



Federal Aviation
Administration

WG1: Qualification of Additive Manufacturing (AM) Parts of No, or Low Criticality (for use in Certified products) + WG4: Part Criticality

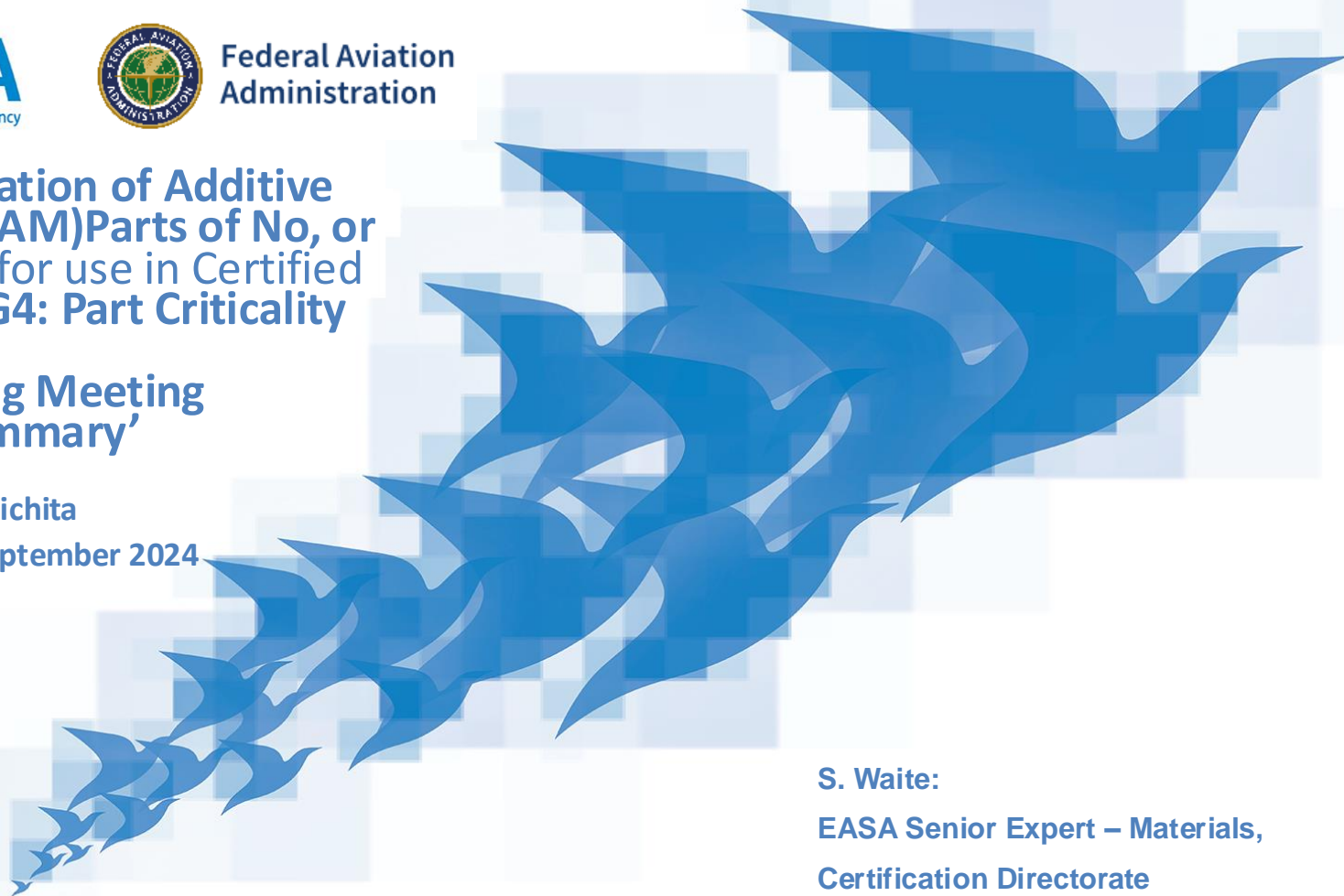
‘Working Meeting - Summary’

Wichita

17-19th. September 2024

S. Waite:

**EASA Senior Expert – Materials,
Certification Directorate**



EASA – AM WG1

Qualification of Additive Manufacturing (AM) Parts of No, or Low, Criticality (for use in Certified products) – Introduction and Scope:

WG1 Scope: **metallic** and **non-metallic AM parts** (of no/low criticality), AM repairs (including repair by replacement), as applicable to a **range of products** (airframe, systems, cabin safety, propulsion etc)

Who is this for? - Decision makers, typically in the supply chain beyond Type Cert Holder:

Reminder: Decision makers/designers exist in a **diverse range of organisations with a broad range of capabilities and experience supporting a broad range of approvals...** impact upon safety may not be clear to some of these organisations

- Supplemental Type Cert Holders
- Design Organisation Approval (DOA) Holders supporting MROs etc, e.g. under minor change approval, provided all aspects of the change meet the requirements for minor classification.
- ETSO/TSOs
- PART 145 organisations interpreting PART 145 etc (for information - allows repair by replacement)
- Stakeholders new to aviation, e.g. AM Machine Manufacturers.
- Regulators (in order to help define a 'level playing field' for industry)

no/low criticality – broader generic concept, not only of interest to AM

EASA - AM

FAA EASA AM Event - WG1 Breakout Agenda:

17th Sept (13:30-16:05hrs approx. 2hrs 35mins): **WG1**

- introduction/EASA CM-S-008 Revision Process reminder (since issue 3 release 30th April 2021)
- start CM CRD/CM Final Text Review (main points)

18th Sept (13:40-16:50hrs, approx. 3hrs 10mins): **WG1 + WG4 'Part Classification'**

- **AIA 'MRO' document** review (Drew Korte F2F (Delta Airlines), Eric Sager Virtual (Boeing) - 30 mins + Qs)
- **AIA 'More Critical Applications'** document (Morgan Mader F2F (Joby) - 30 mins + Qs)
- **NADCAP Audit – Findings** Summary (Richard Freeman F2F (PRI) – 25 mins)
 - Brief overview of Nadcap programme
 - Audits to date in metallic powder bed fusion AM and types of NCRs found in audits
 - Development of DED AM Audit Criteria
 - Plans for Audit Criteria for non-metallic AM processes
 - Audit Criteria for the manufacture of metallic powder for AM
 - Q&A/discussion time
- CM CRD/CM Final Text Review (brief) Summary (Simon)
- WG4 discussion slides (Mark)

19th Sept (08:20-10:00 hrs approx. 1hr 40 mins + Debrief): **WG1+WG4**

- continue CM CRD/CM Final Text Review?
- future WG1 and CM revision activities (Simon), FAA (Cindy) etc (WG1 - please be prepared to discuss)?
- WG1 Summary debrief (icw WG4 for combined Summary (+ 20 mins))

EASA - AM

EASA CM-S-008 Revision Process

Comments Response Document
(CRD) CM amendments discussion

EASA - AM

Reminder: EASA AM CM-S-008 'Additive Manufacturing' revision process

Issue 3 released 30th April 2021

Revision process since issue 3 included **many open shared industry – regulator meetings and webexs including evolving draft text:**

- Industry – Regulator AM Events (EASA – FAA 2021, 2022, 2023, 2024)
- WG1 webexs (9+ Event breakout sessions)
- EAAMIRG meetings (10)
- EASA AMPs WG – internal EASA (10)
- EASA Structures Staff
- Various SDO meetings (SAE, ASTM)

...so, no surprises should have been expected in the CM released for comment!

Draft initially released for comment 6th May 2024 (extended close date from 27th May to 6th June due to many May holidays)

<https://www.easa.europa.eu/en/document-library/product-certification-consultations/proposed-update-issue-4-certification>

- 13 organisations commented, included regulators, and industry (various products, Large Pax, GA, Rotorcraft, 1st tier suppliers)
- approx. 60 comments

EASA - AM

EASA CM-S-008 Revision CRD amendments:

- *35+ attendees on-line, estimate 30-50 F2F (during sessions on 17th and 18th Sept)*
- *slides presented summarising CRD and CM amendments*
- *CM stepped through in order to highlight changes*

EASA - AM

EASA CM-S-008 Revision CRD amendments:

- *no significant objections to proposed changes on slides and following step through CM document + CRD input*
- *consider moving Section 2 'background' (plus discussion tables etc) to appendix in order to emphasise 'discussion only'*
- *part criticality v manufacturing process criticality v certification process criticality was discussed to emphasise 'consequence of failure' (safety!) in text*
- *include 'coat hanger' example of not needing B-Basis as an example of trying to avoid unnecessary regulation*
- *amend appendix 2 check list to indicate vibration evidence required for Class C (not Class D, if clearly Class D!)*

EASA - AM

EASA CM-S-008 Revision CRD amendments:

- *CM revision has documented aspects of a **low and no criticality safe working space** (generic beyond AM) for practical use by part of the AM community based upon actual questions from industry to regulators and in response to real flying projects (see Appendix 4)*
- *CM and 'step by step' approach has allowed time to start to develop a broader and more knowledgeable AM workforce*
- *Do we develop CM for higher criticality (e.g. discuss tables in Section 2?) and/or use AIA 'MRO' and 'Higher Criticality' documents? TBD (to be discussed at EAAMIRG 8th Oct 2024)*

EASA - AM

EASA CM-S-008 Revision CRD amendments:

- *share CM review slides from this meeting with WG1, which with the AM CM-S-008 issue 4 shared for comment (May 2024), should be close to that discussed at this meeting*
- *aim to publish 4Q/2024, 1Q/2025*
- *Future? (see later slides, WG1 WG4 merge for next step?)*

EASA - AM

Discussion relative to future CM-S-008 and WG1 development

- AIA 'MRO' document
- AIA 'More Critical Applications'

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AIA 'MRO' document:

- *AIA reports an increased interest and activity of MRO companies within AM (lead by Airframe and Powerplant companies)*
- *interested parties evenly distributed between wanting to have the whole value chain in-house and purchasing any or qualified parts*
- *discussion definitely indicated need for more interaction between the various stakeholders (including FAA and EASA regs, e.g. noting some differences regulatory structure/guidance, e.g. AC43 (e.g. Charles Park – possible loop hole issue?)etc*
- *better co-ordinate/standardise criticality discussion (ASTM F3572 4 levels v AIA 3 levels?)*

EASA - AM

AIA 'More Critical Applications' document:

- *Reminder – AM does not change the regs, e.g. need to classify, mark, and track critical parts (in the future, possibly!) does not change. However, fleet leader/sampling strategies are likely to form part of an AM introduction to aviation confidence building process (for Class B and C?)*
- *need for more regulator engagement with this document, if considered to be the way forward*
- *AIA documents appear to be a good starting point for moving beyond no and low criticality and the proposed revision to the CM*

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- NADCAP Findings
- NADCAP

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NADCAP Findings:

- *provided a useful example of 'lessons learned' for metallic NADCAP processes (80+ audits), with potential for development for expanding AM M&P and application experience*
- *anonymous sharing of 'lessons learned' could provide useful leverage for industry progress (e.g, see Rotor Integrity Steering Committee (RISC) example)*
Note: NIAR intent to develop an 'anonymous' reporting and sharing system further

NADCAP AM development/plans:

- *intent to develop for non-metallic AM noted. Potential benefit to the MRO and interiors community, particularly those in complex supply chains*

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Discussion relative to future CM-S-008 and
WG1 development

- co-ordination with WG4

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Co-ordination with WG4:

- agreed to combine WG1 and WG4
- see Mark's summary
- see Cindy's slides (What next for the CM, WG1+WG4? expect a survey!)

WG1 - Thanks to:

Drew Korte (Delta Airlines)
Eric Sager Virtual (Boeing)
Morgan Mader (Joby)
Richard Freeman (PRI)
Jonas Vom Weg (EASA)
+ WG1
+ WG4
Mark Shaw
Charles Park
Cindy Ashforth (FAA)

QUESTIONS?

EASA - AM

Reminder: EASA AM CM-S-008 'Additive Manufacturing' revision process

Revision developed for issue 4 included changes relating to:

- **'criticality classification'**
- **'certification effort being proportionate to criticality'** (WG1 'no and low' criticality, particularly non-TCH applications)
- increased emphasis upon **'Safety Assessments'**, e.g. FHAs, FMECA, or RASs (WG1 'no and low' criticality, particularly non-TCH applications)
- addition of AM parts of 'no or low' criticality **'Examples'**
- updates references

EASA - AM

Reminder: EASA AM CM-S-008 'Additive Manufacturing' revision process

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EASA - AM

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Reminder!: What is the scope of a CM?

Notification of a Proposal to issue a [delete for final] Certification Memorandum

[Title]

EASA CM No.: [Proposed] CM-XXX-XXX Issue XX issued DD Month YYYY

Regulatory requirement(s): [List regulatory requirement(s) the CM relates to]

EASA Certification Memoranda clarify the European Union Aviation Safety Agency's general position on specific initial airworthiness, validation, continuing airworthiness or organisational items. They are intended to provide guidance on a particular subject and may provide complementary information for compliance demonstration, similar to AMC/GM even if not formally adopted through an ED Decision. Certification Memoranda are not intended to introduce new certification requirements or to modify existing certification requirements.

EASA - AM

EASA CM No.: CM-S-008 Issue 04

- Following CM rev. issue 4 proposal text development driven by:
 - responses to industry questions to EASA regarding 'step by step' approach wrt criticality (and EAAMIRG discussion), not 'top down' EASA assumptions
- changes discussed relate to CRD input (ref. 30th April 2024 CM revision)

Certification Memorandum

Additive Manufacturing

EASA CM No.: CM-S-008 Issue 04 issued 30 April 2024

Regulatory references:

Primarily impacted product CSs:

CS 2X.571, CS 2X.603, CS 2X.605, CS 2X.613, CS 2X.853, CS23.2260, CS E.70, CS E.100 (a), CS P.170, CS P.240, CS APU.60, CS-ETSO (see Section 2 Tables, and Appendix 1 for more detailed CS listing)

Other potentially impacted references:

21.A.15, AMC 21.A.15(b), 21.A.31, GM 21.A.91, 21.A.101, 21.A.131, 21.A.133, 21.A.147, 21.A.247, 21.A.307(b), 21.A.433, GM 21.A.435(a), , 21.B.100, 21L, 145.A.42(b), CAO.A.020, M.A.603(c)

EASA - AM

Review (this meeting): EASA AM CM-S-008 issue 4 revision including consideration of CRD comments: before release late Q4 2024)

Note: main points, considered CM section by section, in following slides. See current CM revision file for ‘wordsmithing’ discussion.

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Reminder: **Section 2** is
‘background/discussion/
context/future
development potential
only,
NOT POLICY

Reminder: **ONLY Section 3** is
POLICY, addressing:

- **initial application
information expectations**
- **‘no and low’ criticality
applications only at this
CM revision (supported
by Appendix 2,3,and 4)**

EASA - AM

1. Purpose and scope

‘IMPORTANT REMINDER: AM is a rapidly developing technology supported by many developing industry guideline documents, but lacking regulatory guidance in any detail. Therefore, this CM revision process attempts to periodically document and share progress relative to EASA regulatory expectations and does not represent a complete or final EASA position. EASA is of the opinion that this approach is preferable, i.e preferable to not doing so, for the purposes of visibility and progressing development of the safe use of AM in certified parts.

Section 2 content ONLY provides background and context for the developing Policy, NOT Policy, unless specifically directly referenced from Section 3.

Section 3 content provides Policy. This revision addresses early engagement with EASA regarding AM and also applications of no or low criticality (Class C and D), [see appendix 2 and 3.](#)



Section 2 and 3 limitation message regarding Policy being limited to no and low criticality reinforced by reference to appendix 2 and 3 (very no and low criticality focused content)

1. Purpose and scope

' 1.3.2 Definitions:

Note : Applicants are reminded that inconsistencies exist in literature and throughout industry regarding some definitions and terminology, e.g. definitions of anomalies, flaws, and defects. Therefore, applicants are advised to clearly define intended meanings in certification processes.'...

Anomaly: Flaw or defect that deviates from what is expected or an abnormality that cannot be explained for a specific material type .

Defect (ASTM E1316-23a): One or more flaws whose aggregate size, shape, orientation, location, or properties do not meet specified acceptance criteria and are rejectable.

Flaw (ASTM E1316-23a): an imperfection or discontinuity that may be detectable by non-destructive testing and is not necessarily rejectable.

Flaw characterization (ASTM E1316-23a) : the process of quantifying the size, shape, orientation, location, growth, or other properties, of a flaw based on NDT [non-destructive testing] response.

Note added...this CM is not attempting to address this very broad issue. Definitions added below in order to include 'a definition' in this CM which has been accepted elsewhere...

Note: see also recent related CMH-17 discussions (Scottsdale meeting Spring 2024 etc)

EASA - AM

1. Purpose and scope

' 1.3.2 Definitions:

Point Design (AMC 20-29): An element or detail of a specific design which is not considered generically applicable to other structure for the purposes of substantiation, e.g., lugs and major joints. Such a design element or detail can be qualified by test or by a combination of test and analysis



An existing 'Point Design' definition added.
Concept and definition needs more work!
- see also CMH-17 Composite Tutorial and related discussions

EASA - AM

1. Purpose and scope

1.3.2 Definitions:

...

Full MoC (for the purposes of this CM): Complete MoC, as would be used for a 'conventional', 'safety critical', part, e.g. complete A or B-Basis testing, testing of all appropriate load cases, full instrumentation etc

...

Minimal MoC (for the purposes of this CM): Requires, at least, the applicant to demonstrate completing the appropriate classification process, even for C & D, and/or appropriate reference to appropriate applicable databases, and/or definition of Simplified MoC, see also table footnotes.

...

Simplified MoC (for the purposes of this CM): Reduced and/or selective MoC, as might be used in proportion to lower criticality applications, e.g. use of reduced test item numbers for B-Basis (e.g. using factors associated with normal distribution), reduced load case and/or 'Point Design' testing (as might be used for a part/detail with a dominant load case), reduced instrumentation, use of higher design factors etc.

Note: 'M' – 'Minimal' Replaces 'N' – 'No/Negligible', in posted draft CM – 'N' potentially miss leading. Consideration of all design feature classifications is necessary, at least, as part of MoC, even if only to determine Class D...

EASA - AM

2. Background – increasing development of AM use in aviation and the EASA regulations

Certification Reminder:

- the extent of substantiation necessary to demonstrate meeting design safety needs is likely to be a function of safety criticality – this is not new!
- the intent of all appropriate regulations should be met – this is not new!
- the information typically requested by the regulator of the applicant necessary to demonstrate satisfying the MoC will be a function of novelty, criticality, complexity and will usually be addressed on a 'case by case' basis – this is not new!
- the regulators retain the right to access further data beyond that initially requested for demonstration of satisfactory MoC – this is not new!

Text revised throughout to capture intent above (also in reaction to CRD comments), see following slides

EASA - AM

2. Background – increasing development of AM use in aviation and the EASA regulations

Design certification ‘Criticality’ and proportionate certification effort:

The regulators and industry have long recognised that design, design substantiation, and associated certification efforts have been developed in proportion to criticality of a design to safety. This has been recently more formalised from a regulatory certification demonstration perspective in LoI requirements, which prioritises regulatory expectations for industry to demonstrate appropriate MoCs (including supporting test and analysis work), when meeting CSs and AMC needs, in proportion to criticality, novelty (to the industry and/or applicant and /or regulator), and complexity. This may be supported by use of established and applicable databases, but **does not alleviate the need for industry from having to complete all necessary work to meet all appropriate safety requirements and may be tested by the regulators exercising the rite to request further supporting information.** For example, for the purposes of the intent of this revision to the CM, this may include need for an applicant to provide additional evidence in support of a criticality classification determination, which determines the extent of work necessary to show compliance, complete a project, and acceptability for certification.

New introduction paragraph added in an attempt to better clarify the various understandings of the meaning of ‘criticality’ and ‘proportionality’ of effort

EASA - AM

2. Background – increasing development of AM use in aviation and the EASA regulations

Design certification ‘Criticality’ and proportionate certification effort... continued:

The word ‘criticality’ is used extensively throughout the regulations and in industry in various contexts which may impact product and/or passenger safety, e.g. part criticality, technical process criticality, and procedural criticality.

For the purposes of this CM, part criticality is a measure of the significance of a part to the overall safety of a product or its occupants.

Manufacturing process ‘criticality’ is a measure of significance of sensitivity of AM engineering properties to M&P and manufacturing method process variations. This may, or may not, have safety implications, depending upon the part criticality.

Furthermore, procedural/administrative processes may also impact product and/or passenger safety, e.g. inappropriate use of certification processes, e.g. Lol, may adversely impact effective and safe certification.

Initial paragraphs re-written in an attempt to better clarify the various understandings of the meaning of ‘criticality’

EASA - AM

2. Background – increasing development of AM use in aviation and the EASA regulations

Design certification ‘Criticality’ and proportionate certification effort... continued:

Although part criticality is a characteristic that should not be affected by material and fabrication processes, the potential for poorly understood processes to impact part criticality may exist for a new technology application and is explicitly emphasised in this revision to the CM as a necessary consideration for applicants wishing to develop no and low criticality applications because such consideration should support conservative definitions of no and low criticality, e.g. consideration of the potential for poor process to result in non conformity, possibly resulting in Part Departing Aircraft threats (not explicitly emphasised in many existing part criticality classifications), may help an applicant to define a broader threat envelop in the part criticality assessment than may have been considered for a more conventional design and M&P application...

EASA - AM

2. Background – increasing development of AM use in aviation and the EASA regulations

Design certification ‘Criticality’ and proportionate certification effort... continued:

...This does not allow an excuse for poor process, but should support an additional margin in conservative assessment of no or low part criticality, i.e. ensuring that a C or D Classification is correct. Note that regulation of other highly sensitive M&P in existing designs include further mitigations intended to support safety, but which explicitly do not allow use of such mitigations to permit poor process. This is of particular importance for configurations which could result in defects which may be challenging to detect by inspection. For example, bonded structures require ‘backup features’ intended to meet specific residual load capability requirements if bond failure occurs upon rare occasions (‘weak bonds’ not being readily detectable). **However, this does not permit poor process.** Certification requires that process design and production control maintains UL capability.

Initial paragraphs re-written in an attempt to better clarify the various understandings of the meaning of ‘criticality’

EASA - AM

Table Key:

X = full MoC*, S = Simplified MoC*, M ** = Minimal MoC*, (?) = 'footnote' number, see 'footnotes' following tables.
CAT = 'Catastrophic', Haz = 'Hazardous', MAJ = 'Major', MIN = 'Minor', NSE = 'No Safety Effect', NA = Not Applicable

*reference being different for each box, each box to be referenced to 'conventional' MoC practice in each case.

**'Minimal' requires, at least, the applicant to demonstrate completing the appropriate classification process, even for C & D, and/or appropriate reference to appropriate applicable databases, and/or determination of need for Simplified MoC, see also table footnotes.

N = 'No or Negligible' changed to 'M' = 'Minimal to indicate that, at least, the 'criticality' needs to be convincingly assessed, thus being more than 'No' MoC

EASA - AM

N = 'No or Negligible' changed to 'M' = 'Minimal to indicate that, at least, the 'criticality' needs to be convincingly assessed, thus being more than 'No' MoC

			Material and Process control	Design Values / Material soundness	Static Strength	Fatigue / Damage Tolerance	Powerplant	Systems
Requirements for Structures, Equipment and Installations	Large Aeroplanes		CS 25.603 Materials CS 25.605 Fabrication methods	CS 25.613 Material strength properties and Material Design Values	CS 25.305 Strength and deformation CS 25.307a Proof of structure	CS 25.571 Damage tolerance and fatigue evaluation of structure	CS25.901c and 25.903c Sustained Engine Imbalance (windmilling)	CS 25.1309 Equipment, systems and installations CS25.1435 Hydraulic systems
Part Classification (see new ASTM-F42 standard)	A	(CAT)	X	X (3)	X (4)	X	As required (6)	As required (8)
		(HAZ)	X	X (3)	X (4)	M(9)	As required (6)	As required (7)
	B	(MAJ)	X	X (3)	X (4)	M(9)	As required (6)	As required (7)
	C	(MIN)	S (2)	S(5)	S (4)	M(1)	M(1)	As required (7)
	D	(NSE)	M (1)	M(1)	M(1)	M(1)	M(1)	M(1)

Table 2a: CERTIFICATION EFFORT PROPORTIONALITY TO PART CRITICALITY
– Large Aeroplanes (table key above)

EASA - AM

Footnotes:


(1) subject to design review by appropriate design authorities, e.g. TCH, DOAH, STCH, ETSO, etc., minimal showing for Class D parts (and minimal showing for some requirements associated with Class C parts) may be accepted if no effect on safety can readily be demonstrated, including consideration of the material and process selected for construction. Effective and safe use of this table relies significantly upon the correct classification of criticality as being Class C or D, also see Appendix 2 and 3.

'no' changed to 'minimal' to indicate that, at least, the 'criticality' needs to be convincingly assessed, thus being more than 'No' MoC

EASA - AM

3.1. Design certification – early engagement with EASA

Note: EASA would expect applicants to use a ‘step by step’ approach to product criticality evolution, i.e. initially develop experience with applications of no or low criticality (significantly below potentially hazardous or catastrophic), prior to considering more critical applications. Furthermore, EASA certification expectations of an applicant will likely be proportionate to the application criticality, novelty, and complexity, see Appendix 2, 3, and 4 regarding parts of no or low criticality (C and D Classifications only, higher criticality applications are likely to be addressed in future CM revisions). **However, this does not alleviate the need for industry from having to complete all necessary work to meet all appropriate safety requirements and may be tested by the regulators exercising the rite to request further information supporting classification and/or substantiation of MoCs.**



POLICY: Bold text added to clarify points made in earlier slides

EASA - AM

Appendix 2: Design certification for AM parts of no or low criticality (Class C and D)

For parts of no or low criticality (C and D ONLY, see also ASTM 3572-22 Table 1), i.e. being of no, or minimal, safety concern, either at aircraft or passenger level, and considering the potential for demonstrated 'Certification Effort Proportionality to Part Criticality' tables and 'footnotes', see Section 2 in this CM, the applicant will be required to demonstrate, at least:

....

- appropriate performance when subjected to vibration loads, which may result in failure modes, extents, and variabilities significantly different to those resulting from static loads. Although certification effort expectations are likely to be minimal for C and D classified parts, some justification regarding performance in a vibratory environment would be expected (and/or including reference to previous similar experience), e.g. demonstration of durability, testing in accordance with DO-160 etc. EASA is of the opinion that such consideration is likely to have formed part of any commercially driven material and process selection decision, so should also (at least) form part of any potentially safety related assessment

EASA - AM

Appendix 2: Design certification for AM parts of no or low criticality (Class C and D)

Reminder: Aligned with the intent of CMs (see cover sheet), this CM is not intended to ‘introduce new certification requirements, or to modify existing certification requirements’. However, for the purposes of pursuing proportionate regulation relative to criticality, the intent is for parts manufactured using AM considered to be of no or low criticality (in accordance with the guidance above) to be addressed under a minor change approval, even upon initial use of AM for “D” parts, provided all other aspects of the change meet the requirements for minor classification in accordance with established EASA processes based upon the amount of work required for approval (as indicated in PART 21). Design organisations (including holders of or applicant for ETSO authorization(s)) are expected to inform EASA, and POA Holders are expected to inform their respective Competent Authority, of intent to use AM (and the intended applications, criticalities, etc..) and to provide an impact assessment for the introduction of AM process based on a gap analysis, although EASA/the respective POA Competent Authority retains the right to change the assessment in accordance with established EASA/respective POA Competent Authority processes.

- Reminder!
- inform EASA
 - demonstrate capability and application within scope of ‘minor approval’