



European Union Aviation Safety Agency
Comment-Response Document 2019-03

Appendix
to ED Decision 2019/018/R

RELATED NPA: 2019-03 — RMT.0262 (MDM.060) — 28.8.2019

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1. Summary of the outcome of the consultation

During the NPA 2019-03 public consultation, 57 comments from 17 stakeholders were received.

The list of stakeholders who commented on NPA 2019-03 included national aviation authorities (NAAs), type certificate holders (TCHs), manufacturers of parts, aircraft owners, and others.

The following Table 1 shows the number of comments received from each commentator:

Commentators	# of comments
Airbus Helicopters	4
Airbus-EIAIX-SRg	10
AQUILA	2
Dassault-Aviation	2
DGAC France	1
Duane Kritzinger	3
EUROCONTROL	1
Europe Air Sports	1
FAA	3
Federal Office of Civil Aviation (FOCA), Switzerland	1
Franz Redak	2
Fulvio Oloferni	5
Leonardo Helicopters	3
Luftfahrt-Bundesamt	1
Rolls-Royce Deutschland / DOA Manager D. Stege	10
UK CAA	1
Yuksel Kenaroglu	7
<i>Total</i>	<i>57</i>

Table 1

The following Table 2 shows the number of comments received per subject.

Subject	# of comments
General Comments	9
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AMC 21.A.15(b)	5
GM 21.A.15 (c)	2
GM No 1 to 21.A.15(d)	6
Appendix 1 to GM No.1 to 21.A.15(d)	1
GM 21.A.21(f)(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.110(b)	1
GM 21.A.101	7

Subject	# of comments
GM 21.A.247	3
AMC 21.A.605(a)(1)	3
AMC 21.A.606(d)	1
GM 21.B.82	1
AMC 21.B.100(a) and 21.A.15(b)(6)	8
GM 21.B.107 and 21.B.110	3
Total	57

Table 2

The nature of the comments received ranged from specific technical aspects to comments that were intended to improve the wording of the proposed amendments.

The following table shows the percentage of comments that have been accepted, partially accepted, noted, or not accepted:

	ACCEPTED	PARTIALLY ACCEPTED	NOTED	NOT ACCEPTED	Σ
# of comments	14	5	16	22	57
percentage	25 %	9 %	28 %	38 %	100 %

Table 3

As several comments were ‘accepted’ or ‘partially accepted’, the text proposed by NPA 2019-03 has been reworded and improved, and a number of editorial corrections have been made.

The list of individual comments that were received, and the responses to them, is provided in Chapter 2.

A summary of the comments and of the amendments, if any, that were made to the NPA text that the European Union Aviation Safety Agency (EASA) wishes to highlight is provided below.

Adaptation of the risk assessment in AMC 21.A.15(c)

Some commentators reported that the proposed wording of the note added in AMC 21.A.15(c) was open to interpretation. The scope of that note was to make clear that, under certain conditions, an update of the DOA dashboard after the first issuance of the certification programme may trigger an update of the risk assessment, and consequently an update of the certification programme.

Although it would be impossible to define all the possible cases, EASA agreed to introduce more clarity on this aspect, and the note has been reworded.

OSD definition in GM No 1 to 21.A.15(d)

Some commentators noted that the definition of OSD proposed in GM 21.A.15(d) is different from the definition provided in Commission Regulation (EU) No 748/2012, as amended by Commission Delegated Regulation (EU) 2019/897.

In fact, after the consultation of NPA 2017-20 ‘Embodiment of level of involvement acceptable means of compliance and guidance material to Part-21’¹, point 21.A.15(d) was amended to add clarity. Instead of explaining in 21.A.15 what the OSD constituents were, OSD is now defined in the Article 1 of Regulation (EU) No 748/2012, as amended by Commission Delegated Regulation (EU) 2019/897. The repetition of the OSD constituents is not necessary in the GM, therefore EASA agreed to remove the OSD definition from the GM.

Some commentators also correctly highlighted a difference between Regulation (EU) 2018/1139 (the Basic Regulation) and the definition of OSD in Commission Regulation (EU) No 748/2012. This misalignment does exist; however, it cannot be solved by adding GM to Part 21 of Commission Regulation (EU) No 748/2012. The Commission and EASA are currently assessing the amendments brought in by Regulation (EU) 2018/1139, and will adapt Commission Regulation (EU) No 748/2012 accordingly, as required by Article 140(1) of Regulation (EU) 2018/1139.

Application for the approval of operational suitability data (OSD) — MMEL for ELA1 and ELA2

Some commentators noted that with the proposed deletion of the contents of GM 21.A.15(d), the existing guidance related to the MMEL for ELA1 and ELA2 would be lost.

EASA agreed to reinstate the relevant note in the GM.

OSD applicability

The overall applicability of OSD is determined in the related certification specifications (CSs), which are CS-SIMD, CS-GEN-MMEL, CS-MMEL, CS-CCD, CS-FCD, and CS-MCSD (its publication is under way; refer to NPA 2018-11). Therefore, there is no need to repeat the applicability in this GM.

GM No 1 to 21.A.15(d) has been amended to provide guidance regarding the possibility for ELA1 and ELA2 to establish a list of equipment that is equivalent to the MMEL. The applicability of the OSD constituents is established in the relevant CSs, and has been removed from the GM to avoid any duplication of information. On the non-applicability of MMEL for ELA1 and ELA2, please refer to NPA 2018-08 ‘Regular update of CS-MMEL and CS-GEN-MMEL’². Refer also to the response to comment #37.

Failure conditions for ETSO application

Some commentators expressed their concern regarding the capability of an ETSO applicant to perform a safety assessment as described by point (b)(6) of AMC 21.A.605(a)(1).

¹ <https://www.easa.europa.eu/document-library/notices-of-proposed-amendment/npa-2017-20>

² <https://www.easa.europa.eu/document-library/notices-of-proposed-amendment/npa-2018-08>

EASA wishes to clarify that the applicant is expected to perform a safety assessment based on either the flow down of the failure conditions expected for the installation, or based on assumptions if installation data is not available. It should be noted that some minimum performance standards already identify a certain criticality for the related function, while others do not provide any predefined assessment.

The failure condition classification is also needed to establish the item development assurance level for the development of the software items and the airborne electronic hardware items.

Clarification on point 3.3 of AMC 21.B.100(a) and 21.A.15(b)(6)

The first example of a criticality listed in AMC 21.B.100(a) and 21.A.15(b)(6) has been reworded for reasons of clarity, and to be in line with the current practices. According to the new wording, a compliance demonstration item (CDI) should be considered to be critical if it introduces a function, component or system whose failure may contribute to a failure condition that is classified as hazardous or catastrophic at the aircraft level.



2. Individual comments and responses

In responding to the comments, a standard terminology has been applied to attest 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)	-
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comment	23	comment by: <i>UK CAA</i>
Thank you for the opportunity to comment on this NPA 2019-03. Please be advised that there are no comments from the UK CAA.		

response	Noted.
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comment	25	comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i>
The European Commission has published proposed changes to Part 21 in document C(2019) 1845 final.		
The proposed Part-21 includes a requirement (ref. 21.A.15(b)(5) and (6)) for Design Organisations to create a breakdown of the certification programme into meaningful groups and a requirement in 21.B.100 requesting the EASA to determine its involvement (titled as Level of Involvement). The text for these two Part 21 requirements is approximately one page long, while the text details of the NPA 2019-03 together with amending text in Annex 1 to CRD 2017-20 are of massive volume.		
It should be therefore mentioned that the required workload (CDI creation, justifications, cert programme updates, LOI procedures, surveillance activities, etc..) does impose an additional burden on Design Approval Holders. The amount of AMC/GM details indicating a high level of administration rather than simple implementation rules.		
It should also be recognised that the CRD to NPA 2017-20 states on page 5 that EASA has either 'not accepted' or only 'noted' 56% of the comments received.		
It is strongly recommended to simplify the LOI implementation ensuring a robust LOI concept understanding and maintaining the compliance with the applicable Part 21 requirements with the focus on the safety of the design and instructions approved and issued under an EASA TC.		



response Noted.

The new Lol concept was heavily tested by EASA and volunteer DOAs between 2016 and 2018. Additionally, training and advertising campaigns were launched by EASA to ensure a common understanding of the changes related to this new concept. The experience gathered so far confirms that once the applicant becomes familiar with the new concept, the additional workload required by 21.A.15(b)(5) and (6), or similar, is reasonable. It is important to consider that the new approach is compliant with ICAO Annex 19, as it introduces a traceable and transparent risk-based approach to compliance verification. Additionally, it also provides some remarkable benefits for applicants because investing more effort in the preparation (and acceptance) of the certification programme would allow the earlier identification of issues/findings, thus facilitating and expediting the next phases of the certification process.

comment 34 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

The Federal Office of Civil Aviation (FOCA) would like to thank the Agency for the opportunity to comment on this NPA.

response Noted.

comment 39 comment by: *EUROCONTROL*

EUROCONTROL does not have comments on the NPA

response Noted.

comment 43 comment by: *Luftfahrt-Bundesamt*

The LBA has no comments to NPA 2019-03.

response Noted.

comment 44 comment by: *Europe Air Sports*

Europe Air Sports thanks EASA for this NPA and generally supports it. We have no specific comments on this NPA.

On a related topic, EAS is looking forward to the “Part 21 Light” rulemaking task announced at this years AERO, and are interested to contribute to that task as its task force begins its work.

response Noted.

EXECUTIVE SUMMARY

p. 1-2

comment 58 comment by: *Franz Redak*

General:



	<p>Given the importance and the impact of the text for the DOA/ADOAs it would be required to have one conclusive NPA with all changes to be commented. The reshuffle of certain paragraphs and the partial changes in other sections to previous approved text can only be reasonably commented when</p> <p>a) the current adopted version b) the previously accepted (Opinion) including the EU proposed wording (changes) d) the NPA 2019-03</p> <p>version can be clearly seen AND identified in one document.</p>
response	<p>Not accepted.</p> <p>All the AMC and GM affected by Opinion No 07/2016 were consulted by means of NPA 2017-20. At the time of the publication of NPA 2017-20, the text of Opinion No 07/2016 was still under review by the European Commission. The final text of the new Part 21 amendment is, in some points, different from that proposed with Opinion No 07/2016, and therefore some AMC and GM needed to be adapted to remain aligned with the new Part 21.</p> <p>The scope of NPA 2019-03 was actually to perform a dedicated consultation on these adaptations. To provide a better picture and to ensure better understanding, NPA 2019-03 was published together with CRD 2017-20, which included an annex that contained the text that resulted from the first consultation (refer to Annex 1 'Draft resulting text' to CRD 2017-20³).</p>

2. In summary — why and what

p. 5-10

comment	<p>27 comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i></p> <p>Page 5:</p> <p>The NPA is referring to the Opinion No 07/2016 issued by EASA on 23 May 2016. The European Commission has based on that Opinion updated the proposed changes to Part-21 concerning LOI on 12 March 2019 under document number C(2019) 1845 final.</p> <p>The NPA issued on 3 April 2019 should therefore be updated to reflect the latest changes proposed in the EC document not the Opinion.</p>
response	<p>Accepted.</p> <p>NPA 2017-20 contained the proposed amendments to the AMC and GM to Part 21 based on the contents of Opinion No 07/2016.</p> <p>The scope of NPA 2019-03 is actually to adjust the AMC and GM to Part 21 on the basis of EC document C(2019) 1845 final⁴.</p>
comment	<p>51 comment by: <i>Duane Kritzinger</i></p> <p>Point 21.B.100(a) needs to clarify:</p>

³ <https://www.easa.europa.eu/document-library/comment-response-documents/crd-2017-20>

⁴ <https://ec.europa.eu/transparency/regdoc/rep/3/2019/EN/C-2019-1845-F1-EN-ANNEX-1-PART-1.PDF>



	<ul style="list-style-type: none"> - whether the applicant needs to propose the LOI, or whether EASA will determine this on their own. - whether “compliance demonstration activities” is the same as CDI.
response	<p>Noted.</p> <p>Part 21 Section A contains the requirements for the applicants, while Part 21 Section B contains the requirements for the authority.</p> <p>Regarding the new LOI concept, in Section A, there are points (e.g. 21.A.15(b)(5) and (6), 21.A.113(b), etc.) that require the applicant to make a proposal to EASA regarding the LOI.</p> <p>In Section B, there is point 21.B.100, which requires the authority to determine and notify its LOI.</p> <p>For those types of applications in which the LOI proposal is requested by Section A, the LOI determination performed by EASA is based on the proposal that is received.</p> <p>The CDI is a grouping of compliance demonstration activities and data taken from the certification programme.</p>

3. Proposed amendments and rationale in detail — 3.1. Draft AMC and GM (draft EASA decision) — 3.1.1. Annex I (Part 21) to Regulation (EU) No 748/2012	p. 11-39
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comment	<p>1</p> <p style="text-align: right;">comment by: <i>Yuksel Kenaroglu</i></p> <p><i>'...for a major change to a type certificate.'</i></p> <p>This sentence may be stated like below:</p> <p><i>'...for a major change to a type certificate. Design, or, certified type (of the aircraft).</i></p> <p>Rationale: 'Type Certificate' is only a piece of paper. It doesn't express or resembles the design of the aircraft. The certified system (aircraft) should be highlighted.</p>
response	<p>Not accepted.</p> <p>The type certificate includes the whole type that goes beyond the type design; please refer to point 21.A.41, which describes the meaning of a type certificate. This terminology was already introduced before this Part 21 amendment.</p>
comment	<p>2</p> <p style="text-align: right;">comment by: <i>Yuksel Kenaroglu</i></p> <p><i>'...TC components...'</i> (I assumed that, open statement is: <i>'... Type Certificate components...'</i>)</p> <p>As I stated in my first comment: Using the statement <i>'Type Certificate'</i> for <i>'Certificated Design, Operating Characters,...'</i> seems little problematic. (to me !)</p> <p>Rationale: If we use the statement <i>'Type Certificate'</i> for a sheet of colorful (it may include attachments also.) paper, it may be problematic to use same statement to resemble the Certified Design (of the aircraft), and other related documentations. (To my understanding, all of the other documents (operational,etc...) should be considered</p>

	parts of the Certified Type of the aircraft; in other words, 'Type Design'(of the aircraft.)
response	Not accepted. See the response to comment #1.
comment	3 comment by: Yuksel Kenaroglu <i>'- the approval of certain major changes to a type certificate (...).!</i> In here, also, for the statement, 'Type Certificate', 'Certified Type Design' may be used. (This comment includes (covers) all this NPA document.)
response	Not accepted. See the response to comment #1.
comment	4 comment by: Yuksel Kenaroglu 21. <i>'...type certificate design data...'</i> <i>Comment: 4. '...type design data...' or, '...type certification design data...'</i>
response	Not accepted. See the response to comment #1.
comment	5 comment by: Yuksel Kenaroglu <i>(6) '...supporting the safety aspects...'</i> <i>Comment: (6) '...supporting the ground and flight safety aspects...'</i>
response	Not accepted. Applicants for ETSO authorisations have to identify all the functions performed by their equipment (refer to CS-ETSO, Subpart A, paragraph 2.4, and the dedicated MOPS); this is not limited to flight or ground conditions only. For this reason, EASA does not consider that the proposed clarification is needed.
comment	6 comment by: Yuksel Kenaroglu 21. GM 21.B.82 In the 'Title Statement': <i>'...type certificate or restricted type certificate'</i> <i>Comment: '...type certification or restricted type certification'</i>
response	Not accepted. As stated in the title, the certification basis refers to the 'type certificate' and not to the certification process. The 'type certificate' is defined in point 21.A.41.



comment	<p>7 comment by: <i>Yuksel Kenaroglu</i></p> <p>21.2.:</p> <p>In this paragraph and in the related paragraphs of this NPA, the statements, 'type certificate' and 'supplemental type certificate' may be changed as '...certification' when the process is indicated, not the certificate (sheet) itself.</p> <p>21.5:</p> <p><i>'Note: Alternative means of compliance' should not be confused with 'AMC'.</i></p> <p>Comment:</p> <p>To prevent confusion, another abbreviation may be used for 'Alternative Means of Compliance', such as AL-MC, or, AI-MC.</p>
response	<p>Not accepted.</p> <p>The introduction of a new abbreviation is not considered necessary by EASA. With this approach, potential misinterpretations should be prevented.</p>
comment	<p>9 comment by: <i>Airbus-EIAIX-SRg</i></p> <p>Page13/53, 0, 3rd section, 4th bullet point:</p> <p>Airbus comment:</p> <p>By default the applicable version of the DOA dashboard is the latest one available at issuance of the initial issue of the certification program. However after the first issuance of the certification program an updated version of the DOA dashboard should be considered by the applicant in case a significant change in performance has been measured by the agency.</p> <p>Airbus proposal:</p> <p>Replace the wording "<i>not automatically</i>" by a more pragmatic approach.</p>
response	<p>Accepted.</p> <p>The wording has been amended.</p>
comment	<p>10 comment by: <i>Airbus-EIAIX-SRg</i></p> <p>Page 30/53, GM 21.A.247, section "3. Procedure", 5th bullet point:</p> <p>Airbus proposal:</p> <p>Modify "— the issue of information and instructions under the privilege of 21.A.263(c)(3)"</p> <p>Rational:</p> <p>21.A.263(c)(3) was converted to 21.A.265(h).</p>
response	<p>Accepted.</p> <p>The bullet point that was referred to has been deleted.</p>
comment	<p>11 comment by: <i>Airbus-EIAIX-SRg</i></p>

	<p>Page33/53, AMC 21.A.606(d), last / new sentence</p> <p>Airbus proposal: Move the sentence “Additionally, the applicant should demonstrate that the non-ETSO functions do not interfere with the ETSO functions.” From AMC 21.A.606(d) to AMC 21.A.606(b)</p> <p>Rationale: The sentence asks for a “<i>demonstration</i>” whereas the AMC 21.A.606(d) is only a requirement for “<i>declaration</i>”. AMC 21.A.606(b) is more appropriate.</p>
response	<p>Partially accepted. As noted by the commentator, some elements of the sentence referred to partially cover 21.A.606(b). 21.A.606(d) has been amended to better reflect the declaration aspects.</p>
comment	<p>12 comment by: Airbus-EIAIX-SRg</p> <p>Pages 36&37/53, AMC.B.100(a) and 21.A.15(b)(6), section “2. Background”</p> <p>Airbus Proposal: Replace the sentence: “The applicant has to break down the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as CDIs, and provide their proposal for EASA’s Lol.” by the following version: “The applicant has to break down the certification project into meaningful groups of compliance demonstration activities and data, hereinafter referred as CDIs, and provide their proposal within the certification program for EASA’s Lol determination.”</p> <p>Rationale: Not the certification programme but the certification <i>project</i> is relevant for the breakdown into CDIs. The certification programme contains a paragraph dedicated to the description of the various CDIs.</p>
response	<p>Not accepted. The commented wording is aligned with point 21.A.15(b)(5) and should remain consistent at the AMC level.</p>
comment	<p>13 comment by: Airbus-EIAIX-SRg</p> <p>Page 37/53, AMC 21.B.100(a) and 21.A.15(b)(6), section “3.4 Method for the determination of risk classes”</p> <p>Airbus comment: In the sentence: “Furthermore, when a truly identical CDI is reused for the compliance demonstration in a new project, there is no Lol involvement is reduced to the acceptance of the certification plan, in the compliance demonstration verification, as the likelihood of an unidentified non-compliance is very low.”</p>

response	<p>The term “truly identical” should be defined in “Article 1 – Scope and definitions”, Section “2. For the purpose of this Regulation, the following definitions shall apply:” Alternatively, remove the word “truly”.</p> <p>Rationale: The term “truly identical” is subject to individual interpretation.</p> <p>Accepted. The word ‘truly’ has been deleted.</p>
comment	<p>14 comment by: Airbus-EIAIX-SRg</p> <p>Page 39/53, GM 21.B.107 and GM 21.B.111, 1st section:</p> <p>Airbus comment: For clarification of the updated OSD responsibility for the applicant / DOA holder a cross-link to the new amended GM to 21.A.90A should be provided.</p> <p>Airbus proposal: Add a reference as follows: “By analogy, these requirements should also be considered by design organisation approval (DOA) holders who approve changes or issue supplemental type certificates (STCs) under their privileges (without EASA’s involvement) as stated in GM to A.21.A.90A”.</p> <p>Rationale: The amended GM –as per CDR 2017-20, Annex 1- reads as follows: GM 21.A.90A Scope The term ‘changes to the type certificate’ is consistently used in Part-21Part 21, Subpart D and E, as well as in the related AMC and GM. This term does not refer to changing the document that reflects the type certificate (TC) but to the elements concept of the TC as defined in 21.A.41. It means that the processes for the approval of changes, as described in the said two Subparts, do not only apply to changes to the type design, but may also apply to changes to:</p> <ul style="list-style-type: none"> — the operating limitations; — the type certificate data sheet (TCDS) for airworthiness and emissions; — the applicable type-certification basis and environmental protection requirements with which the Agency applicant has to demonstrates compliance; — any other conditions or limitations prescribed for the product in the applicable certification specifications (CSs) and environmental protection requirements by EASA; — the applicable operational suitability data (OSD) certification basis; — the OSD; and — the TCDS for noise. NOTE: OSD is only applicable to aircraft TCs and not to engine or propeller TCs. Therefore, changes to the OSD are only relevant for changes to aircraft TCs.
response	<p>Accepted. The proposed reference has been added to the GM text.</p>
comment	<p>15 comment by: Fulvio Oloferni</p>

response	<p><u>GM 21.A.15(c)</u> VULCANAIR would like to express some doubts regarding the wording of the new addition to GM 21.A.15(c): “However, an update of the DOA dashboard after the first issuance of the certification programme does not automatically require the applicant to adapt the proposed risk assessment”.</p> <p>The wording seems to be generic and does not contain any threshold value by which it can be established when an update of DOA dashboard should be reflected into a modification of the risk assessment.</p>
	<p>Accepted. See the response to comment #9.</p>
comment	<p>16 comment by: <i>Airbus-EIAIX-SRg</i></p> <p>Page 14/53, GM N°1 to 21.A.15(d)</p> <p>Airbus proposals:</p> <p>First bullet point: “- the minimum syllabus of the type rating training for the maintenance certifying staff;” is to be replaced by: “- the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;”</p> <p>Second bullet point: “— the minimum syllabus of the pilot type rating and the reference data for the objective qualification of associated simulators;” is to be replaced by:</p> <p>a) “- the minimum syllabus of pilot type rating training, including determination of type rating;” b) “- the definition of scope of the aircraft validation source data to support the objective qualification of simulators or the provisional data to support their interim qualification;”</p> <p>Fourth bullet point: “— aircraft type data that is relevant to cabin crew;” is to be replaced by: “- determination of type or variant for cabin crew and type specific data for cabin crew;”</p> <p>Rationale: The list of OSD constituent should re-use the wording in “Regulation (EU) N° 748/2012, ANNEX 1” (fourth amendment) which give more details in 21.A.15(d). [Airbus is aware that 21.A.15(d) will be revised with “PART21 new amendment”. Airbus proposes to keep the actual definition within the revised GM N°1 to 21.A.15(d)]</p>
response	<p>Noted. The definition of OSD has been removed from GM No 1 to 21.A.15(d); see also the responses to comments #24 and #17. Additionally, it must be noted that 21.A.15(d) refers to the content of an application for OSD, while the proposed GM No 1 to 21.A.15(d) refers to the definition of the OSD.</p>

comment	17	comment by: <i>Fulvio Oloferni</i>
	<p><u>GM No.1 to 21.A.15(d)</u> VULCANAIR does not agree on the unification, under an unique bullet, of minimum syllabus for pilot type rating training and data for qualification of simulators. Even though these the two arguments are related, they are subjected to different Certification Specifications, CS-FCD and CS-SIMD respectively, with different applicability. Also in the pending revision to Part 21 reported into Opinion 07/2016, the distinctions between the two OSD constituents remain unchanged. The unification under a single bullet with the conjunction “and” could be misinterpreted at the applicability level.</p>	
response	<p>Noted. The definition of OSD will be removed from GM No 1 to 21.A.15(d), and will be maintained in Regulation (EU) No 748/2012 under Article 2 ‘Definitions’, where the two constituents are indeed separated.</p>	

comment	18	comment by: <i>Airbus-EIAIX-SRg</i>
	<p>Page 21/52, GM 21.A.21(f)(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.110(b), last paragraph</p> <p>Airbus proposal Delete second part of the sentence as shown below: “The derogation in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.11021.B.111(b) is applicable to all major changes to a TC. so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes where in which at least one of the OSD constituent changes is major.”</p> <p>Rationale: No more separate classification for design and OSD.</p>	
response	<p>Not accepted. Although the comment is formally correct, EASA believes that it may be better to highlight that the mentioned derogations also apply to major changes that are only driven by OSD changes.</p>	

comment	19	comment by: <i>Airbus-EIAIX-SRg</i>
	<p>Page 14/53, GM 21.A.15(c)</p> <p>Airbus proposal: Change last bullet point: “— any changes to the schedule that impact the EASA involvement.” As shown below: “Changes to the project schedule for major milestones”.</p> <p>Rationale: To be consistent with the AMC 21.A.15(b) which use similar wording.</p>	

response	<p>Not accepted.</p> <p>GM 21.A.15(c) describes the updates of the certification programme which should be notified to EASA, while AMC 21.A.15(b) provides the contents of the certification programme.</p> <p>With reference to the first, EASA has to be informed in cases of changes to the schedule that have an impact on its Lol.</p>
comment	<p>20 comment by: <i>Fulvio Oloferni</i></p> <p><u>Appendix 1 to GM No.1 to 21.A.15(d)</u></p> <p>VULCANAIR does not agree on the deletion of the “OSD applicability tables”. These are very helpful to understand or verify the applicability of OSD constituents. In addition, for MMEL applicability (for example), it seems that neither CS-GEN-MMEL nor CS-MMEL contains the statement of non-applicability of MMEL for ELA-1 and ELA-2 aircraft, as reported in the MMEL table of this Appendix.</p>
response	<p>Not accepted.</p> <p>The applicability of the OSD constituents is established in the relevant CSs, and has been removed from the GM to avoid any duplication of information. On the non-applicability of MMEL for ELA1 and ELA2, please refer to NPA 2018-08 regarding CS-MMEL and CS-GEN.MMEL.</p> <p>Refer also refer to the response to comment #37.</p>
comment	<p>21 comment by: <i>Fulvio Oloferni</i></p> <p><u>GM 21.A.247 point 3 “Procedures”</u></p> <p>VULCANAIR believes that the fifth bullet with the wording “the issue of information and instructions under the privilege of 21.A.263(c)(3)” should be deleted. This privilege seems to be cancelled into the revised Part 21 as per Opinion 07/2016, and it is also in conflict with the new obligation according to 21.A.265(h).</p>
response	<p>Accepted.</p> <p>The bullet point that was referred to has been deleted.</p>
comment	<p>22 comment by: <i>Fulvio Oloferni</i></p> <p><u>GM 21.B.107 and 21.B.111</u></p> <p>VULCANAIR believes that, after the last sentence “Interrelated change should be approved together under a single approval”, it should be added at least a reference to the derogation provided in GM 21.A.21(f)(b), [...], 21.B.107(b) and 21.B.111(b): “the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents...”</p>
response	<p>Not accepted.</p> <p>The sentence was not intended to preclude the use of the derogation, but it means that the approval of the OSD should be included in the same TC or STC approval.</p>

comment	<p data-bbox="368 183 416 241">24</p> <p data-bbox="1059 183 1394 241" style="text-align: right;">comment by: <i>DGAC France</i></p> <p data-bbox="368 248 1394 293"><u>GM N°1 to 21.A.15(d) OSD :</u></p> <p data-bbox="368 300 1394 405">This GM is modified and copies the Article 19 (b) (ii) of the NBR 2018/1139 except the last bullet which replaces “additional specifications to ensure compliance with Section III” by “other type-related operational suitability elements”.</p> <p data-bbox="368 412 1394 479">Therefore, DGAC France suggests to revise this GM to ensure its consistency with the Basic Regulation 2018/1139 wording.</p> <p data-bbox="368 517 1394 797">In addition, the list of OSD constituents is moved from the Annex I – Part-21 to the new cover regulation changing the regulation n°748/2012. But it appears that the OSD list in the new cover regulation changing 748/2012 is inconsistent with the Article 19 (b) (ii) of the NBR 2018/1139 and this new GM n°1 to 21.A.15(d). Moreover, the notion “as applicable” is missing in the new cover changing 748/2012. This omission can be very harmful because the applicability of the OSD constituents is only established in the relevant CS and not by the cover regulation changing 748/2012.</p>
response	<p data-bbox="368 808 1394 853">Partially accepted.</p> <p data-bbox="368 860 1394 1032">After the consultation of NPA 2017-20, point 21.A.15(d) was amended to add clarity. Instead of explaining in 21.A.15 what the OSD constituents were, OSD is now defined in Regulation (EU) No 748/2012. The commentator is correct that there should not be any contradictions between Regulation (EU) No 748/2012, its Part 21 points and its GM. The repetition of the OSD constituents is not necessary in the GM.</p> <p data-bbox="368 1039 1394 1294">The commentator also correctly highlights a difference between Regulation (EU) 2018/1139 and the definition of OSD in Regulation (EU) No 748/2012. This is correct, but it cannot, however, be solved by adding GM to Part 21 of Regulation (EU) No 748/2012. The European Commission and EASA are assessing the amendments brought in by Regulation (EU) 2018/1139, and will adapt Regulation (EU) No 748/2012 accordingly, as required by Article 140(1) of Regulation (EU) 2018/1139.</p>
comment	<p data-bbox="368 1339 416 1384">28</p> <p data-bbox="619 1339 1394 1384" style="text-align: right;">comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i></p> <p data-bbox="368 1391 1394 1435">Page 13:</p> <p data-bbox="368 1458 1394 1559">The AMC 21.A.15(b)(5) as revised in the Annex 1 to CRD 2017-20 contains explanatory information and should be therefore transformed into a GM.</p>
response	<p data-bbox="368 1559 1394 1603">Not accepted.</p> <p data-bbox="368 1610 1394 1794">AMC 21.A.15(b)(5) describes an acceptable means to comply with the corresponding requirement to provide ‘a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data including a proposal for the means of compliance and related compliance documents’. For this reason, it should not be reclassified as GM.</p>
comment	<p data-bbox="368 1839 416 1883">29</p> <p data-bbox="619 1839 1394 1883" style="text-align: right;">comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i></p> <p data-bbox="368 1890 1394 1977">Page 13:</p>

	The AMC 21.A.15(b)(5) as revised in the Annex 1 to CRD 2017-20 contains explanatory information and should be therefore transformed into a GM.
response	Not accepted. See the response to comment #28.
comment	30 comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i> Page 22: The content of the proposed GM 21.A.101 doesn't reflect the header and content changes to the requirement 21.A.101 proposed in Opinion No 07/2016 and the EC C(2019) 1845 final text.
response	Partially accepted. The titles of the points of Part 21 that were referred to have been aligned with the new amendment of Part 21.
comment	31 comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i> Page 23: Text 1.2.7 in GM 21.A.101 says 'This GM is not mandatory and is not an EU regulation'. As this is applicable to all GMs that sentence could be deleted here.
response	Accepted. Point 1.2.7 has been reworded.
comment	32 comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i> Page 23: Text 1.2.7 in GM 21.A.101 is saying 'This GM describes an acceptable means, ..., to comply with...' requires improvement not to be mixed-up with an AMC.
response	Accepted. Point 1.2.7 has been reworded.
comment	33 comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i> Page 28: Titles of Part 21 requirements should be identical with the proposed titles of EC C(2019) 1845 final or at least the Opinion 07/2016.
response	Accepted. The titles have been aligned.
comment	35 comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i> Page 36:

	<p>The symbol [...] at the end of AMC 21.B.100(a) and 21.A.15(b)(6) is replacing the rest of the text of the AMC 21.B.100(a) and 21.A.15(b)(6) as published in Annex 1 to CRD 2017-20:</p> <p>On page 65 of the Annex 1 to CRD 2017-20 the NPA refers under point 3 to a proposed Certification Memorandum (CM) Issue 1 written to support Opinion 07/2016. Comments to that particular CM Issue 1 were sent to EASA and a CRD document was published by EASA in April.</p> <p>Since April 2017 no update of the CM has been published by EASA in reaction to the CM CRD statements. The CM requires a consistency check against the EC published document with the reference C(2019) 1845 final.</p> <p>The CM should be updated to be used in this NPA.</p>
response	<p>Noted.</p> <p>The draft CM on Lol that was consulted in Q1/2017 contains two main parts. These are a generic section, which describes the criteria to be used in order to propose and determine the Lol, and a number of attachments that contain additional considerations that are applicable to each EASA panel.</p> <p>The generic section of this CM has been transferred into AMC 21.B.100(a) and 21.A.15(b)(6), and therefore it has been publicly consulted for a second time through NPA 2017-20.</p> <p>The generic part of the draft CM on Lol has been aligned with the resulting AMC 21.B.100(a) and 21.A.15(b)(6), while the attachments have been slightly amended on the basis of the experience gained during the internal consultation phase.</p>
comment	<p>36 comment by: <i>Rolls-Royce Deutschland / DOA Manager D. Stege</i></p> <p>Page 36:</p> <p>The symbol [...] at the end of AMC 21.B.100(a) and 21.A.15(b)(6) is replacing the rest of the text of the AMC 21.B.100(a) and 21.A.15(b)(6) as published in Annex 1 to CRD 2017-20:</p> <p>On page 65 of the Annex 1 to CRD 2017-20 the NPA is using the term ‘knowledge management aspect’.</p> <p>A request was raised to include more clarification to that term and EASA accepted the request with the statement to introduce additional clarification (ref. CRD to NPA 2017-20 page 83 (comment #50)).</p> <p>This additional clarification is missing and should be added as stated in the CRD.</p>
response	<p>Noted.</p> <p>The following sentence has been added to AMC 21.B.100(a) and 21.A.15(b)(6) as a result of the comments received during the public consultation of NPA 2017-20.</p>

‘Regardless of the extent of an organisation’s previous experience in similar projects, a CDI may be classified as novel if there are specific discontinuities in the process for transferring information and know-how within the organisation.’

comment	<p>37 comment by: AQUILA</p> <p>GM No 1 to 21.A.15(d) [page 14 to 19]: After this proposed ammendment where will be explicitly stated that for ELA1 / ELA2 aircraft “the list of required equipment as included in the TCDS and/or AFM/POH therefore [these aircraft are] not required to establish an MMEL.”? And also that ELA1 / ELA2 aircraft do not need OSD (beside special cases)?</p>
response	<p>Partially accepted.</p> <p>The overall applicability of the OSD is determined in the related certification specifications, which are CS-SIMD, CS-GEN-MMEL, CS-MMEL, CS-CCD, CS-FCD, and CS-MCSD (its publication is under way; refer to NPA 2018-11⁵). Therefore, there is no need to repeat the applicability in this GM. The GM that was commented on has been amended to provide guidance on the establishment of a list of equipment that is equivalent to the MMEL for ELA1 and ELA2.</p>
comment	<p>38 comment by: AQUILA</p> <p>AMC 21.B.100(a) and 21.A.15(b)(6) [36 to 38]: A qualitative risk assessment with 4 classes is definitely unsuitable for complex aerospace certification tasks. This only seems to be a management tool for “having done something” but shifts resources from real technical assessment and prioritization to useless statistics. Furthermore with sentences like “...when a truly identical CDI is reused for the compliance demonstration in a new project, there is no involvement...” future product airworthiness is endangered from my point of view, because this leads to argumentations like I’ve already done a functional MCAS so the next one will be implemented without any supervision by the Agency?? For certification supervision it should always be relied onto the judgment of qualified PCMs without any prefiltering of the CDIs the want to review!</p>
response	<p>Noted.</p> <p>The AMC proposed is one means to conduct the risk assessment required by Part 21. It supports the identification of the elements of a certification project in which there is a risk of a non-compliance with the certification basis that is not identified. It does not provide a definite conclusion, but guides EASA on what to verify. In particular, it does not determine whether a specific compliance activity or data item is to be verified or not. As part of its Lol determination, EASA always has the possibility to decide which elements of the certification project and which compliance demonstration activity or data of a given CDI it verifies, based on the risk assessment that was conducted. In addition, as part of its general oversight responsibility, EASA always has the possibility to request and review any of the activities or data of a certification project.</p> <p>It should also be noted that according to the AMC, EASA shall also apply sound engineering judgement for the determination of its Lol.</p>

⁵ <https://www.easa.europa.eu/document-library/notices-of-proposed-amendment/npa-2018-11>

comment	<p>40 comment by: Airbus-EIAIX-SRg</p> <p>Page 13/53, AMC 21.A.15(b) Content of the certification programme:</p> <p>Airbus comment: The compliance demonstration items (CDI) are subject to the certification <u>project</u>.</p> <p>Airbus proposal: Replace sentence: "...a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as compliance demonstration items (CDI),..." By the following version: "...a proposal for a breakdown of the certification project into meaningful groups of compliance demonstration activities and data, hereinafter referred as compliance demonstration items (CDI),..."</p> <p>Rationale: Not the certification programme but the certification project is relevant for the breakdown into CDIs. The certification programme contains a paragraph dedicated to the description of the various CDIs.</p>
response	<p>Accepted. See the response to comment #12.</p>
comment	<p>41 comment by: Dassault-Aviation</p> <p><u>Text:</u> page 14 GM No 1 to 21.A.15(d)</p> <p><u>Comment:</u> Inconsistency between cover regulation, basic regulation and GM to Part 21 as other type-related operational suitability elements are only addressed in the GM</p>
response	<p>Partially accepted. See the response to comment #24.</p>
comment	<p>42 comment by: Dassault-Aviation</p> <p><u>Text:</u> page 30 GM 21.A.247 Significant changes in the design assurance system. "...the issue of information and instructions under the privilege of 21.A.263(c)(3);..."</p> <p><u>Comment:</u> 21.A.263(c)(3) does not exist anymore</p>
response	<p>Partially accepted. See the response to comment #24.</p>
comment	<p>45 comment by: FAA</p>

response	<p>Pages 23-26</p> <p>Referenced Text: Reference source not found Comment: All these pages have missing references Proposed Resolution: Add the correct references</p> <p>Accepted. The cross reference has been added, and a corrected version of the NPA has been made available on the EASA website⁶.</p>
comment	<p>46 comment by: FAA</p> <p>Page 28 Para J-4 Referenced Text: Certification Basis – Deviations</p> <p>Question: What are these deviations to? Are they equivalent to exemptions, as used by other aviation authorities? Are these deviations to only airworthiness or environmental standards, or anything further.</p> <p>Proposed Resolution: Suggest being more specific to what deviations are referring to.</p>
response	<p>Noted.</p> <p>A deviation records that although the proposed design does not comply with the certification specifications or special conditions, either literally or with its intent, the level of safety targeted by the essential requirements of the Basic Regulation is achieved through mitigating factors. In any case, compliance with the essential requirements of the Basic Regulation shall be demonstrated.</p>
comment	<p>47 comment by: FAA</p> <p>Page: 28 Para: J-4 Text: Certification Basis Comment/Question: Mandatory Airworthiness Actions (AD)- There may be unsafe conditions that are corrected by the authority before the application for a change is approved.</p> <p>Is this intentionally missing or not addressed in certification basis here?</p> <p>Proposed Resolution: Suggest adding a reference for the evaluation for a changed product certification basis.</p>
response	<p>Not accepted.</p>

⁶ <https://www.easa.europa.eu/document-library/notices-of-proposed-amendment/npa-2019-03>

For the purpose of the guidance to point 21.A.101, the type certification basis of the changed product is considered. The airworthiness directives (ADs) are not considered here; please refer to 21.B.80 for the definition of the type certification basis. However, according to 21.B.103 and similar points, before issuing an approval, EASA shall verify that no feature or characteristic has been identified that may make the product unsafe for the uses for which the certification is requested.

comment 48 comment by: *Leonardo Helicopters*

“Page 14”
“4. GM No 1 to 21.A.15(d) is amended as follows:”

Provision to include new OSD element within the TCDS on voluntary basis (electing to comply to CS) have to be included to allow the possibilities to make visible to the aviation community the new OSD element and make aware any entities other than TCH (in this way those entities can take into account in implementing or developing their responsibilities/business)

response Noted.
Any approved OSD constituent is made visible to the aviation community by referencing it in the TCDS.

comment 49 comment by: *Leonardo Helicopters*

"22.AMC 21.B.100(a) and 21.A.15(b)(6) is amended as follows:"
"2. Background"

To introduce clarification on how consider the Certification Memo dealing with the same topic

response Not accepted.
The certification memorandum (CM) is an informative document only. A footnote has been introduced into the AMC and GM to provide a link to the additional criteria.

comment 50 comment by: *Leonardo Helicopters*

“23. GM 21.B.107 and 21.B.110 is amended as follows:”

To include instructions on how manage the application requiring the introduction of new OSD element within TCDS (Ref. comment #48)

response Noted.
The referenced GM refers to the interactions between changes to the type design and their impact on the OSD. Any change to the type design that requires additions or changes to any existing OSD constituents should be managed accordingly.

comment 52 comment by: *Duane Kritzinger*

AMC 21.A.605(a)(1)(b)(6):



	<p>How can the applicant do a safety assessment on a component if they do not know the architecture in which it is fitted? At best they can only do a FMEA (either functional or piece part) on a component.</p> <p>If this AMC specifies “classification” then EASA needs to provide the classification criteria (and the criteria in AMC25.1309 is not appropriate to a component – hence why they cannot do an FMECA)</p>
response	<p>Not accepted.</p> <p>The applicant is expected to perform a safety assessment based on either the flow down of the failure conditions expected for the installation, or based on assumptions if installation data is not available. This analysis is also needed to establish the item development assurance level for the development of the software items and the airborne electronic hardware items.</p>
comment	<p>53 comment by: <i>Duane Kritzinger</i></p> <p>On page 37 para 3.4: If this is in Section B, does it mean it applies to the Competent Authority only? In other words, it is not up to industry to do the risk assessment?</p> <p>On page 37 para 3.4: If the applicant needs to do this, then why is it in Section B</p>
response	<p>Noted.</p> <p>See the response to comment #51</p>
comment	<p>54 comment by: <i>Airbus Helicopters</i></p> <p>The AMC 21.A.15(b)(5) as revised in the Annex 1 to CRD 2017-20 contains explanatory information and should be therefore transformed into a GM.</p> <p>Indeed for change to TC and STC, the equivalent material is proposed in GM 21.A.93 (b) that refers to the AMC 21.A.15 (b). Having an GM referring to an AMC is confusing and it is therefore proposed to have the details of the certification programme (which content is already specified at rule level) moved to GM level. Also the requirement for subcontracting arrangements to be included in the certification programme is not necessary as long as this is already covered by compliance with 21.A.239(c).</p>
response	<p>Not accepted.</p> <p>Regarding the proposal to reclassify AMC 21.A.15(b)(5) into GM, see the response to comment #28.</p> <p>Regarding GM 21.A.93(b), it should be noted that it has already been reclassified as AMC; refer to Annex 1 to CRD 2017-20.</p> <p>Regarding the last part of the comment, EASA appreciates that there may be some duplication between 21.A.15(b) and 21.A.239(c). However, the latter only applies to DOA, while 21.A.15(b) applies to all applicants for a TC. For certain products, e.g. ELA1 or ELA2 aircraft, the applicant is not required to hold a DOA.</p>
comment	<p>55 comment by: <i>Airbus Helicopters</i></p>

response	<p>The text of the GM does not reflect the new text of 21.A.101 (b). Indeed the amended rule has replaced the text “the applicant may show that “ by “an earlier amendment to a certification specification ..may be used” in the situations described under (b)(1) to (3) where it is always the Agency that finds the criteria to be applicable (or not). Indeed 21.B.105 ensures the Agency establishes the certification basis for changes to TC iaw 21.A.101 and notifies the applicant for a major change to the type certificate.As a consequence it is proposed to use the wording”an earlier amendment of the certification specificatiosn may be used” as well in the paragraph 2.2.2 of the GM for consistency with the text of the related rule.</p>
	<p>Accepted. This point has been reworded to be more consistent with the new wording of Part 21.</p>
comment	<p>56 comment by: <i>Airbus Helicopters</i></p> <p>This comment is related to the need of an AMC 21.B.100 (c) Further guidance regarding the update of the level of involvement is recommended Indeed the 21.B.100.c indicates that when an <i>appreciable impact</i> on the risk is identified, an update of the LOI is required. Applicant have also to consider GM 21.A.15(c) updates to the certification programme together with 21.A.20 (b) reporting requirement in case of "any difficulty or event encountered during the process of demonstration of compliance that may have <i>an appreciable effect on the risk assessment</i> under point 21.A.15(b)(6) or on the certification programme, or may otherwise necessitate a change to the level of involvement of the Agency previously notified to the applicant in accordance with point 21.B.100(c). Indeed the evolution of the risk assessment towards a reduction of the EASA LOI should not be considered as appreciable as the initial LOI proposal should remain acceptable. Conversely an increased risk level from one class to the one upper may also not be considered as appreciable. Depending on the subject involved and the related EASA panel(s) guidance on LOI level of activities, the updated LOI may not have a significant effect on the level of verification activities performed by the Agency.</p>
response	<p>Not accepted. The intent of the Part 21 update regarding Lol is to implement a risk-based process to determine the EASA involvement. If the risk changes during the certification process, EASA should determine whether this affects the level of involvement that was already determined. For a traceable process, the certification programme is the means per 21.A.15 to document a change both in the risk and the involvement. A lower risk and a corresponding lower level of involvement are considered to be appreciable.</p>
comment	<p>57 comment by: <i>Franz Redak</i></p> <p>Item 17: AMC 21.A.605(a)(1) - (b)(6): The ETSO should typically consider in their MPS the function (and criticality) based on the function described. Also we believe that could only be applied on a non-ETSO function which per definition is not identified and quantified in the ETSO or related standard. We also assume that the final classification and safety assessment is to be done by the integrator (installer) once</p>

response	<p>he defines the criticality in his installation. Consequently suggest to change wording to: In case of non-ETSO functions, an overview.....</p> <p>Not accepted. Some minimum operational performance specifications (MOPS) may identify a certain criticality for the related function, but some do not. In some installations, the requirements are more stringent than in the ETSO MOPS. Therefore, in any case, the safety assessment has to be performed by the ETSO applicant for the ETSO compliance, but also for the installer who will need this data to perform the safety assessment for the TC/STC.</p>
comment	<p>59 comment by: Airbus Helicopters</p> <p>The classification of the CDI using the criteria described in the AMC 21.B.100(a) and 21.A.15(b)(6) by the applicant would benefit from the EASA Panels specific guidance as proposed in CM–21.A/21.B-001 Issue 01 issued 23 January 2017. Please confirm the CM will be published in its final version and referenced in the AMC.</p>
response	<p>Noted. The generic section of the proposed CM–21.A/21.B-001 is identical to the AMC and GM to Part 21. The panel-specific attachments are the additional information which will be published. AMC 21.B.100(a) and 21.A.15(b)(6) refer to this material in the following note: ‘Additional panel-specific criteria are available in further informative material published by EASA. This material should not be considered to be AMC.’</p>

