criteria remain consistent through all the documents EASA has issued on LoI, but for some reason the wording used for criticality/severity criteria varies from one document to another or even in the same document like in this very NPA. We would like to understand the reason to do so, if there is one, even if we consider it to be misleading and would recommend being consistent with the wording and using just one of them.
response	Accepted. The AMC has been amended to eliminate the term 'severity'.
comment	*146* comment by: *Antonio PARADIES* As exposed on page 93 table, for minor changes and minor repairs, LoI can be determined through 3 Risk Classes (A, B and C). It has been proposed and discussed during previous EASA Workshops to define just three classes for major changes as well. We would like to propose again an amendment for the major change Risk Class determination on a single table.

The proposed risk classes would be as follows:

		Risk Class		
Non-Critical	No novel or complex	Class 1	Class 1	Class 2
	Novel or complex	Class 1	Class 1	Class 2
	Novel and Complex	Class 1	Class 2	Class 2
Critical	No novel or complex	Class 1	Class 2	Class 2
	Novel or complex	Class 2	Class 2	Class 3
	Novel and Complex	Class 2	Class 3	Class 3
		High	Medium	Low or Unknown
		DOA Performance		

Where the proposed EASA LoI based on these Risk Classes is proposed to be defined as follows:
— Risk Class 1: after acceptance of the certification programme, there is no further EASA involvement in verifying the compliance activities performed by the applicant to demonstrate compliance at CDI level;
— Risk Class 2: EASA's LoI typically comprises the review of a defined small portion of the compliance data; there is either no participation in compliance activities or participation in a small number of compliance activities (witnessing of tests, audits, etc.);
— Risk Class 3: EASA's LoI typically comprises the review of a high amount of compliance data, the detailed interpretation of test results, and the participation to a high number of compliance activities (witnessing of tests, audits, etc.).

The main identified advantages of this approach are:
- Standard traffic lights 3 color system (green/yellow/red)
- No more confusion between Classes 2 and 3
- Easier to handle 3 Risk Classes than 4
- To have every criteria in one single table facilitates the risk class determination

response

Not accepted.
EASA is convinced that applications for major changes/major repairs, new TCs or STCs should have one additional risk class in order to better cover all the possible cases. The risk assessment related to minor changes and minor repairs is simpler by its nature.

comment

155 comment by: *AIRBUS*

PAGE 82 / PARAGRAPH 69 related comments

No 49

EASA discipline - is there a list of typical discipline per EASA panel ?

Airbus proposes the list of EASA discipline should be defined (at least in certification memorandum)

Comment is substantive or is an objection: Yes

PAGE 82 / PARAGRAPH 69 related comments

No 50

Within the background should be useful to add that EASA will determine and inform the applicant in due time to enable him to develop his project as described in the planning included in the certification program.

The sentence should be amended as follow: "EASA will review the proposal, determine its LoI and formally inform the applicant in due time to enable him to develop his project as described in the planning included in the certification program. Both parties, in mutual trust, should ensure that the certification project is not delayed through the LoI proposal and determination."

Comment is substantive or is an objection Yes

PAGE 83 / PARAGRAPH 69 related comments

No 51

"In such a case or when EASA has other information affecting the assumptions on which the LoI was based, EASA will revisit its LoI determination" - the date of reference for the DOA performance should be defined

See previous Airbus comments

Comment is substantive or is an objection: Yes

PAGE 83 / PARAGRAPH 69 related comments

No 52

Additional panel-specific criteria are available in further ***"interpretative material"*** *published by EASA. - 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).*

Airbus proposes to reword the sentence to reuse the intent of CM "Additional panel-specific criteria are available in complementary information and guidance published by EASA"

Comment is substantive or is an objection: Yes

PAGE 83 / PARAGRAPH 69 related comments

No 53

The principles based on 3 steps should be seen as a proposal indeed applicants may decide to combine steps 1 & 2 in a single step and to provide the EASA with the final result of these two steps.

Airbus proposes to add the note: Note: the applicant may provide EASA with the result of combination of both steps 1 & 2.

Comment is substantive or is an objection Yes

PAGE 84 / PARAGRAPH 69 related comments

No 54

The determination of "likelihood of an unidentified non-compliance is only an intermediate step to determine the proposed LoI (Risk Class). Airbus propose to remove this intermediate step which do not bring any added value for the final result.
Indeed the only useful information remains the proposed LoI (risk class).

Airbus proposes to restructure the §3.2, §3.3, §3.4 to remove the useless notion of "likelihood of an unidentified non-compliance and directly build the Risk class based on the 4 elements: Novelty, Complexity, Severity and DOA performance

Comment is substantive or is an objection: Yes

PAGE 85 / PARAGRAPH 69 related comments

No 55

"Additional new guidance/interpretative material ***"in the form of the new certification memoranda (CMs) may be considered"*** *for the determination of novelty if its incorrect application/use may lead to an unidentified con-compliance." - this is not the intent of Certification memo.*

Airbus proposes to remove the sentence as it considers the CM as binding guidance material

"*In the context of novelty, the time between the last similar project and the current project of the applicant should also be considered*" – what are the item to consider should the time between 2 project should not be long or not to short ? the time between project is not the key parameters, it is the experience of the applicant and its competence management combined with change in organisation which are relevant

Comment is substantive or is an objection: Yes

PAGE 85 / PARAGRAPH 69 related comments

No 56

"*In the context of novelty, the time between the last similar project and the current project of the applicant should also be considered*" – what are the item to consider should the time between 2 project should not be long or not to short ? the time between project is not the

key parameters, it is the experience of the applicant and its competence management combined with change in organisation which are relevant

Airbus proposes to remove or reword the sentence to clarify the true intent

Comment is substantive or is an objection Yes

PAGE 86 / PARAGRAPH 69 related comments

No 57

"the classification of structures, depending on the conservatism of the method;" - what is the source of complexity ?

Airbus believes that Classification of structure does not generate complexity

Comment is substantive or is an objection: Yes

PAGE 86 / PARAGRAPH 69 related comments

No 58

"the representativeness of the test specimen" - the source of complexity should be further developed as by definition the test specimen should be representative.

If we consider complexity, Airbus should rather read the lack of representativeness of the test specimen due to its complexity.

Comment is substantive or is an objection: Yes

PAGE 86 / PARAGRAPH 69 related comments

No 59

"introduction of a complex work sharing with system or equipment suppliers" - Airbus believes the word Complex should be better defined and why is it limited to system or equipment.

The complexity is rather based on the highly integrated system developed by suppliers supporting multiple A/C level function

Comment is substantive or is an objection: Yes

PAGE 86 / PARAGRAPH 69 related comments

No 60

With regard to complexity, the requirements requiring qualitative assessments are not always Complex indeed the experience of the applicant has to be considered.

Airbus proposes to modify the sentence as follow "for requirements of a subjective nature **and taking into account the applicant experience,** i.e. those that require a qualitative

assessment, and do not have an explicit description of the means of compliance with that requirement, or the means of compliance are not a common and accepted practice;

Comment is substantive or is an objection: Yes

PAGE 86 / PARAGRAPH 69 related comments

No 61

With regard to complexity, the requirements requiring a "multidisciplinary compliance" is not always complex. The complexity is directly driven by the experience of the applicant in such compliance demonstration.

Airbus proposes to modify the sentence as follow “a multidisciplinary compliance demonstration where several panels are involved and interface areas need to be managed nature **and taking into account the applicant experience** (e.g. sustained …

Comment is substantive or is an objection: Yes

PAGE 87 / PARAGRAPH 69 related comments

No 62

The § "the determination of the performance of the design..." is proposed to be removed because my create perturbations in the determination of the proposed EASA LoI. Indeed EASA will determine his involvement not on the based on shared and available information at the start of the project but only on internally available data. The will create conflict when reviewing the certification program proposed by *the applicant***.**

Airbus proposes to remove this paragraph: "The determination of the performance of the design organisation may also take into account consideration information that is more specific or more recent as compared to the DOA holder´s dashboard, e.g. experience gained during technical familiarisation with the current certification project, the performance of compliance verification engineers and of the affected technical areas, as well as the performance of the design organisation in overseeing subcontractors and suppliers."

Comment is substantive or is an objection: Yes

PAGE 87 / PARAGRAPH 69 related comments

No 63

"For each CDI proposed by the applicant, the DOA holder´s performance associated with the affected disciplines or panels is to be considered." The reference date for the DOA performance should be defined.

See previous comments.

Comment is substantive or is an objection: Yes

	PAGE 87 / PARAGRAPH 69 related comments **No 64** *"if the applicant fully delegates the demonstration of compliance to suppliers holding a DOA, the performance level of the supplier may be proposed."* *The condition of applicability should be precised, it is under the same DOA term of approval ? same scope? -could we use Engine DOA performance for A/C DOA performance even if panel are different ?* Comment is substantive or is an objection: Yes **PAGE 88 / PARAGRAPH 69 related comments** **No 65** "The likelihood "**of an unidentified non-compliance**"" - as the analysis is based on novelty and complexity, should it be rather the likelihood of unidentified behaviour rather that non-compliance. Airbus proposes to read "unidentified behaviour" in lieu of "unidentified non-compliance". Comment is substantive or is an objection :Yes
response	Partially accepted. Comment #54: Not accepted. The new LoI concept is based on the risk assessment as indicated in ICAO Annex 19. The risk is the combination of two elements (most likely of the hazards and the consequences of the hazards), therefore the structure proposed by EASA is more adherent to the risk-based approach. Comment #55: See the response to comment #95. Comment #56: Noted. The true intent is to consider whether the experience gathered during previous projects can still be considered to be valid. There is no fixed rule for this, so common sense, together with engineering evaluation, should be applied. Comment #57: Not accepted. Whereas the classification of structures does not have to be a complex subject, many applicants make it complex by using intricate and detailed criteria for making classifications that require significant scrutiny. Examples are the amount of variation that EASA observes in PSE classification and the identification of critical characteristics for critical parts. Comment #58: Partially accepted. The acceptability of a test specimen is most challenging when there are aspects that are not representative. It is not always the case that its complexity is what leads it to be unrepresentative. The text has been amended. Comment #59: Noted.

Highly integrated systems are to be considered to be complex according to the proposed guidance. Regarding work sharing, it is to be noted that the assessment of complexity is to be performed at the CDI level.

Comment #60: Not accepted.
The experience of the applicant is to be considered for the assessment of the novelty.

Comment #61: Not accepted.
By definition, the complexity is independent from the experience of the applicant.

Comment #62: Not accepted.
Although EASA appreciates that the provisions of the commented paragraph should be used only in specific circumstances, EASA does not agree with the proposal to delete them.

Comment #63: Not accepted.
See the response to Airbus comment #62.

Comment #64: Noted.
The utilisation of this provision is not limited to specific cases; however, it should be made using common sense and engineering assessment. When this provision is used, a proper explanation is expected.

Comment #64: Not accepted.
The proposed rewording does not seem to add any further clarification.

comment *182* comment by: *Leonardo Helicopters*

Relevant Certification Memo is not mentioned. Will it be cancelled upon AMC publication?

If that will be cancelled then it is necessary to assure that the last version of CM will be embodied.

response Noted.
The Certification Memorandum is mentioned in a footnote to paragraph 3. See also the response to comment #51.

comment *203* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege*

RRplc comment on page 83: the following is stated "Note: this AMC should not be considered as interpretative material for the classification of changes or repairs." thus if it is not interpretative material for the classification of changes or repairs where is this covered since the title of the section "Level of Involvement (LoI) in a certification project for a type certificate (TC), a major change to a TC, a supplemental type certificate (STC) or a major repair design".

response Noted.
Point 21.A.91 and the related interpretative material cover the classification of changes and repairs.

comment *222* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067*

	For clarity and common understanding please add reference to EASA document or publication specifying EASA panels and disciplines.
response	Noted. Although currently there are no published documents that describe the EASA panels and disciplines, their scope can be deduced by reviewing the attachments to the Certification Memorandum on LoI, which is available at: http://www.easa.europa.eu/documents/public-consultations/proposed-cm-21a21b-001

comment	*223* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* For clarity add "the use of new ... in-house methods to be approved by the DOA".
response	Not accepted. EASA considers that the wording is already sufficiently clear.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 70. New AMC 21.B.100(b) p. 92-93

comment	*55* comment by: *Rolls-Royce Deutschland / DOA Manager D. Stege* Why is the risk class determination for EASA LOI different compared with AMC 21.B100(a) and 21.A15(b)(5)? Seems to be a more straight forward approach here. Why not for inital TC under 21.B.100(a) as well?
response	Noted. The risk-class determination is substantially different because this AMC only addresses minor changes, which, by their nature, are considerably simpler. This approach would not properly address the more complex cases of new TCs, or major changes/major repairs to TCs or STCs.

comment	*145* ❖ comment by: *Antonio PARADIES* The wording used for Novelty, Complexity and DOA Performance criteria remain consistent through all the documents EASA has issued on LoI, but for some reason the wording used for criticality/severity criteria varies from one document to another or even in the same document like in this very NPA. We would like to understand the reason to do so, if there is one, even if we consider it to be misleading and would recommend being consistent with the wording and using just one of them.
response	Accepted. The AMC has been amended to delete the term ‘severity’.

comment	*146* ❖ comment by: *Antonio PARADIES* As exposed on page 93 table, for minor changes and minor repairs, LoI can be determined through 3 Risk Classes (A, B and C). It has been proposed and discussed during previous EASA Workshops to define just three classes for major changes as well.

We would like to propose again an amendment for the major change Risk Class determination on a single table.
The proposed risk classes would be as follows:

		Risk Class		
Non-Critical	No novel or complex	Class 1	Class 1	Class 2
	Novel or complex	Class 1	Class 1	Class 2
	Novel and Complex	Class 1	Class 2	Class 2
Critical	No novel or complex	Class 1	Class 2	Class 2
	Novel or complex	Class 2	Class 2	Class 3
	Novel and Complex	Class 2	Class 3	Class 3
		High	Medium	Low or Unknown
		DOA Performance		

Where the proposed EASA LoI based on these Risk Classes is proposed to be defined as follows:
— Risk Class 1: after acceptance of the certification programme, there is no further EASA involvement in verifying the compliance activities performed by the applicant to demonstrate compliance at CDI level;
— Risk Class 2: EASA's LoI typically comprises the review of a defined small portion of the compliance data; there is either no participation in compliance activities or participation in a small number of compliance activities (witnessing of tests, audits, etc.);
— Risk Class 3: EASA's LoI typically comprises the review of a high amount of compliance data, the detailed interpretation of test results, and the participation to a high number of compliance activities (witnessing of tests, audits, etc.).

The main identified advantages of this approach are:
- Standard traffic lights 3 color system (green/yellow/red)
- No more confusion between Classes 2 and 3
- Easier to handle 3 Risk Classes than 4
- To have every criteria in one single table facilitates the risk class determination

response

Not accepted.
EASA is convinced that applications for major changes/major repairs, new TCs or STCs should have one additional risk class in order to better cover all the possible cases. The risk assessment related to minor changes and minor repairs is simpler by its nature.

3. Proposed amendments and rationale in detail — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision) — 3.1.1. Annex I (Part-21) to Regulation (EU) No 748/2012 — 71. New AMC 21.B.100(b) p. 93-98

comment *145* ❖ comment by: *Antonio PARADIES*

	The wording used for Novelty, Complexity and DOA Performance criteria remain consistent through all the documents EASA has issued on LoI, but for some reason the wording used for criticality/severity criteria varies from one document to another or even in the same document like in this very NPA. We would like to understand the reason to do so, if there is one, even if we consider it to be misleading and would recommend being consistent with the wording and using just one of them.
response	Accepted. The AMC has been amended to delete the term 'severity'.

comment	*188* comment by: *CAA CZ* Correct full wording of the abbreviation DDP is "Declaration of Design and Performance".
response	Accepted. The text has been amended accordingly.

comment	*189* comment by: *CAA CZ* Content of the box "Focused review & issue of the certificate" is inaccurate. Final action of the minor change process on ETSOA is not issuance of certificate, but update of authorisation ETSOA made by EASA.
response	Accepted. The schematic has been amended accordingly.

comment	*224* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* "2 or 3 years" is not adequate as a long period, since sufficient knowledge and experience is still available if the same personnel from last ETSo project is still acting. However, a more adequate limit should be "5 years" or without time limit if the personnel from last ETSO project is still acting in the new ETSO project.
response	Not accepted. The period of 2-3 years is commonly understood at EASA to be a reasonable period of time to carry over experience from one project to another. It refers to the period between the time of the LoI evaluation and the last 'ETSOA project assessment'. The proposal regarding the applicant's personnel is arguable, depending on the different organisations of the applicants. Adding this point would imply that if there is a change in personnel, the LoI should be increased. This might not be correct for any change in personnel.

comment	*225* comment by: *Zodiac Aerospace - Sell GmbH DOA 21J.067* Add "new in-house methods approved under the applicant's ADOA"
response	Accepted. EASA concurs that new methods or procedures under the applicant's ADOA would impact the LoI. A new sentence has been added within Section 1.2.

4. Impact assessment (IA) p. 99

comment	*101* comment by: *Dassault-Aviation* Dassault-Aviation **Text:** Option 1 was the preferred one as the documented risk-based approach is expected to 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, this Option already includes some safety management system (SMS) elements to ensure compliance with ICAO Annex 19. **Comment:** Current NPA proposal does not provide evidence that the objectives set in section 4 will be met, because of the effort of the applicant to establish the LOI levels without noticeable effect on the EASA real LOI
response	Noted. The clear, transparent and risk-based approach introduced by EASA in the determination of the LoI is considered to be a valuable achievement. The aim of this new concept is not to reduce, or increase, the overall LoI, but instead to establish an effective and risk-based process for its determination.

5. Proposed actions to support implementation p. 100

comment	*145* ❖ comment by: *Antonio PARADIES* The wording used for Novelty, Complexity and DOA Performance criteria remain consistent through all the documents EASA has issued on LoI, but for some reason the wording used for criticality/severity criteria varies from one document to another or even in the same document like in this very NPA. We would like to understand the reason to do so, if there is one, even if we consider it to be misleading and would recommend being consistent with the wording and using just one of them.
response	Accepted. The AMC has been amended to delete the term 'severity'.

4. Annex 1 to CRD 2017-20 — Draft resulting text

The document ‘Annex 1 to CRD 2017-20 — Draft resulting text’ is published separately.