European Union Aviation Safety Agency

COMMENT RESPONSE DOCUMENT

EASA CRD of Proposed CM-S-008 Issue 02
Additive Manufacturing
[Published on 3 November 2020 and officially closed for comments on 24 November 2020]

Commenter 1: Rolls Royce PLC – Sharron Welch / Project Controller - Airworthiness – 17.11.2020

Comment # 1

In addition to the identification of key variables and their link to design values, which is noted several times through the document, it is important to stress the need for consistency through manufacturing hardware control. The requirement for robust machine qualification, maintenance, calibration and monitoring processes should be re-enforced at this level due to the process intensive nature of the produced material and the perceived gap in machine maturity. Inclusion at this level would also further encourage the knowledge transfer from AM equipment providers to users.

EASA response: Agreed

Adapted version of comment text added to Section 3, page 5.

Commenter 2: ADSE B.V. – Eelco Bakker / title / service – 20.11.2020

Comment # 2 (section: General)

Dear EASA, thank you for the revision of the Certification Memorandum CM-S-008 regarding Additive Manufacturing. We have reviewed the document internally and are pleased with the added information. We have some specific comments which we address separately, however in general we see that the document has become abundant with (good) information. Some of the newly added and existing important text might become lost in this abundance of information. We would suggest EASA to highlight the more important parts with the use of subsections or dedicated chapters in order to quickly provide an overview of crucial information and to improve the readability.

Suggested resolutions:
Split chapter 2 in a background section and a summary section.
Rewrite chapter 3 to highlight the important issues that are now somewhere hidden in the abundance of text.
Rewrite chapter 3 to highlight the important difference between OEM and non-OEM designed parts and the influence of this regarding Additive Manufacturing.

Introduce a separate chapter to discuss the possible use cases, implications and limitations for MOA's

EASA response: Partially agreed

EASA appreciates the supporting comments and recognises that scope for improvement always exists. However, the CM is simply being used as a high-level industry discussion tool which is being developed in response to perceived, and rapidly developing, industry needs as communicated with EASA. Therefore, aligned with intent of the comment, this revision already starts to breakout themes of evident interest to industry into new sub-sections, for example 'no criticality' content was added. Furthermore, in response to progress towards 'performance' based regulations' the CM also encourages industry development of further guidance via standards bodies etc. Noting that the AM subject is moving rapidly and further revision to the CM is likely in the near future, EASA does not wish to use resource re-organising the existing text significantly at this time (unless to correct errors) or attempt to develop a comprehensive detailed check list. However, EASA believes that the comments might provide useful content for future industry standards development, iaw the final notes in the existing Section 3 text. Concluding: EASA appreciates and agrees with the intent of the comment. However, these could best be captured in future standards and/or revisions of the CM following development during the upcoming AM Events, e.g. EASA FAA AM Event November 2021.

Comment # 3 (Chapter: 2: Background / Chapter 3: EASA Certification Policy and Guidance for DOA, ADOA and POA holders)

One of the most important issues to be highlighted w.r.t. the technology of additive manufacturing is the critical relation of key design parameters and key process parameters both in communication (between DOA and POA) and quality assurance of the production process. If additive manufacturing is compared to "conventional manufacturing", the level of criticality of the design and process parameters is much higher. This means that the DOA-POA agreement needs to focus on these specific items during development e.g. more (first) article inspections due to the variability of the production processes. Any critical design parameter should be identifiable by an inspection in the production process and these should be communicated by the DOA to the POA.
This criticality plays a crucial role in replacement parts designed by non-TC holders who do not know the complete design philosophy of the original non-AM TC part. The original non-AM TC part might have hidden safety features that are inherent to the way of manufacturing. An AM non-TC replacement part can be designed without the original knowledge of the failure cases of the original part, introducing new failure modes in the product, part or appliance (due to e.g. newly introduced internal loads, other material optimizations and less "free" oversizing (material redundancy)). The production of replacement parts in general (not only focusing on AM) have this same risk, however due to the criticality of the design and the criticality of the production methods using AM, this essential failure case knowledge becomes critical for these AM non-TC replacement parts.

Suggested resolutions:
Split the text in a part specifically focussed on new parts designed by the original TC holder and a part specifically focussed on non-TC holders that create replacement parts.
Add a specific paragraph regarding the influence of the AM process on the failure modes that can be introduced on product level due to e.g. part optimization and the emerging of previous hidden failure cases or non-critical anomalies.

EASA response: Partially agreed

EASA agrees with the technical aspects of the comment. However, please see comment 2 regarding any intent to significantly re-organise the text. The comment provides some potential direction to further industry guidance development. Note: Text regarding 'process optimisation' potentially impacting failure modes has been added to page 6 reference to 'weight optimised designs'

Comment # 4 (Chapter: 3, paragraph 3 to 9 (pages 5/6))

Due to the addition of the text, this paragraph has become hard to read and it is difficult to distil the important information.

Suggested resolutions:
Structure this paragraph in several sub sections / bullets:

- Material and process should be sufficiently tested to obtain representative design allowables and to determine the variability.
- AM specific process parameters, process characteristics and environmental effects should be covered in testing as well, to show sufficient understanding of the effect of these.
- All potential anomalies or damage threats and consequential damaged states should be identified, both inherent to the novel production technology, such as inaccessible surfaces, and related to the novel design possibilities, such as more weight optimized designs resulting in different failure mechanisms.
- Add a specific paragraph regarding the influence of the AM process on the failure modes that can be introduced on product level due to e.g. part optimization and the emerging of previous hidden failure cases or non-critical anomalies.

EASA response: Partially agreed.

Please see response to comment 2.

Comment # 5 (Chapter: 3, paragraph 5 (page 6))

This paragraph does not state what kind of attention is mentioned here.

Suggested resolutions:
Explain explicitly what EASA means with "attention". Does EASA mean here additional inspection after production or design inspections etc?

EASA response: Agreed

Text amended to reference both attentions being required from 'design and production' perspectives and reference to inspection challenges added.

Comment # 6 (Chapter: 3, paragraph 5 (page 6))

This paragraph does not state what EASA defines under “conventionally manufactured” or (in the next paragraph) with “mature fixed process”. Using e.g. prepregs can also introduce manufacturing anomalies at, or near the surface.

Suggested resolutions:
Delete the added text and replace by: "Using AM can introduce manufacturing anomalies that do not exist in other processes or anomalies that have not yet been identified. Any post-process machining or surface treatment should identify these potential manufacturing anomalies to avoid non-intentional material properties."

EASA response: Partially agreed

‘(other than AM)’ added to emphasis difference with respect to ‘conventionally’. Note: Existing text retained in order to emphasise the ‘near surface anomalies’ and to emphasise that simply machining away obvious surface irregularities may not be adequate.

Comment # 7 (Chapter: 4, note)

Perhaps it is good to add a specific chapter or section in chapter 3 for MOA Holders instead of a final note in the final chapter of this Certification Memorandum. As it is rightfully stated in the note, a Part-145 / Part CAO approved organization could also use AM for fabrication of certain parts for own use. However, the production of these parts should be approved by a DOA including any production technique, both via and limited to approved data. However, where a DOA is involved in the production process when new parts are designed and then produced by a POA via the DO-PO agreement, in the maintenance environment the DOA (not specifically being the (S)TC holder) is not involved in the production process of this restricted range of parts to be used in the course of undergoing work within the facilities of the MOA.

Suggested resolutions:
Introduce a specific chapter with guidance for maintenance organisations.
Change the title of the chapter 3 subsection “Repairs and Design Changes:” to “Repair designs and Design Changes:” in order to avoid confusion for MOA’s

EASA response: Partially agreed.

Title amended. Please see response to comment 2 regarding reorganisation/addition of chapters.

Comment # 8 (Chapter: Appendix 1)

The requirements of CS23 are missing in the text. The CM is now purely focussed on Large Aircraft, while this technology can also be used in the General Aviation environment

Suggested resolutions:
Add CS23.2240, CS23.2260 and CS23.2325 to the list of requirements.
Add CS23.2265 wherever CS2x.619 or Cx.619 is mentioned.

EASA response: Agreed.

Missing references added.

Commenter 3: The Boeing Company – Tanya Boisseranc / Senior Engineering Analyst – 20.11.2020

Comment # 9

Type of comment: Editorial

Page:4
Paragraph: "*-statistical coverage of engineering properties important to safety (noting the potential for many influencing parameters, variability, and different competing damage and failure modes). It is essential that design values account for variables introduced throughout the AM process used to fabricate production parts, including consideration of the variables associated with the constituent materials (e.g. powder or wire) and post processing*"

THE PROPOSED TEXT STATES:
This provision applies when certification by analysis approach is used (25.613).

REQUESTED CHANGE:
"-statistical coverage of engineering properties important to safety (noting the potential for many influencing parameters, variability, and different competing damage and failure modes). When certification is by analysis, it is essential that design values account for variables introduced throughout the AM process used to fabricate production parts, including consideration of the variables associated with the constituent materials (e.g. powder or wire) and post processing"

JUSTIFICATION: Clarification would help applicants who use certification by testing approach.

EASA response: Partially agreed.

Comment text added, but with a note indicating that statistical management by test is yet to be standardised

Comment # 10

Type of comment: Editorial

Page: 6

Paragraph: "*Independent of the facility where AM parts are to be fabricated, the applicant should demonstrate by test and/or experience, that the material is and process are suitable for the intended use of the part being fabricated and that the material is being purchased per an approved material specification and controlled by approved inspection methods.*"

THE PROPOSED TEXT STATES:

Inspection requirements are part of material and process specifications.

REQUESTED CHANGE:

"*Independent of the facility where AM parts are to be fabricated, the applicant should demonstrate by test and/or experience, that the material and process are suitable for the intended use of the part being fabricated and that the material is being purchased per an approved material specification and controlled by approved inspection methods required by the material specification.*"

JUSTIFICATION: Clarification will help applicants understand that material and/or process specifications should have inspection requirements.

EASA response: Agreed

Proposed text added.

Comment # 11

Type of comment: Editorial

Page: 6

Paragraph: "*It should be shown that the derived AM design values are based upon representative and statistically significant test data (to the level required by the applicable CS and application) which adequately addresses the Key Parameters, including consideration of machine-to-machine variation within and between facilities. Furthermore, it should be shown that values obtained from tests conducted on simple specimens accurately represent the mechanical properties of the intended parts.*"

THE PROPOSED TEXT STATES:
This provision applies when certification by analysis approach is used (25.613). Does not apply to certification by testing approach.

REQUESTED CHANGE:
"*When certification is by analysis, it should be shown that the derived AM design values are based upon representative and statistically significant test data (to the level required by the applicable CS and application) which adequately addresses the Key Parameters, including consideration of machine-to-machine variation within and between facilities. Furthermore, it should be shown that values obtained from tests conducted on simple specimens accurately represent the mechanical properties of the intended parts.*""

JUSTIFICATION: Clarification will help applicants who use certification by testing approach.

EASA response: Agreed.

Proposed text added with further note indicating that statistical management by 'point/detail' test is yet to be standardised.

Comment # 12
Type of comment: Editorial

Page: 6
Paragraph: "*However, complex parts and processes may, dependent upon criticality, require testing in the test/analysis pyramid in addition to test coupon level tests to truly represent the engineering properties resulting from the material, process, and fabrication method used for the application. For some configurations, this approach could be supported using appropriate Fatigue and Damage Tolerance design, including crack propagation analysis.*"

THE PROPOSED TEXT STATES:
This provision applies when certification by analysis approach is used (25.613). May not apply to certification by testing approach.

REQUESTED CHANGE:
"*However, complex parts and processes may, dependent upon criticality, require testing in the test/analysis pyramid in addition to test coupon level tests to truly represent the engineering properties resulting from the material, process, and fabrication method used for the application. Certification by testing approach may be considered for complex parts. For some configurations, this approach could be supported using appropriate Fatigue and Damage Tolerance design, including crack propagation analysis.*"

JUSTIFICATION: Clarification will help applicants who use certification by testing approach.

EASA response: *Agreed*

Proposed text added with further note indicating that statistical management is yet to be standardised (see also response to comment 11)

Comment # 13

Type of comment: Substantive

Page: 6

Paragraph: "*All anomalies (inherent and rare) and damage modes should be identified in order to ensure that the impact upon criticality (including the potential impact upon any associated hazard analysis) is fully understood, noting that new governing damage and failure modes may be introduced relative to previous experience, resulting in potentially new damage sequences and safety consequences.*"

THE PROPOSED TEXT STATES:

The term "rare" is not defined in the draft CM, and it is not certain if it supports a probabilistic support.

REQUESTED CHANGE:

"*All anomalies inherent to the material and the process used, ~~(inherent and rare)~~ and damage modes should be identified in order to ensure that the impact upon ~~criticality (including the potential impact upon any associated hazard analysis)~~ the consequence of failure is fully understood, noting that new governing damage and failure modes may be introduced relative to previous experience, resulting in potentially new damage sequences and safety consequences.*"

JUSTIFICATION: Clarification will be helpful to avoid using a subjective term "rare"

EASA response: *Partially agreed.*

Text amended to address production defects (anomalies, flaws etc), including potentially other defects outside specifications (rare) via an F&DT thought process, e.g. identifying all damage modes etc. The intent is to capture 'rare' defects via the broader robust design.

Comment # 14
Type of comment: Substantive

Page: 6
Paragraph: "*Such considerations may be of increasing importance if the potential benefits of AM are to be fully exploited, e.g. weight optimised designs may introduce new failure modes and expose the structure to more low reserve factors when compared to more conventional designs which have defined the existing 'acceptable' level of safety. For example, parts typically designed to be static strength critical could become fatigue critical, or changes in damage mode may change the critical failure modes in a structural element of a critical system, etc. These considerations emphasise the importance of the need to follow a cautious 'step by step' approach to the introduction of AM in applications which could be of significance to safety.*"

THE PROPOSED TEXT STATES:
Design optimized for AM is similar to other optimization efforts (e.g. reducing margins for weight savings). Critical failure modes within a part may change, but the overall consequence of the failure of a part wouldn't typically depend on the manufacturing methods.

REQUESTED CHANGE:
"*Such considerations may be of increasing importance if the potential benefits of AM are to be fully exploited. ~~, e.g. weight optimised designs may introduce new failure modes and expose the structure to more low reserve factors when compared to more conventional designs which have defined the existing 'acceptable' level of safety.~~ For example, parts typically designed to be static strength critical could become fatigue critical, or changes in damage mode may change the critical failure modes in a structural element of a critical system, etc. These considerations emphasise the importance of the need to follow a cautious 'step by step' approach to the introduction of AM in applications which could be of significance to safety.*"

JUSTIFICATION: Design optimized for AM is similar to other optimization efforts (e.g. reducing margins for weight savings). Critical failure modes within a part may change, but the overall consequence of the failure of a part wouldn't typically depend on the manufacturing methods.

EASA response: *Partially agreed.*

EASA partially agrees with the intent of the comment, i.e. criticality should not depend upon the manufacturing method. However, the risk exists that a hazard analysis based upon conventional experience may not adequately address potential new damage modes etc which may change the failure sequence and hazard assessment. This point may be of particular relevance to non-TCH organisations engaged in repair or modifications. Following text added to better qualify the existing text :'Furthermore, design organisations, other than the TCH, are unlikely to have access to the TCH design and hazard analysis assumptions, particularly as they relate to the airplane level of safety.'

Comment # 15
Type of comment: Editorial

Page: 6
Paragraph: "*Applicants should provide evidence that materials and processes are addressed by specifications that are under revision control.*"

THE PROPOSED TEXT STATES:
Revision controlled fabrication control documents are sometimes used to supplement the specifications

REQUESTED CHANGE:
"*Applicants should provide evidence that materials and processes are addressed by specifications and/or fabrication control documents that are under revision control.*"

JUSTIFICATION: Revision controlled fabrication control documents are sometimes used to supplement the specifications

EASA response: *Agreed*

Proposed text added.

Comment # 16
Type of comment: Substantive

Page: 7
Impact of AM on design organizations:
Paragraph: "*Note: The introduction of additive manufacturing may represent a significant change to the Design Assurance System of the DOA Holder according to 21.A.247*"

THE PROPOSED TEXT STATES:

REQUESTED CHANGE:
"*Note: The introduction of additive manufacturing may represent a significant change to the Design Assurance System of the DOA Holder according to 21.A.247. However, depending on circumstances, such a change may not necessarily be a significant change.*"

JUSTIFICATION: It is not certain if the proposed note suggests a change to the major/minor determination for the design assurance system when involving AM. The use of AM should not make a change major. Subpart D, 21.A.101 *Designation of applicable certification specifications and environmental protection requirements* should still apply in determining if a change is significant.

EASA response: *Partially Agreed*

Adapted version of comment text added to the CM. Note: The text in this section addresses the Design Assurance System, not the product change classification.

Comment # 17

Type of comment: Substantive

Page: 8

Certification Plans and Means of Compliance:

Paragraph: "*EASA typically expects applicants to submit a certification plan, referenced to the appropriate CSs and other means prescribed or required by EASA in the certification basis, supported by MoCs on how the applicant intends to demonstrate compliance with the certification basis.*"

THE PROPOSED TEXT STATES:

REQUESTED CHANGE:

"*For a major type design change, EASA typically expects applicants to submit a certification plan, referenced to the appropriate CSs and other means prescribed or required by EASA in the certification basis, supported by MoCs on how the applicant intends to demonstrate compliance with the certification basis.*"

JUSTIFICATION: It will provide clarity to state that certification plans are required for major changes to the type design.

EASA response: *Agreed.*

Noting that the CM does not intend to change high level EASA certification process, an adapted version of the proposed text has been added.

Comment # 18
Type of comment: Substantive

Page: 9
Further developing guidance CS2x.603, CS2x.605, and CS2x.613:
"*Further to the previous discussion in this CM, the following text is intended to support existing AMC 2x.603, 2x.605, and 2x.613 content, particularly when associated with the need to avoid catastrophic failure due to fatigue, manufacturing defects, environmental deterioration, or accidental damage, e.g. per CS2x.571. It should be read in conjunction with the referenced CSs and AMCs.*"

THE PROPOSED TEXT STATES:

REQUESTED CHANGE:
"*Further to the previous discussion in this CM, if MoC is by analysis, the following text is intended to support existing AMC 2x.603, 2x.605, and 2x.613 content, particularly when associated with the need to avoid catastrophic failure due to fatigue, manufacturing defects, environmental deterioration, or accidental damage, e.g. per CS2x.571. It should be read in conjunction with the referenced CSs and AMCs. Although following text focuses on cert by analysis MoC, similar considerations should be made if MoC is by testing.*"

JUSTIFICATION: The contents are focused on cert by analysis approach. Clarification will be helpful for the readers to understand that similar considerations should be made if MoC is by testing.

EASA response: *Partially agreed.*

EASA partially agrees with the intent of the comment. However, the existing text is intended to indicate a high-level intent associated with MoC. EASA believes that previous EASA responses to related comments, e.g. comments 9 and 11, have adequately addressed the matter in this revision to the CM. Therefore, EASA does not intend to amend text in response to this comment. Note, the Rulemaking task NPA 2020-11 RMT.673 is available for comment with more recent text proposals associated more directly with these CS AMCs. Noting the transient function of a CM, EASA proposes that the NPA be reviewed for more permanent consideration.

Comment # 19
Type of comment: Substantive

Page: 11
Parts of no Criticality:
"- for structure, or other parts, for which strength properties are important to maintaining fit, form, and function, e.g. maintaining shape, supporting its own weight, or limited loads (see note below), that a minimal set of coupon test data is presented showing that the applicant can produce consistent material properties, e.g. in tension, shear, and compression, such that it can be shown that safety will not be compromised. This may be important for ensuring that repair or replacement does not introduce new damage modes, damage sequences, or safety outcomes etc, such that the criticality of the item is increased. Furthermore, for some cases, e.g. complex parts, it may become necessary to test the part (subject to determination of meaningful load cases) in order to determine unique failure characteristics."

THE PROPOSED TEXT STATES:

REQUESTED CHANGE:
"- for structure, or other parts, for which strength properties are important to maintaining fit, form, and function, e.g. maintaining shape, supporting its own weight, or limited loads (see note below), that a minimal set of coupon test data is presented showing that the ~~applicant can produce consistent~~ material properties consistently meet or exceed the application requirement, e.g. in tension, shear, and compression, such that it can be shown that safety will not be compromised. This may be important for ensuring that repair or replacement does not introduce new damage modes, damage sequences, or safety outcomes etc, such that the criticality of the item is increased. Furthermore, for some cases, e.g. complex parts, it may become necessary to test the part (subject to determination of meaningful load cases) in order to determine unique failure characteristics."

JUSTIFICATION: The obligation should be to demonstrate that requirements are consistently met.

EASA response: *Agreed*

Text amended according to comment.

Comment # 20
Type of comment: Editorial

Page: 13
Appendix 1: Applicable regulations and guidance
"*Further to the CS's above, the showing of compliance with the following PART 21 regulations may be impacted by the introduction of AM into aviation products:*"

THE PROPOSED TEXT STATES:

REQUESTED CHANGE:
"*Further to the CS's above, unless the applicant demonstrates that the AM application is for Parts of no Criticality, the showing of compliance with the following PART 21 regulations may be impacted by the introduction of AM into aviation products:*"

JUSTIFICATION: Separate low critical AM parts from more critical applications.

EASA response: *Disagreed.*

Although EASA agrees with the thoughts within the comment, the interpretation of an application as being a part of no criticality, or not, is considered to be an interpretation being made within the higher level PART 21 frame work of regulations and guidance, e.g. within the scope and capabilities of an organisation approved under PART 21 etc.

Commenter 4: UK CAA – Keith Dodson / Policy Specialist – Airworthiness – 23.11.2020

Comment # 21
Section 2, page 5, 4th line:
The use of AM here is not necessary, recommend deletion of the term.

EASA response: Agreed

Redundant text deleted

Comment # 22

Section 2, page 5, 8th line
The reference to repair here needs clarity. Does it mean repair of AM parts or AM repairs to parts either produced by subtractive or additive manufacturing methods.

EASA response: Agreed

Text amended to clarify that it applies to any repair activities using AM

Comment # 23

Section 3, page 5, 48th & 49th line
"that the material and process are suitable for the intended use of the part being fabricated and that the material is being purchased per an approved material specification and controlled by approved inspection methods."
This could confuse the reader. The first use of the word "material" refers to the material of the part, however the second use of the word could apply to either the raw material feedstock (the powder) or the material of the part or both?

EASA response: Agreed

Text amended to maintain reference to design related production related issues. Note, reference to materials in the CM applies to all materials in the supply chain as referenced elsewhere in the CM. Reference to all possibilities is not being repeated, unless considered to be necessary to highlight a point.

Comment # 24

Section 3, page 6, 1st line
Does "approved inspection methods" refer to inspection methods of the raw material feedstock or the material of the part?
Additionally, the quality of material whether feedstock or part material is not simply controlled by inspection methods but by production process control, T. Simpson of PSU presentation at FAA-EASA Workshop on Qualification/Certification of AM Parts Nov 2020 illustrated the potential important process control methods.

EASA response: Partially agreed

Ref. to 'control' methods added'. See also comments 23.

Comment # 25

Section 3, page 6, 1st line
The use of AM here is not needed, recommend deletion. Design values must be associated with specified material standards/specifications.

EASA response: Agreed.

Comment # 26

Section 3, page 7, 30th line
"It is ultimately the responsibility of the design approval holder to ensure the method, or any changes, are appropriately addressed."
What is meant by "method"? Should there be a definition of AM method?

EASA response: Partially agreed

Example reference to 'processes, fabrication technologies' added for emphasis

Comment # 27

Section 3, page 7, 38th line
In case of such a change, the competent authority is recommended to inform EASA, and, as usual, these parties are also recommended to cooperate closely.
Agree.

EASA response: Noted

Comment # 28

Section 3, page 8, 1st - 2nd line
21.A.139(b)(1)(xi) requires a POA to have control procedures for personnel competence and qualification.
GM 21.A.139(b)(1)2. states that in addition to ISO 9001 requirements for a quality system the quality system needs to cover personnel training and qualification procedures especially for certifying staff.
21.A.145(a) requires a POA to demonstrate it has sufficient competent staff.
Also, personnel with the appropriate levels of knowledge and training are not necessarily competent.
Recommend that the referenced requirement is 21.A.145(a) not GM 21.A.139(b)(1).

EASA response: Partially agreed.

The existing CM text is addressing transfer of knowledge and training in the context of the overall knowledge, and its distribution, in the supply chain safety system, i.e. what it is, who has it, how it is ensured etc. The reference to 139b1 is simply an example of part of that process. However, ref. to 21.A.145(a) has also been added.

Comment # 29

Section 3, page 8, 2nd – 3rd line
Recommend 21.B.25(c) is directly referenced, instead of the GM 21.B.25(c), as this requires the competent authority to have "all staff shall be appropriately qualified and have sufficient knowledge, experience and training to perform their allocated task".

EASA response: Partially agreed.

Reference to PART 21.B.25 (c) added. See also comment 28.

Comment # 30

Section 3, page 9, 13th – 16th line
"This requires that all material and process related production defects and those defects resulting from repair processes in in-service environments be identified and the effects of defects be characterised at the appropriate levels of part configuration complexity, such that the strength and other properties used in the design data can be defined and maintained using the specifications."

Understand and agree with the objective of this paragraph. A word of caution with the use of the term "defect". A material anomaly or flaw is only classified as a defect when the design authority declares that the part is unable to maintain its function for the desired life of the part containing such an anomaly/flaw. Note in a single crystal engine high temperature compressor blade a grain boundary would be classified as a defect whereas in airframe structural components grain boundaries are not considered as defects. Recommend an alternative to the term "defect" is used.

EASA response: Partially agreed

This is fully understood and forms part of a long established industry discussion regarding terminology, which will not be resolved in this CM. In order to provide a 'proportionate' and 'performance' based position, the phrase 'effect of defects' was used in the safety context. This is important. Furthermore, a note has been added to recognise that differences exist regarding terminology and its use, e.g. flaws/anomalies, typically substantiated within specs etc. Note: According to some uses of the word 'flaw', a 'flaw' is not a 'flaw' (identified and accepted within the scope of a spec) until proved to be the case. Until then, it is a defect…etc.

Note: This subject is likely to be discussed in the Rulemaking task NPA 2020-11 RMT.673. Noting the transient function of a CM, EASA proposes that the NPA be reviewed for more permanent consideration.

Comment # 31

Section 3, page 10, 33rd line
One is either competent or not, thus the use of the word "adequately" is meaningless, recommend deletion of "adequately".

EASA response: Partially agreed.

Partially agree with the generic aspect of the comment, i.e. the use of 'adequate' can be meaningless relative to 'competent'. However, one is either competent, or not, relative to any particular task within a broad range of subject knowledge, experience, successful completion of similar tasks etc. The use of 'adequate' in the context of the CM sentence is relative to 'AM parts of any significant criticality'. Therefore, the details of what is 'adequate' knowledge, experience, successful completion of similar tasks etc remains to be determined. Therefore, the use of 'adequate' would seem to be appropriate in this case.

Comment # 32

Section 2. Background, page 5, 8th line
Please make it explicit that a repair carried out using Additive Manufacturing approach is treated as a modification. The term Repair may confuse organisations in treating this as a privilege under their DOA approval (specially the organisations with Major Repair as a DOA privilege).

EASA response: Partially agreed.

Although the comment point is generally true, PART 145.A.42 and GM allows repair by replacement etc for some less critical items. Although clearly requiring supporting design data etc, this is not necessarily requiring a mod, e.g. it could be via a manual or other guidance. Also, in practice, for parts of no safety concern, material change sometimes appears in repairs, not mods, in organisations without mods in their scope of approval.

Note: The introduction of the 'parts of no criticality' discussion in the CM is attempting to develop and better resolve this matter. Reference to this CM as being of relevance to PART 145 organisations is included for awareness purposes and to improve interaction between non-TCH DOAs and PART 145 organisations which they support. Text to remain unchanged until the discussion has been resolved.

Commenter 5: Lufthansa Technik DO – Rob van den Bosch / Certification Engineer – 24.11.202

Comment # 33

Section "parts of no criticality":

Based on the guidance provided in this chapter, we suggest to change the chapter title to "Parts of no and low criticality".

EASA response: Partially agreed.

EASA originally considered this possibility. However, criticality, e.g. as defined by example to AMC 21.B.100a repeated in the CM text, only discusses hazardous and catastrophic outcomes. This leaves considerable scope for interpretation of 'lower criticality'. Therefore, EASA would prefer a 'step by step' approach which formalises the 'no criticality' issue first, noting that there will be common elements in the process which can be used if moving towards slightly higher 'criticality' applications. This is a subject for the next AM workshops, e.g. EASA FAA AM Event November 2021. Note: Reference to the need to consider appropriate fatigue data has been added to the 'no criticality' section in order to seed discussion for content regarding expectations for items of 'low criticality'

Comment # 34

Section "parts of no criticality":

The guidance suggests that secondary structure could fall into the "low/no criticality". Same seems to apply to failures of a function, component or system which are classified as a minor or major event at aircraft level based on Cx.1309 principles.

LHT kindly request EASA to confirm this understanding or to provide further details to define the intended boundaries of "parts of low/no criticality".

EASA response: Partially agreed.

See response to comment 33. EASA believes that the comment refers to the discussion that industry and regulators are starting now. Note: This CM is a discussion tool which is likely to be subjected to frequent revision as content is evolved. Hopefully, the theme in the comment can be addressed in the upcoming meetings and the CM revised accordingly.

Comment # 35

Section "parts of no criticality":

LHT agrees that interior items of mass < 1 lb will usually not to create a significant risk to cabin occupants. Nevertheless, parts with a higher mass should not be considered automatically being of higher critically, if their function and installation environment does not require this.

The weight limit may rather serve as an additional parameter to set the required level of data for compliance demonstration.

Note: LHT prefers 0,5 kg instead of 1 lb.

EASA response: Partially agreed.

See response to comment 33. Inclusion of this possible reference only represents an example of a criteria which could be used to initially bound 'parts of no criticality'.

Comment # 36

Section “parts of no criticality”:

The required data to be presented by the applicant should include the option for point testing and post-production testing as an alternative to coupon test data. For low production batch numbers this may be a more practical approach.

EASA response: Partially agreed.

See also response to comments 33, 34, and 35. Reference to this possibility has been added, including recognition of possible challenges. Note: Further content can be added in future CM revisions and/or industry standards when defined. Note: Any move towards consideration of ‘parts of low criticality’ from ‘parts of no criticality’ is likely to require inclusion of fatigue considerations. A note has been added for future reference purposes.

Commenter 6: Airbus Commercial Aircraft – Stephan Runge / Regulations Manager – 24.11.2020

Comment # 37, page 9 pdf tracked, **Text supporting interpretation of CS2x.603**

3rd sentence, quote:

“[…] and those defects resulting from repair processes in in-service environments […]”

Unquote

Airbus comment:

The type of defects coming from repair processes should not be covered under this chapter.

Rational:

CS2x.603 is linked to the suitability of the materials itself and the material specifications.

Airbus propose therefore to delete the quoted wording from this paragraph to read as follows:

“This requires that all material and process related production defects ~~and those defects resulting from repair processes in in-service environments~~ be identified and the effects of defects be characterised at the appropriate levels of part configuration complexity, such that the strength and other properties used in the design data can be defined and maintained using the specifications.

EASA response: Partially agreed

Reference to 'responsible organisation' added in order to make clear to non-TCH repair organisations the challenge that may exist for AM repair.

Comment # 38, page 9 pdf tracked, **Text supporting interpretation of CS2x.605(b)**

1st sentence, quote:

Unless demonstrated otherwise the strength and properties resulting from each new material and process configuration should initially be assumed to be anisotropic and to be affected by the environment.

Unquote.

Airbus comment:

This statement is more or less a repeat of the message included for CS2x.603 and CS2x.613.

As reference is made to strength and properties, it seem not relevant to mention this under CS2x.605 that is about the method of fabrication and the test programme.

Airbus propose therefore to delete the quoted sentence (*in italics above*) from this paragraph to read as follows:

"Text supporting interpretation of CS2x.605(b):

The test programme required for new fabrication processes should help establish and evaluate the critical parameters

[…]

if the use of shared databases is intended."

EASA response: Partially agreed

EASA agrees that repetition exists. However, this was intentional, noting that material, process, and/or configuration of more complex parts can make possible anisotropy, environmental sensitivity etc.

Note: This subject is likely to be discussed in the Rulemaking task NPA 2020-11 RMT.673. Noting the transient function of a CM, EASA proposes that the NPA be reviewed for more permanent consideration of the discussion.

Comment # 39, page 10 pdf tracked, **Parts of no criticality**

Quote:

"Note: The amount of work associated with the certification process bares *some* correlation to criticality and/or novelty (novelty to the industry and/or applicant)."

Unquote

Airbus comment:

The word *some* leads to ambiguity on the link between part criticality and certification work. There is definitely a correlation, it is a matter of case by case assessments what this means in terms of work. Already the design change or repair classification is highly driven by the criticality.

Airbus propose to remove the word *some* (*in italics above*) from this sentence, reworded to read as follows:

""**"Note: The amount of work associated with the certification process is correlated ~~bares some correlation~~ to criticality and/or novelty (novelty to the industry and/or applicant)."**

EASA response: Agreed

Text amended accordingly

Commenter 7: Atkins – Matt Copus / Engineer / - 24.11.2020

Comment # 40

Currently to comply with CS-25 or CS-23 a full material qualification and development of A and B basis material properties is required, regardless of part criticality. Further, it is encouraged that low criticality parts are manufactured using Additive Manufacturing (AM) initially, before higher criticality parts are considered. This can make it challenging to develop the business case for the use of AM rather than conventional manufacturing. Low criticality parts are often low cost, so if material qualification has not already been performed the cost of carrying out the qualification for that part will be prohibitive. We have seen in industry that conventional manufacturing has been selected over AM for this reason.

We appreciate the proposed amendment to CM-S-008, issued 3rd November 2020, and note the guidance that certification expectation from EASA is proportionate to the criticality and novelty of the application. This will enable AM to become an economically viable option for low criticality AM parts.

We are looking at using this amended guidance to support the development of the certification approach for a low criticality polymer AM part for a military customer, which in fact will be approved by the UK Military Aviation Authority as opposed to EASA. One proposed route could involve reduced material qualification

testing and increased part level testing. This could prove to be a more financially attractive approach and mean that AM is adopted to replace conventional manufacturing in a wider range of circumstances.

Our interpretation of this CM amendment is that grading of qualification is permitted based on criticality. However, more in depth or prescribed guidance will give greater confidence to design and production organisations that AM can be used to produce certifiable solutions in an economically attractive way.

EASA response: Agreed

This CM is considered to be an evolving tool with which industry and the regulators can identify and address issues, such as the thoughts expressed in the comment. Guidance via future CM revision and/or use of standardisation bodies may be appropriate, as indicated in the CM. This could be progressed through future events, such as the EASA FAA AM Event 8-12th Nov. 20211. Please also see the response to comment 2.