

EASA – Structures and Materials Safety

EASA - Additive Manufacturing

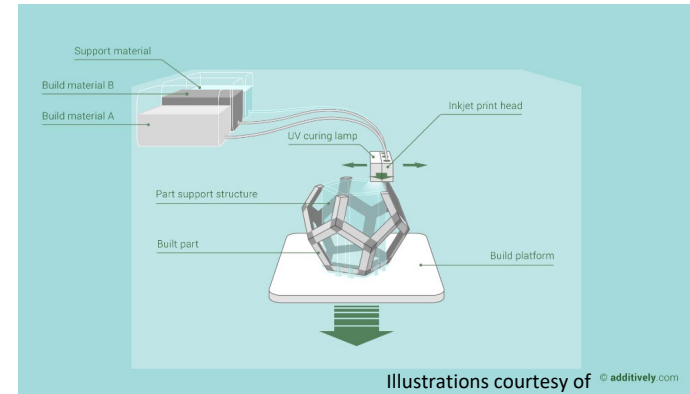
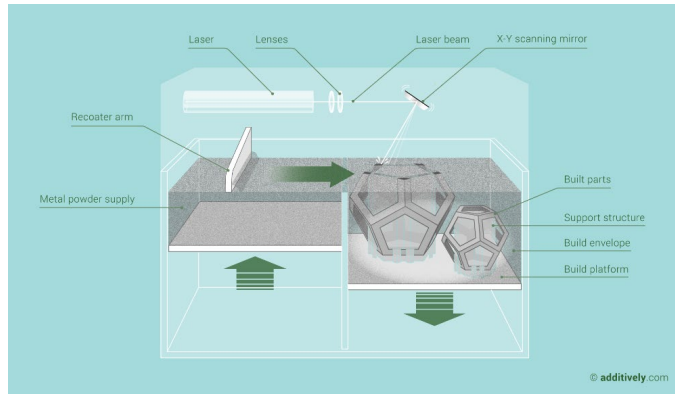
EASA ETSO Workshop – 21st. Sept 2022

S.Waite, Senior Expert – Materials, Certification Directorate, EASA

Your safety is our mission.

EASA - AM

ADDITIVE MANUFACTURING (AM) is a term used to cover a broad range of new and emerging manufacturing processes (also known as 3D printing) that involve sequential-layer material addition (metallic and/or non-metallic) throughout a 3D work envelope under automated control. For example, for metallic materials, typically the as-purchased material is deposited in the machine by various methods and fused using lasers, electron beams, plasma or electrical arc into a near final shape component or surface, whilst non-metallic materials may be heated and extruded through a moving nozzle to create a final part.



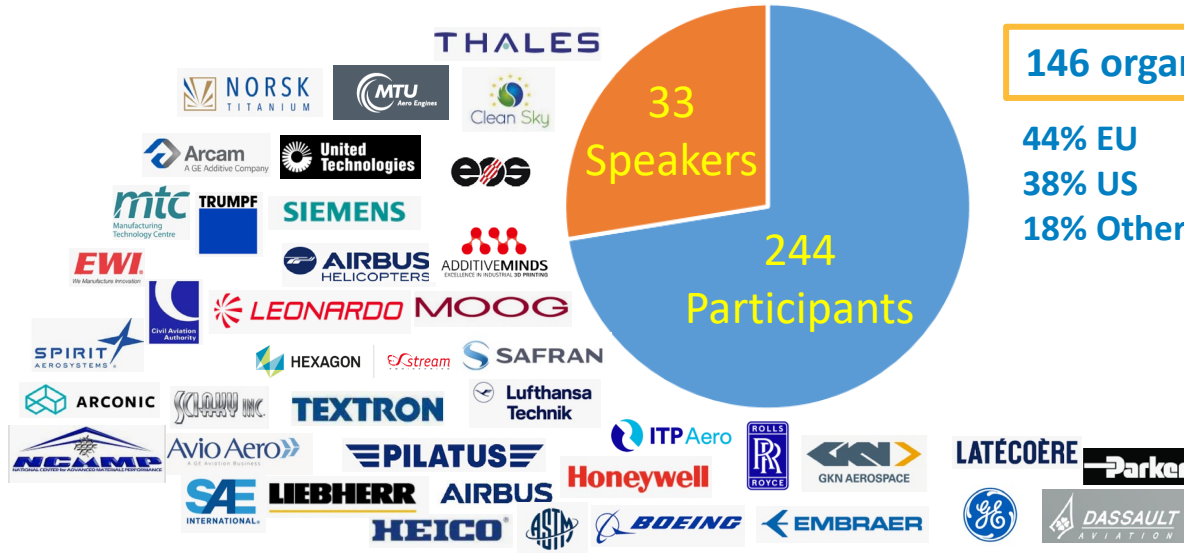
Rapidly expanding interest
across products and applications
of increasing criticality...



2021
EASA - FAA



Industry-Regulator AM Event (Virtual)*



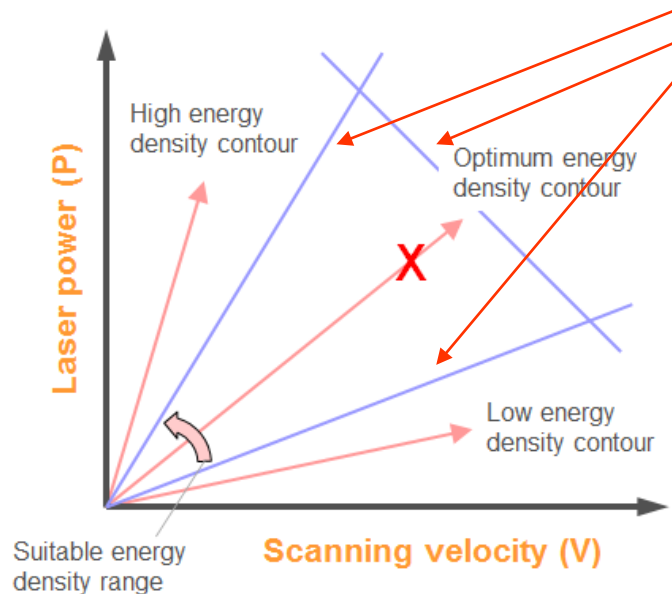
146 organisations represented

44% EU
38% US
18% Other

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CERTIFICATION CHALLENGE: The technology allows for complex (and 'optimised') configurations,

- sensitive processes and competing damage modes
- identify Key Process Variables & Parameters, including sensitivity of engineering properties to these...



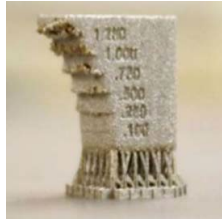
Boundary definitions:

- **Key Parameter (KP)** definition?
- **Competing defect/damage modes?**
- **Statistical credentials** (A, B-Basis etc)?
- **Sensitivity** (% change in 'engineering properties' wrt boundaries and KPs?)

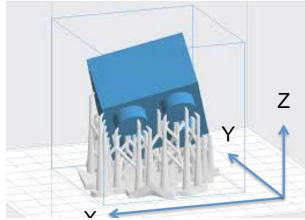
EASA - AM

CERTIFICATION CHALLENGE: The technology allows for complex (and 'optimised') configurations,

'Engineering Properties' are defined by
'material, process, and fabrication methods'
built directly into the (complex) part or repair,
i.e. partly defined by the configuration...



e.g. no access to
free edges –
fatigue issue?



e.g. support structure on the
build platform

Where are the
'engineering
properties'
developed in
the pyramid?

Complex part:
Reduced part count?
Optimised design etc?

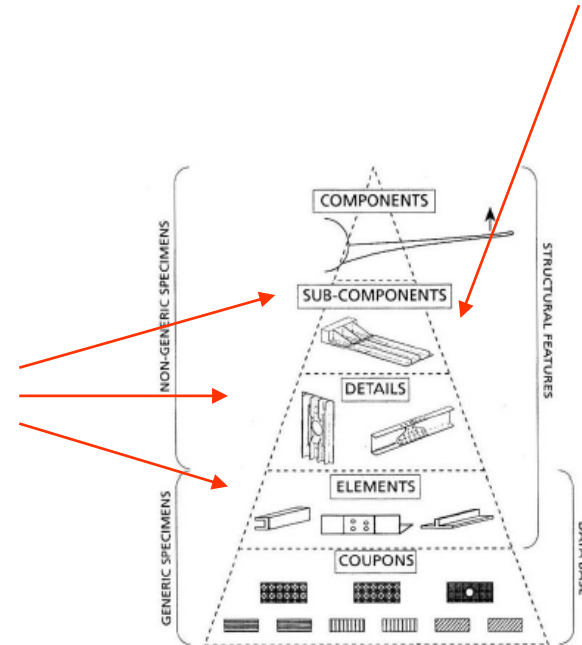
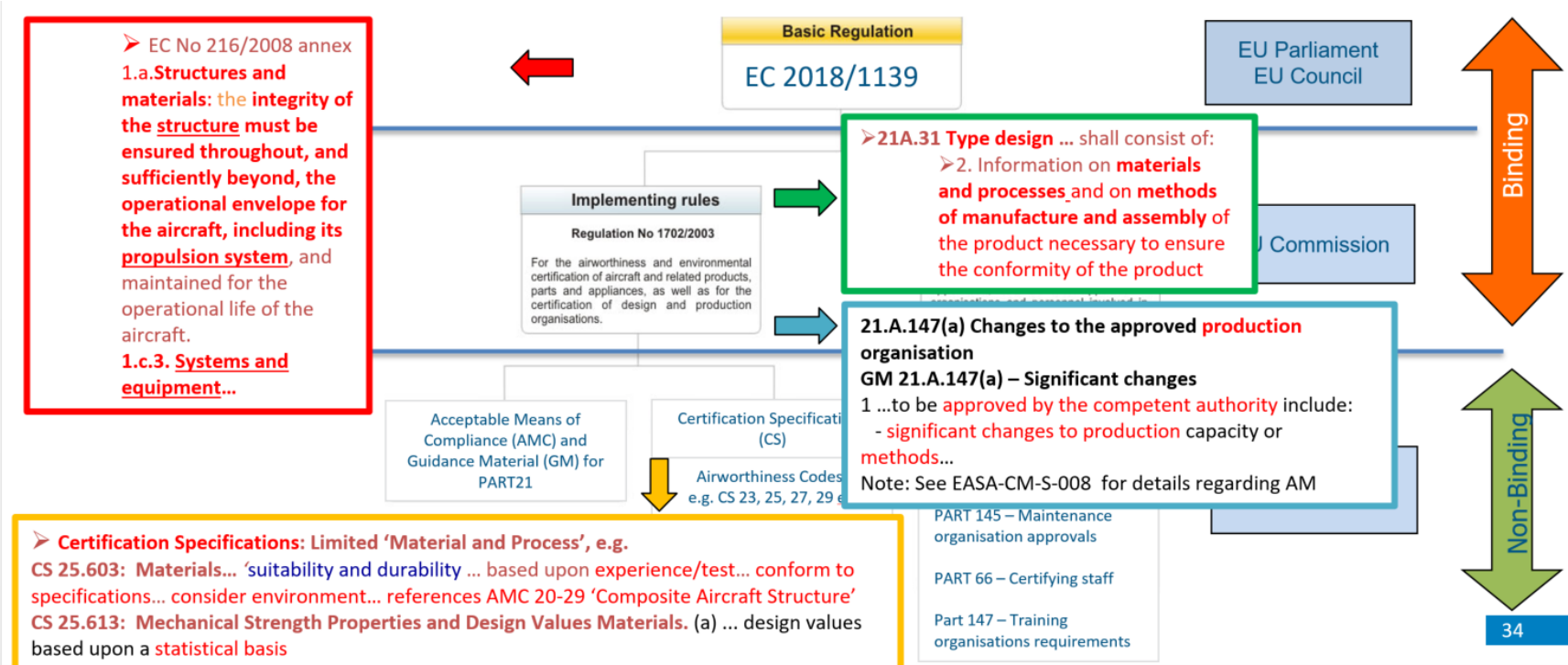


Figure 1 - Schematic diagram of building block tests for a fixed wing.

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NOT MATERIAL, PROCESS, or
FABRICATION METHOD SPECIFIC!

MATERIALS, PROCESSES, FABRICATION METHODS – THE REGULATIONS



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AM (and other Advanced Manufacturing methods) remain covered at the CS level, e.g. for CS25, materials, process, and fabrication methods are governed by CS25.603, CS25.605, CS25.613 (similarly for other products) e.g. CS25.603*, which are not material, process, or fabrication method specific...

CS25.603 Materials (See AMC 25.603; for composite materials, see AMC 20-29; for use of glass in passenger cabins, see AMC No 2 to CS 25.603(a))

The suitability and durability of materials used for parts, the failure of which could adversely affect safety, must:

- (a) *be established on the **basis of experience or tests**; (see AMC No°1 to CS 25.603(a));*
- (b) *conform to approved specifications that ensure their having the strength and **other properties assumed in the design data** (see AMC 25.603(b)); and*
- (c) *take into **account the effects of environmental conditions**, e.g. temperature and humidity, expected in service.*

* Note: see recent CS25 amdt.27 revision to AMC 25.603, 605, 613, revised to address broader integrated technologies and to be similarly applied to other product CSs

e.g. flammability, corrosion
resistance, conductivity etc

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CS25.605 *Fabrication Methods*

- (a) The *fabrication methods* used (i.e. the manufacturing and assembly methods, including consideration of the materials and material processes) must produce the *strength and other properties* necessary to *ensure a consistently safe part*. If a fabrication method includes processes that require close control to reach this objective, then those processes must be performed under representative approved fabrication process specifications, supported by appropriately approved material specifications (including considering the raw/feedstock/unfinished material specifications) with appropriate controls for the design data.
- (b) *Each new fabrication method must be substantiated by a test programme that is representative of the application.*

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Sensitivity of the ‘engineering properties’ to ‘end to end’ considerations, e.g. raw material supply, through to definition and final manufacturing of a complex part, requires particularly attention, potentially more so for ‘optimised’ complex designs made possible by AM. This may be a particular challenge for smaller organisations in complex supply chains if not under direct competent TCH control.

Note: New damage modes, e.g. relative to experience with more conventional technologies and configurations, may change the safety outcome beyond consideration of the direct functionality of the part, e.g. debris definitions relative to impact and control system jamming threats!

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MATERIALS, PROCESSES, FABRICATION METHODS – THE REGULATIONS

EASA – move towards ‘performance’ based regulations*:

Performance-Based Regulation (PBR): A regulatory approach that focuses on desired, measurable outcomes.

Prescriptive Regulation: A regulation that specifies requirements for mandatory methods of compliance.

- work with standardisation organisations and other industry groups, e.g. SAE, ASTM, NCAMP**, CMH-17*** , EAAMIRG, AIA etc

Note: PBR has been, and is being, applied to other industries, so there may be some useful ‘lessons learned’ for aviation (see the Food and Drug Administration presentation EASA FAA AM Event 2021)

*<https://www.easa.europa.eu/sites/default/files/dfu/Report%20A%20Harmonised%20European%20Approach%20to%20a%20Performance%20Based%20Environment.pdf>

** extending shared database activities beyond composites to include AM

***new non metallic AM Volume 7 in development

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MATERIALS, PROCESSES, FABRICATION METHODS – THE REGULATIONS

Need for ‘harmonised’
position continues to be
noted!

21.B.100 Level of Involvement (LoI) (Part21 amdt Autumn 2019)

.... (a) **The Agency shall determine its involvement** in the verification of the compliance demonstration activities and data related to the application for a type-certificate etc... and **consider at least the following elements:**

1. ... the **novel or unusual features** of the certification project, including operational, organisational and **knowledge management** aspect
3. ... the **criticality of the design or technology** and the related safety and environmental risks, including those identified on similar designs

Certification effort to be
proportionate to
‘criticality’....

Note: flexibility associated with the move towards ‘performance’ based regulation potentially places more reliance upon industry for standardisation and providing a ‘level playing field’

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Criticality:

- **What is 'Criticality'?** (PART 21 AMC 21.B.100(a) 'Level of Involvement' (LoI))... **as defined in context of LoI:**
*'... measure of **the potential impact of a non-compliance with part of the certification basis on product safety** or on the environment'*

The supporting guidance continues:

*'...The **potential impact** of a non-compliance within a Compliance Demonstration Item (CDI) should be **classified as critical if**, for example: ...a function, component or system is introduced or affected where the **failure of that function, component or system may contribute to a failure condition that is classified as hazardous or catastrophic at the aircraft level ...'***

- **any application with any such potential criticality clearly would be expected to fully comply with all requirements** (noting the novelty and complexity aspects of AM, such applications are unlikely to be considered by EASA, other than under experienced TCH control supported by an appropriate 'step by step' approach)

Note: various definitions of
'criticality' across products

EASA – AM STRATEGY

EASA AM Strategy: Certification Memo (CM) CM–S-008 Issue 01: Additive Manufacturing:

... share intent early with EASA in order to support integration within existing regulatory framework, e.g. POA, DOA audits etc

- responsibilities shared within EASA via subject contacts, identified in CM, and internal EASA AM WG meetings etc

Draft CM Appendix 5: EASA AM contacts

Materials	S. Waite	simon.waite@easa.europa.eu
Aircraft Structures	W. Hoffmann	wolfgang.hoffmann@easa.europa.eu
Propulsion (Engines, Propellers & APU)	O. Kastanis	omiros.kastanis@easa.europa.eu
	M. Mercy*	matthew.mercy@easa.europa.eu
Cabin Safety	T. Ohnimus	thomas.ohnimus@easa.europa.eu
	F. Negri	fabrizio.negri@easa.europa.eu
Systems	M. Weiler	michael.weiler@easa.europa.eu
Design Organisation Approvals	C. Caruso	claudio.caruso@easa.europa.eu
Production Organisation Approvals	D. Lamothe	dominique.lamothe@easa.europa.eu
Maintenance Organisation Approvals	R. Tajés	rosa.tajes@easa.europa.eu
ETSO	TBD?	

*original subject member

EASA expectation:
a 'step by step' approach
relative to increasing
criticality...

Industry – Regulator
activities supported by:

- European WG - EAAMIRG
- Industry – Regulator AM Events Working Groups (WGs), e.g. EASA FAA AM Event 2021

European Aviation AM Industry Regulator Group (EAAMIRG)

EAAMIRG – Summary

Scope/Mission:

- define European Aviation AM interests and priorities
 - safe and efficient AM design, production, in-service utilisation, and certification
- work constructively with other AM groups, e.g. AIA
 - recognising need for harmonisation in increasing complex global industry
 - avoid 'reinventing the wheel'

Organisations Involved - initially European TCHs, 1st Tier suppliers, EASA, European NAAs

- meetings (approx. 3 per year)

- current membership, leading TCHs and 1st Tier suppliers...need to develop membership recognised
 - e.g. STCHs, ETSOs, MROs, Operators and others in smaller organisations and complex supply chains?

EAAMIRG – Industry and Regulator membership:

- Airbus – Commercial
- Airbus – Defence and Space
- Airbus – Helicopters
- **Boeing***
- BAZL (Switzerland)
- **CAA UK***
- Dassault
- EASA
- **FAA***
- **GE***
- GKN
- ITP
- LBA (Germany)
- Liebherr
- MTU
- Rolls Royce
- Safran
- Thales
- Traficom (Finland)

* **NEW!** non-EU 'associate members' invited to support harmonisation intent

European Aviation AM Industry Regulator Group (EAAMIRG)

EAAMIRG Activities:

- support **revision to EASA CM-S-008 issue 3**
- identify **EAAMIRG PRIORITIES/ACTIONS** (based upon priority matrix, and outputs from various workshops etc)
 - **Part Classification and Authority Engagement** (LoI etc)
 - improve **standardisation of the ‘criticality’ determination process**
 - improve industry and regulator understanding of the subject
(note: potential to support the CM ‘Parts of No or Low Criticality’ discussion in user communities)
 - **Standardisation: understanding and use of ‘standards’**
 - **better understand and identify common ‘good practices’ when using standards** relative to
 - Criticality of application
 - organisation experience
 - organisational structure in the end to end product chain, e.g. large integrated organisations (including machine suppliers etc) v small organisations in extensive subcontractor chains

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EASA FAA Event 2021 - Working Groups supporting industry – regulator activities: WG1

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

Co-chairs: Simon Waite (EASA), Mitch Rife (Delta), Omiros Kastanis (EASA)

WG2: Fatigue and Damage Tolerance (F&DT) and Non-Destructive Inspection (NDI) Considerations for Metal AM:

Co-chairs: Michael Gorelik (FAA), Andreas Fischerworrings-Bunk (MTU)

WG3: AM Machine Makers and End Users – Key Process Parameters (KPPs), Qualification, Requalification, and the Ideal ‘End State’ : Co-chairs: Richard Mellor (Rolls Royce), Don Godfrey (SLM)

* WG1 recognises:

- need for ‘step by step’ approach to using a new technology relative to criticality
- need for industry ‘level playing field’

EASA – AM WG1

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

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 issue,
not only of interest to AM

EASA – AM WG1

Criticality:

Criticality has product specific definitions... but ‘performance based regulation’ requires consideration at aircraft and pax level...

Efforts to standardise criticality definitions include, ASTM F42 (draft) Document standardisation: ‘Additive Manufacturing – General Principles – Part Classifications for Additive Manufactured Parts Used in Aviation’, adapted in developing EASA CM-S-008 (draft) revision:

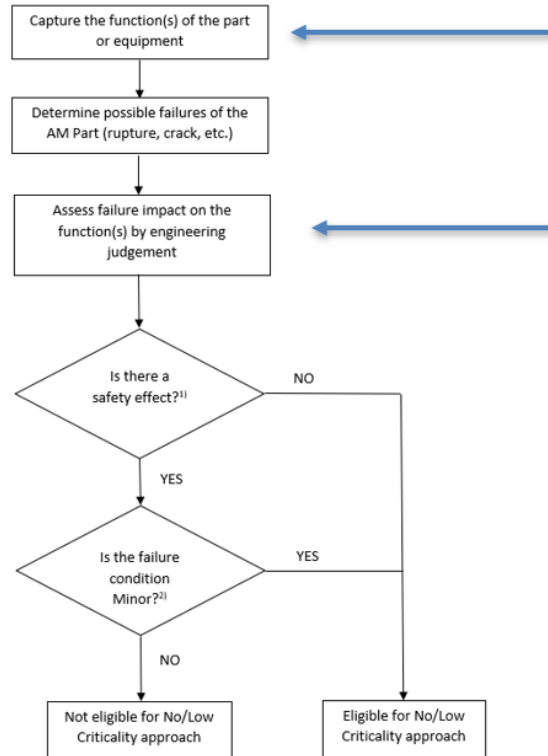
Classification	Consequence of Failure	General Description
A	High	Part the failure of which can directly affect continued safe flight and landing
		Part the failure of which can result in serious or fatal injury to passenger or cabin crews or maintenance personnel
		Part the failure of which can result in excessive load for the flight crew
B	Medium	Part the failure of which can indirectly affect continued safe flight and landing
		Part the failure of which can result in injury to passenger or cabin crews or maintenance personnel
		Part the failure of which can result in a significant increase in workload for the flight crew
C	Low	Part the failure of which has no affect on continued safe flight and landing
		Part the failure of which has no affect on passengers and cabin crews
		Part the failure of which can result in a slight reduction in operational/functional capabilities
		Part the failure of which can result in a slight increase in workload for the flight crew
D	Negligible or No Effect	Part not covered above
		Part the failure of which would pose no risk of damage to other equipment or personnel
		Part not affecting operational/functional capabilities



Example of development iaw industry needs: WG1 ‘no and low criticality applications’

EASA – AM WG1

Support criticality assessment using simplified FHA, FEMCA, including consideration beyond immediate functionality considerations...



Consider any potential for interaction between functions
- Airframe, Systems, Propulsion, Interiors (including seats) etc

Also consider potential for any new failure modes (relative to conventional technologies and applications) to change the safety outcome beyond direct functionality to include other potential threats, e.g. debris, PDA impact, system ingestion, flammability, introduction of sharp interior edges etc

- 1) **No Safety Effect (Cat 4?)**: Part the failure of which would pose no risk of damage to other equipment, personnel, or reduce operational/functional capabilities
- 2) **Minor (Cat 3?)**: Part the failure of which has no affect on continued safe flight and landing, no affect on pax or cabin crews, but can result in a slight reduction in operational/functional capabilities or a slight increase in workload for the flight crew

EASA – AM WG1

Certification effort proportionate to Criticality:

Efforts to standardise certification effort being proportionate to criticality include, SAE Commercial Aircraft Composite Repair Committee (CACRC) 'Guidelines for Modifying Composite Aircraft Structures' (draft), adapted in developing EASA CM-S-008 (draft) revision:

F42?	Criticality	Material Control	Process Control	Design Values	Static Strength	F&DT	Flammability	Other design drivers, e.g. fuel resistance, corrosion resistance, erosion?
A	1. High - parts whose failure directly affects continued safe flight and landing	x	x	x	x	x	As required	
B	2. Medium-High - parts the failure of which indirectly affects continued safe flight and landing	x	x	x	SMoC	SMoC	As required	
C	3. Medium - Low - (1) structure the failure of which does not affect continued safe flight and landing and (2) parts the failure of which can affect passengers and crew	SMoC	SMoC	SMoC	SMoC	N	As required	
D	4. Low - all other parts	SMoC	SMoC	SMoC, As required	SMoC, As required	N	N	
E?	5. Add 'no criticality'? (identified by some minimal 'rational analysis')? (J. Van Doeselaar presentation from EAAMIRG 6th June 2022)	VSMoC TBD?	VSMoC TBD?	N TBD?	N TBD?	N?	N?	

EASA – AM WG1

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

Supporting a safe industry ‘level playing field’: WG1 is developing concise AM examples which may be included in the CM, including:

- common format and level of detail
- examples (metallic and non-metallic) from across products, e.g. airframe, systems, propulsion, interiors (including seats)

Example 1 (draft in development): (Pilatus/GKN) Nacelle Access Panel Assemblies (2 off), AM hinges and goosenecks, on fuselage mounted engines, T-tail configuration

Design Driver: Static Strength

Criticality: Cat.3

Extent of FHA, FMECA, RAS completed: Safety Assessment, including consideration beyond functionality, e.g. potential for PDA impact, system jam etc

Material and Process: Ti-6Al-4V, Laser Powder Bed Fusion

Material Control: Supplier specs. include selective use of the majority of AMS7003 and partial use of AMS7028 (draft). AMS7028 paras.3.2., 3.3.1 - stress relief (not HIP). Supported by Statistical Process Control (SPC), PCD, and other broader supplier documented processes.

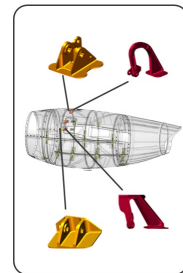
Process Control: Supplier spec. references. AMS7003

Design Values: 300 coupons (10 batches), at qualification.

Static Strength: FE supporting 10x part tests to failure (2 batches – supported by batch witness coupon data, i.e. tensile, chemical, and micro/macro inspect), assembly static tests of each assembly (UL and 1.5xUL, ground handling loads). No fatigue or vibration testing.

Flammability (and/or other considerations): Not located in passenger and crew compartment interiors, thus flammability is not an issue

Further Comments: Some part redundancy, accessible surfaces (only interfaces machined), relatively well established material and process combination supported by extensive development work.



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Conclusion:

AM offers potentially significant commercial benefits to aviation. However, sensitivity of the 'engineering properties' to 'end to end' considerations, e.g. raw material supply, through to definition and final manufacturing of a complex part, requires particularly attention, potentially more so for 'optimised' complex designs made possible by AM*. Therefore, responsible design organisations need full understanding of the supply chain if the correct design values are to be established and achieved throughout production.

*new and/or competing damage modes, e.g. relative to experience with more conventional technologies and configurations, may change the safety outcome relative to more conventional technology experience and/or beyond consideration of the direct functionality of the part, e.g. debris definitions relative to potential impact with structure or control system jamming threats. This may be a particular challenge for smaller organisations to address in complex supply chains if not under direct competent TCH control.

The regulators are working with industry in order to ensure the safe introduction of AM into aviation by taking a 'step by step' approach relative to the development of more critical applications, whilst also expecting certification effort to be proportional to criticality.

For the reasons above, as AM first enters the aviation (methods new to the industry and/or applicants), it is particularly important that the development of applications of no or lower criticality are correctly assessed and managed (in order to ensure that they remain so).

Questions?

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Support Slides

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Rapidly expanding interest
across products and applications
of increasing criticality...

EASA - AM



Federal Aviation
Administration

EASA FAA AM Industry – Regulator Event (virtual) 8-12th November 2021

<https://www.easa.europa.eu/newsroom-and-events/events/easa-faa-industry-regulator-am-event-0>

- building upon previous EASA FAA Industry - Regulator annual Events (alternate regulator hosting)

[2020 FAA–EASA AM Workshop Report and Proceedings](#)

(please use the following link to request access: [2020 AM Workshop - Home \(faa.gov\)](#))

[2019 EASA–FAA AM Workshop Proceedings](#)

<https://www.easa.europa.eu/newsroom-and-events/events/2019-easa-faa-workshop-additive-manufacturing>

[2018 FAA–EASA AM Workshop Report and Proceedings](#)

[Joint FAA—EASA Workshop on Qualification & Certification of Metal Additively Manufactured Parts](#)

EASA FAA AM Industry – Regulator Event:

Context: evolving regulation of the rapidly expanding use of Advanced Material and Processes (AMPs) technologies in many applications...



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Changing technology... and supply chain knowledge management

Other relevant regulations and regulatory activities: Operational Suitability Data (OSD)

- need for the user communities

- *mandating that aircraft manufacturers, including those building helicopters, to submit data EASA considers important for safe operations. OSD covers pilot training, maintenance staff and simulator qualification; the master minimum equipment list (MMEL); and possibly other areas, depending on the aircraft's systems.'*

Example: Composites...

CM-MCSD-001 Issue 1 'Development of **OSD** for **Maintenance Certifying Staff**'

- training/knowledge link to AC20-107B/AMC 20-29/SAE AIR 5719

increasingly important if relying upon
'performance' based regulation

New Technology - some form of mitigation strategy
necessary to link TCH technology evolution with the
appropriate level of in-service
knowledge base and training

Composite Training Guidance
- similar concept for AM?
(avoid re-inventing the wheel when appropriate!)

EASA - AM

Changing technology... and supply chain knowledge management

Other relevant regulations and regulatory activities: support/awareness PART145 activities,
e.g. Point145.A.42(b)(iii) , CAO.A.20(c) or M.A. 603(c)

FABRICATION OF PARTS FOR INSTALLATION

(c) All necessary **data to fabricate the part should be approved either by the Agency or the type certificate (TC) holder, or Part 21 design organisation approval holder, or supplemental type certificate (STC) holder.**

(g) Examples of fabrication within the scope of a Part-145 approval may include but are not limited to the following:

- (1) fabrication of bushes, sleeves and shims;
- (2) fabrication of secondary structural elements and skin panels;
- (3) fabrication of control cables;
- (4) fabrication of flexible and rigid pipes;
- (5) fabrication of electrical cable looms and assemblies;
- (6) formed or machined sheet metal panels for repairs.

- see developing WG1 and WG3 activities

All the above-mentioned **fabricated parts** should be in accordance with the data provided in the overhaul or repair manuals, modification schemes and service bulletins, drawings, or should be otherwise **approved by the competent authority**.

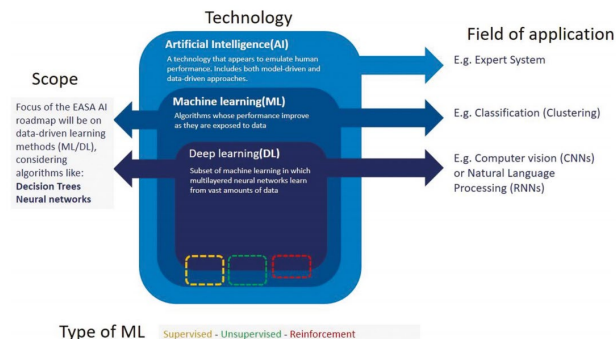
Note: It is **not acceptable to fabricate any item to pattern unless** an engineering drawing of the item is produced which **includes any necessary fabrication process and which is acceptable to the competent authority**.

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Other developing and potentially relevant regulations and regulatory activities:

- EASA Certification Re-organisational Structure – Certification Directorate Roadmap 2020
 - reorganised to facilitate and support technological product innovation
e.g. UAS, VTOL, Electric and Hybrid propulsion
- **Artificial Intelligence (AI) and Machine Learning (ML)*** - initial focus upon ML**....
‘use of data to train algorithms to improve their performance’

■ Figure 1. AI taxonomy in this Roadmap



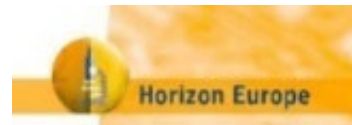
Potential ML impacts include:

- **design** and operation?
- **production and maintenance?**
 - air traffic management?
- drones, urban air mobility, U-space?
- safety risk management?
 - cybersecurity?
 - environment?
- **regulations...** existing regs, e.g. CS2x.1309 + etc?

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Other relevant regulations and regulatory activities: EASA – R&D:

- EASA Basic Regulation amendment... 2018/1139, Article 86.1... **assist the Member States and the Commission in identifying key research themes** in the field of civil aviation
- increasing number of EU integrated technology projects, e.g. combining Materials, Processes, Modelling and Simulation, Structural Health Monitoring etc...



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EASA Update:

2/ Advanced Materials and Processes - Developing Rulemaking and Guidance continued...

Example of likely evolution direction:

- recent **NPA 2020-11 ‘Miscellaneous’** (annual CS update cycle) used as opportunity to start process and provide:
 - minor update CS 25.605 to better reflect more recent AMP technology language and provide more continuity with language already used elsewhere, e.g. CS 25.603*...
 - update to AMC 25.603, 605, 613 to better reflect more recent integrated AMP technology considerations, e.g. emphasise use of the test/analysis pyramid etc

**‘The suitability and durability of materials used for parts, the failure of which could adversely affect safety, must –’*

CS25 amdt due Dec. 2021

EASA - AM

2/ Advanced Materials and Processes - Developing Rulemaking and Guidance, continued...

EASA CM-S-008 issue 1 'Additive Manufacturing'

- inform EASA early in process if intending to use AM (Project Cert, DOA, POA etc)
- **'Step by Step'** approach etc (no criticality/minimal airframe or pax safety first, iaw Lol etc)

EASA AM CM issue 1 released April 2017 - **needed revision:**

- **increasing criticality of applications** in TCH certifications
- **developing in-service community lead interest**, e.g. STCs, MROs, interiors etc
- **growing diverse spread of industry supply chain experience/knowledge management**
 - input from EASA/FAA Workshops, SDO meetings, conferences etc

CM revision (30/4/21) iaw intent shared during the 2020 AM Event

Note: CM is a temporary document, next rev. 2022/23?, subject to content evolution

<https://www.easa.europa.eu/document-library/product-certification-consultations/final-certification-memorandum-ref-cm-s-008>

Part of EASA AM Strategy supported by **EASA AM Working Group**
(internal, across products and domains, e.g. POA, DOA, PAT145 etc) and **EAAMIRG**

becoming
broader EASA
AMP WG (to be
confirmed)

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AOB: Project Certification – AM Certification Review Items (CRIs)

Note: CRIs are regulatory tools used to address delivery of Special Conditions (potential changes to CSs etc) and/or support Means of Compliance evolution, typically beyond established CSs and interpretation of the CSs, e.g. new technology applications

Recent certification projects:

- intent to continue to make reference to CM-S-008 for no/low criticality applications without CRIs, when applicable. However:
 - criticality of applications is increasing
 - increasing cross discipline applications, e.g. structures/systems, propulsion/systems
 - increasing use of multiple subcontractors (some not from aviation background)

- need to standardise/improve knowledge transfer within supply chains

therefore, need for CRIs likely to increase,
particularly MoC CRIs
to be continued...

EASA – AM

Conclusions:

- increasing use of AM across aviation product applications of increasing ‘criticality’
- Rulemaking adapting to ‘advanced materials’, e.g. developing Ceramic Matrix Composites (CMCs), Polymer Matrix Composite (PMCs), etc... **not only AM!**, e.g. EASA CM-S-008 revision, CS25 amdt, AMC 20-XX ‘Materials and Processes’ TBD
- Rulemaking adapting to ‘performance’ based approach
 - certification effort proportional to ‘criticality’, ‘novelty’, ‘complexity’ (LoI) etc
- need to consider impact of other developing technologies upon AM evolution, e.g. AI, ML, modelling and simulation, SHM etc*?
- need to consider impact of other developing technologies upon regulation**?

* How can this be substantiated and certified?...lack of predictability, explainability, robustness, unintended function, lack of standardisation, bias, variance, complexity, extensive data management... many interacting ‘black boxes’? ...need for ‘trustworthiness’ etc

** ‘knowledge management’ with industry via Innovation Partnership Contracts (IPCs) and Memoranda of Cooperation (MoC) + other mitigating actions, e.g. fleet leader, sampling?

EASA – AM

Conclusions... continued:

- Regulators adapting to industry lead need, e.g. EASA AM CM rev. 'Parts of no/low criticality' - improve safety and business case via refined understanding/management of 'criticality'?, use of shared databases, improve knowledge management?, use of CRIs (only if necessary - across panel disciplines, increasing criticality etc)'
- Industry – Regulator WGs and standards bodies of increasing importance to these processes
e.g. European Aviation AM Industry Regulator Group (EAAMIRG), NIAR, AIA, SAE, ASTM, CMH-17
- Industry and Regulators expected to continue with a '**Step by Step**' approach to using AM, supported by EU R&D etc

Note: the next rev. to the EASA AM CM will likely address

- updated coverage of AM Parts of 'no/low criticality'
- parts of higher criticality... TBC 'step by step' approach

EASA – Regulatory Framework and change

The Regulations – EASA priorities and resources:

safety is the priority...

applies to baseline structures,
changes, and repairs

‘change should not reduce the existing acceptable level of safety’

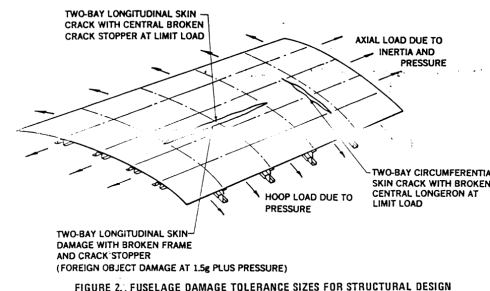
Based upon:

- experience
- reaction to incidents and accidents
- R&D
- ‘engineering judgement’
- regulations existing at the time of certification
- Type Certificate Holder (TCH) in-house design practices

Design with a ‘robust’ design concept

(beyond scope of detailed ‘threat assessment’)

Note: part of broader ‘test v analysis’ issue relating to new technology, equivalence, and existing ‘acceptable’ level of safety – divergent situation... wish to replace test with analysis versus increased complexity and competing failure modes?



e.g. Design for Redundant Structures ...Tom Swift
For conventional metals, a cracked frame and 2 cracked frame bay skins

RMT.0018 Opinion's proposal (1/3)

- Design approval Holder (DAH) may voluntarily identify parts that would not require EASA Form 1 (criteria: negligible safety impact in case of non-conformity → Guidance provided in GM (next slide)).
- DAH identifying such parts in the ICAs may also identify special verifications to be conducted on the part by the installer (mitigates potential risk in case of a non-conformity → more parts can fulfill the negligible safety impact criteria → GM is provided) .
- For General Aviation, permit identification of parts that would not require an EASA Form 1 by EASA in CS-STAN (criteria: negligible safety impact in case of non-conformity → Guidance provided in GM, guidance more relaxed for CS-STAN).
- Existing alleviations in OPS (e.g. CAT.IDE.A.100(a)), standard parts for gliders and 21.A.307(c) remain as today.

Note: EASA CS-STAN contains design data, including acceptable methods, techniques, and practices for carrying out and identifying Standard Changes/Standard Repairs (SCs/SRs). Designed in compliance with these certification specifications, ...not subject to an approval process, ...can be embodied in an aircraft when the conditions set out in the relevant paragraphs of Part 21 for SCs/SRs, i.e. 21.A.90B or 21.A.431B, are met... must not conflict with information and limitations given by the TCH. Some SCs and SRs carry restrictions relative to some product types, and are typically for use with smaller aircraft.

RMT.0018 Opinion's proposal (2/3)

Guidance Material:

- 'Negligible safety effect when installed on the product' means that any non-conformity of the part or appliance not identified by the installer that conducted the specific verifications mentioned in 21.A.307 (c),:

- for ELA1 and ELA2 aircraft, has an effect equal or lower than:
 - a slight reduction in operational or functional capabilities of the aircraft or its safety margins;
 - some physical discomfort on occupants; or
 - a slight increase in the workload of the flight crew nor requires the use of emergency procedures; and,

- for any other aircraft,:
 - **has no effect on the operational or functional capabilities of the aircraft nor on its safety margins;**
 - **has no physical discomfort on occupants; nor**
 - **does not increase the workload of the flight crew nor requires the use of emergency procedures.**

RMT.0018: Be aware...(3/3)

- BR (Basic Regulation) introduced the concept of non-installed equipment. This is not considered in this Opinion. It will be dealt with in another RMT.
- Existing BASAs do not consider this concept. Although the future rule would not create limitations to export European parts if they are produced i.a.w. old rules, it would be desirable to change BASAs to cater for these parts. Vice versa, some exemptions to the foreign form (e.g. FAA 8130-3) could be considered for these parts.

RMT.0018 Opinion's proposal

- Maintenance of these parts will be permitted outside approved MROs.
- Maintenance performed to be recorded for traceability purposes – maintenance record
- Installation on the aircraft of the part after maintenance as per existing continuing airworthiness rules – except for the need of an EASA Form1 with the part.

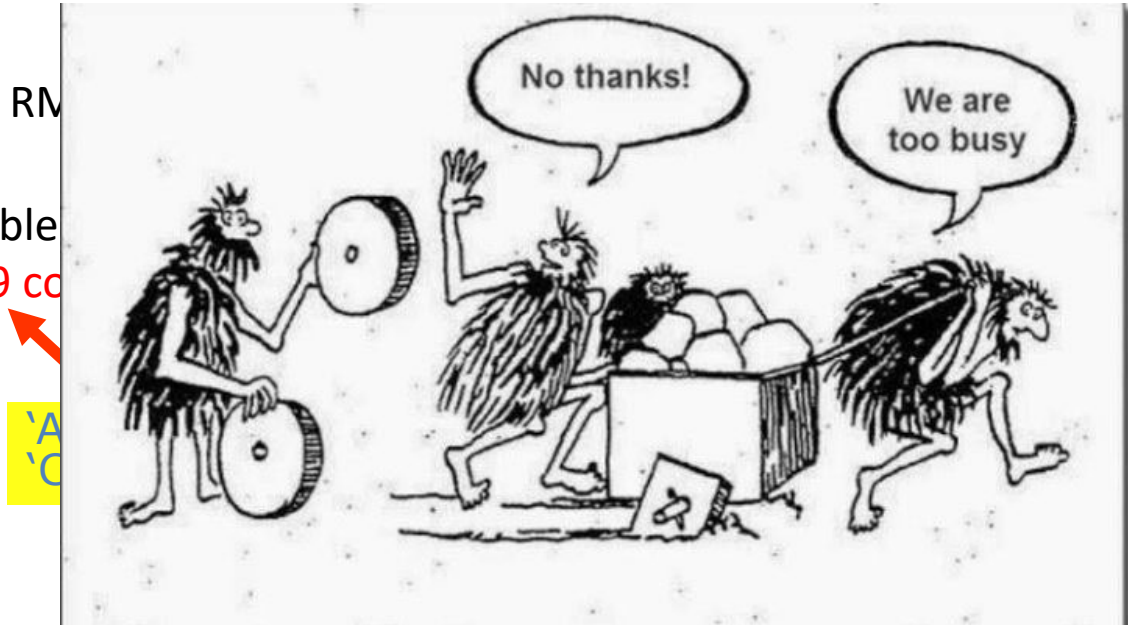
Can we learn something useful from other 'similar' technologies and associated regulatory evolution...?

Example: Composites:

No need to re-invent the wheel
(when appropriate!)

EASA MDM.059 RM

- includes possible
to SAE AIR 5719 co



ng appendix linked

Isaac Asimov – 3 Laws of Robotics

1. A robot must not injure a human being or, through inaction, allow a human being to come to harm.
2. A robot must obey the orders given it by human beings except where such orders would conflict with the First Law.
3. A robot must protect its own existence as long as such protection does not conflict with the First or Second Laws.

Note: These rules soon become problematic.... weak v strong AI etc

EASA - AM

AOB: Opinion 07/2019 RMT.0018

'Installation of parts and appliances that are release without an EASA Form 1 or equivalent'

Decision planned for 2021/Q3

(from EASA presentation AEA European conference Jan 2020
see support slides)

RMT.0018 - Parts without EASA Form 1: Why?

- Currently, all parts need an EASA Form1 (or equivalent) to be installed during maintenance (standard parts and raw/consumable material are excluded).
- An EASA Form1 can only be issued by POAs, i.e. by a production organisation under the oversight of an aviation authority
- ... **but not all parts have the same safety relevance.**
- **The future rule will permit that certain new parts are installed on a product during maintenance without an EASA Form1.**



Note: EASA CS-STAN* contains design data, including acceptable methods, techniques, and practices for carrying out and identifying Standard Changes/Standard Repairs (SCs/SRs). Designed in compliance with these certification specifications,
... not subject to an approval process,
... can be embodied in an aircraft iaw conditions set out relevant paragraphs of Part 21 for SCs/SRs
... must not conflict with TCH information/limitations. Some SCs and SRs carry restrictions relative to some product types, and are typically for use with smaller aircraft

***criteria: negligible safety impact in case of non-conformity**

EASA - AM

Basic Regulation (EU) 2018/1139 – safety of third parties on the ground:

When assessing Parts of No Criticality, BR requires:

Article 4 – Section 2:

The measures taken under this Regulation shall correspond and be proportionate to the nature and risk of each particular activity to which they relate. In preparing and enacting such measures, the Commission, the Agency and the Member States shall take into account, as appropriate for the activity concerned: [...]

(b) to what extent third parties or property on the ground could be endangered by the activity;

Annex II - 2. AIRWORTHINESS ASPECTS OF PRODUCT OPERATION

2.1. The following must be shown to have been addressed to ensure safety for those on board or on the ground during the operation of the product:

(a) the kinds of operation for which the aircraft is approved must be established and limitations and information necessary for safe operation, including environmental limitations and performance, must be established; [...]