

Regulations for AM

FAA-EASA AM Workshop

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Federal Aviation
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STEP SENIOR TECHNICAL
EXPERTS PROGRAM
ADVANCING SAFETY THROUGH SCIENCE

Agenda

- FAA Approvals
- Type Design
- Regulatory Requirements
- Material and Process Specifications
- Relationship Between Design and Production
- Summary



FAA Approvals

- There are three types of approvals related to aircraft defined in Title 14 Code of Federal Regulations (14 CFR) part 21 “Certification Procedures for Products and Articles”
 1. Design Approval

A type certificate (including amended and supplemental type certificates) or the approved design under a PMA, TSO authorization, letter of TSO design approval, or other approved design
 2. Production Approval

A document issued by the FAA to a person that allows the production of a product or article in accordance with its approved design and approved quality system, and can take the form of a production certificate, a PMA, or a TSO authorization
 3. Airworthiness Approval

A document, issued by the FAA for an aircraft, aircraft engine, propeller, or article, which certifies that the aircraft, aircraft engine, propeller, or article conforms to its approved design and is in a condition for safe operation, unless otherwise specified

Design Approvals are granted for *products* and *articles*

- A *product* is an aircraft, aircraft engine, or propeller
- An *article* is a material*, part, component, or appliance

*Although the regulations allow for certifying a material, there are currently no standards for additive manufacturing.



Type Design

- “Type Design” is the collection of drawings, specifications, and other information that is approved by the FAA
 - Compiled on a Master Drawing List

§ 21.31 Type design.

The type design consists of—

- (a) The drawings and specifications, and a listing of those drawings and specifications, necessary to define the configuration and the design features of the product shown to comply with the requirements of that part of this subchapter applicable to the product;
- (b) Information on dimensions, materials, and processes necessary to define the structural strength of the product;
- (c) The Airworthiness Limitations section of the Instructions for Continued Airworthiness as required by parts 23, 25, 26, 27, 29, 31, 33 and 35 of this subchapter, or as otherwise required by the FAA; and as specified in the applicable airworthiness criteria for special classes of aircraft defined in § 21.17(b); and
- (d) For primary category aircraft, if desired, a special inspection and preventive maintenance program designed to be accomplished by an appropriately rated and trained pilot-owner.
- (e) Any other data necessary to allow, by comparison, the determination of the airworthiness, noise characteristics, fuel efficiency, fuel venting, and exhaust emissions (where applicable) of later products of the same type.

[Doc. No. 5085, 29 FR 14564, Oct. 24, 1964, as amended by Amdt. 21-27, 34 FR 18363, Nov. 18, 1969; Amdt. 21-51, 45 FR 60170, Sept. 11, 1980; Amdt. 21-60, 52 FR 8042, Mar. 13, 1987; Amdt. 21-68, 55 FR 32860, Aug. 10, 1990; Amdt. 21-70, 57 FR 41368, Sept. 9, 1992; Amdt. 21-90, 72 FR 63404, Nov. 8, 2007; Amdt. No. 21-107, 89 FR 12653, Feb. 16, 2024]

Acme Aircraft Corporation Drawing List 60DL Flap Hinge Bracket Installation (P-48 Series) Revision Control Page Page 1 of 2			
Revision	Date	Page Nos. Affected	Approved
N/C	01/02/88	1, 2	(approval signature)
A	01/25/88	1, 2	(approval signature)
Company Approved: (approval signature) Date: 01/25/88			

Acme Aircraft Corporation Drawing List 60DL Flap Hinge Bracket Installation (P-48 Series) Page 2 of 2			
Document Number	Title	Rev.	Date
Installation Data	Installation Instructions	A	07/05/87
60-II	P-48 Series Flap Hinge Bracket		
60000	Flap Hinge Brackets Installation	A	02/22/87
Manufacturing Data			
60100	Flap Hinge Bracket Assy.	A	01/25/88
60101	Wing Flap Hinge Bracket	B	01/25/88
•			
AAC41	Epoxy Specification	N/C	04/19/86
AAC60	Inspection Procedures	N/C	01/02/88
Company Approved: (approval signature) Date: 01/25/88			



Type Design

- Type design data are drawings, specifications, information on dimensions, materials and processes, airworthiness limitations, and any other data necessary to describe the design of the product
- What information is necessary?
Per the regulation, “... drawings and specifications necessary to define the ... design features of the product shown to comply with the requirements...”
 - Meaning if strength is required, the design must be sufficient (have enough detail) to ensure strength
 - If flammability is required, the design must be sufficient to ensure flammability
 - If durability is required, the design must be sufficient to ensure durability
 - Etc.

Key concept:

Whatever feature or performance is required of the component, the type design must be sufficiently detailed to ensure that performance will be achieved



Regulatory Requirements

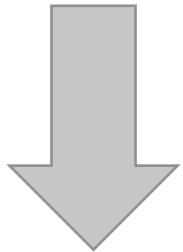
- Additionally, there are specific regulations for different products
 - Part 23: Normal Category Aircraft (i.e., “general aviation”)
 - Part 25: Transport Category Aircraft
 - Part 27: Normal Category Rotorcraft
 - Part 29: Transport Category Rotorcraft
 - Part 33: Engines
 - Part 35: Propellers
- Regulations for material and process control are similar across the different products



Regulatory Requirements

Material Control

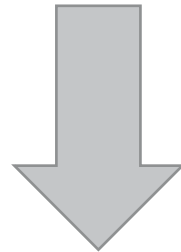
§ 23.603 Materials and workmanship
§ 23.2260 Materials and processes
§ 25.603 Materials
§ 27.603 Materials
§ 29.603 Materials
§ 33.15 Materials
§ 35.17 Materials and manufacturing methods



“Materials ... must meet approved specifications that ensure their having the strength and other properties assumed in the design data”

Process Control

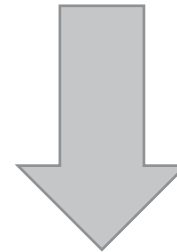
§ 23.605 Fabrication methods
§ 23.2260 Materials and processes
§ 25.605 Fabrication methods
§ 27.605 Fabrication methods
§ 29.605 Fabrication methods
 Nothing explicit in part 33
§ 35.17 Materials and manufacturing methods



*“Methods of fabrication must produce a consistently sound structure”
“If a fabrication process requires close control to achieve this objective the process must be performed according to an approved process specification”*

Material Data

§ 23.605 Material strength properties and design values
§ 23.2260 Materials and processes
§ 25.613 Material strength properties and material design values
§ 27.613 Material strength properties and design values
§ 29.613 Material strength properties and design values
 Nothing explicit in part 33
§ 35.17 Materials and manufacturing methods



“Material strength properties must be based on enough tests of material meeting specifications to establish design values on a statistical basis”

Process Control Requirements for Engines

- Part 33 doesn't have the same general requirement for process control, but requires it for life limited parts under 33.70(b)
- *Regardless, process control is required for all engine components under part 21*
- While there is no explicit requirement for statistical material strength and design values, it is implied in 33.70 (a) "material properties ... are sufficiently well known and predictable"
 - AC 33.15-3 "Powder Bed Fusion Additive Manufacturing Process for Aircraft Engine Parts" refers to use of statistical analysis for design values for all AM components

§ 33.70 Engine life-limited parts.

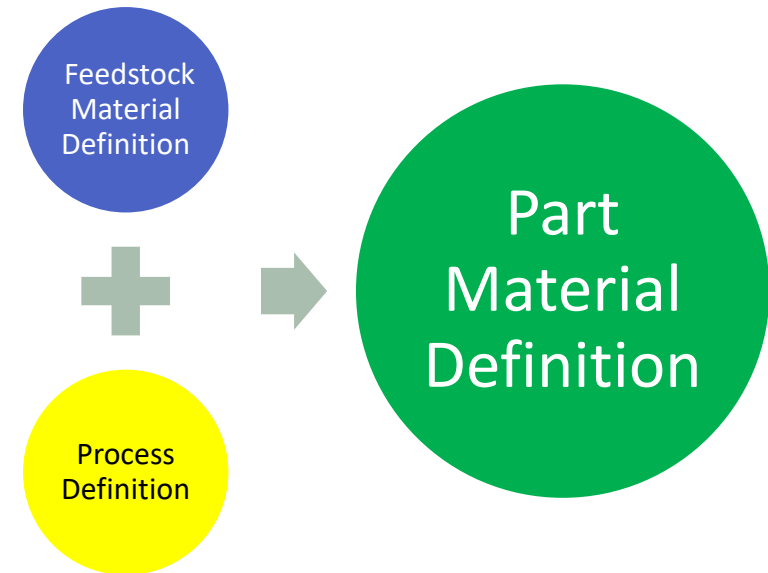
... The applicant will establish the integrity of each engine life-limited part by:

- (a) An engineering plan that ... ensure each life-limited part is withdrawn from service at an approved life ... These steps include validated analysis, test, or service experience which ensures that the combination of loads, material properties, environmental influences and operating conditions ... Are sufficiently well known and predictable ...
- (b) A manufacturing plan that identifies the specific manufacturing constraints necessary to consistently produce each engine life-limited part with the attributes required by the engineering plan.
- (c) A service management plan ...



Material and Process Specifications

- The part manufacturer *is the material manufacturer* with a responsibility to define the properties of the material and ensure they are consistently achieved
- Material and process specifications should control three things:
 1. Feedstock material
 2. Finished material
 3. The process(es) to convert the feedstock to the finished material
- Material specifications should control chemical, physical and mechanical properties that ensure consistent *part performance*
 - Will likely not directly measure all required performance parameters, but the selected ones should be sufficient to ensure the others (i.e., inferred properties) are consistent



There is more to AM alloys than directly measured bulk chemistry and tensile strength. Inferred properties include:

- Strength, ductility, fatigue, heat resistance, cryogenic ductility, toughness, tearing resistance, fatigue crack growth, stress rupture, hydrogen embrittlement, oxidizer compatibility, flammability, intergranular cracking, general corrosion, stress corrosion cracking, etc.

Process Specification

FAA Order 8110.4C “Type Certification” Section 5-6 provides the following expectations for process specifications:

- a. Specifications for Consistently Producing Conforming Parts.** Design regulations require fabrication methods that will consistently produce conforming parts. To attain this objective, approved process specifications must cover all methods requiring close control. The applicant should identify all such process specifications on the related drawings. The manufacturing inspector and ACO project manager should thoroughly evaluate these specifications.
- b. Method of Presenting Information.** Process specifications should be orderly and complete. Use the following as a **checklist of the content of a typical process specification:**

- | | |
|-----------------------------------|-------------------------|
| 1) Scope. | 6) Inspection: |
| 2) Applicable documents. | a) Process inspection, |
| 3) Quality requirements. | b) Inspection records, |
| 4) Materials used in the process. | c) Inspection test, and |
| 5) Manufacturing. | d) Inspection controls. |
| a) Manufacturing operation, | |
| b) Manufacturing controls, | |
| c) Test specimen (construction), | |
| d) Tooling qualifications, and | |
| e) Tooling control. | |

NOTE: Make sure the data submitted in any process for approval **do not contain terms that are subject to interpretation, such as adequate, as necessary, as required, room temperature, periodically**. Also, make sure the applicant defined any tolerances that are required to control the process.

The method for determining product conformity should be measurable and required by the process specification.

These are the step-by-step instructions for the process



Relationship Between Design and Production

Design Regulations

- 21.31 “The type design consists of... the drawings and specifications... necessary to define the ... design features of the product shown to comply with the requirements”
- 25.603 “The suitability and durability of materials used for parts, the failure of which could adversely affect safety, must ... conform to approved specifications ... that ensure their having the strength and other properties assumed in the design data”
- 25.605 “The methods of fabrication used must produce a consistently sound structure.”

The type design defines the materials and processes that must be used in production of the approved product or article

Production Regulations

- 21.137 “Each applicant for or holder of a production certificate must establish and describe in writing a quality system that **ensures that each product and article conforms to its approved design...**”
- 21.146 “The holder of a production certificate must ... **ensure that each completed product or article** for which a production certificate has been issued ... **conforms to its approved design ...**”
- 21.316 Each holder of a PMA must ... **ensure that each PMA article conforms to its approved design**
- 21.616 Each holder of a TSO authorization must ... **ensure that each manufactured article conforms to its approved design**

The quality system assures that the production facility produces products and articles that meet the type design



Relationship Between Design and Production

- People often ask, “*What information is part of the type design and what is part of the quality system?*”
 - It depends on the way things are worded in the type design
 - As a simple example, consider wording for an equipment list in a process specification
 - The process specification is obviously type design
 - Anything referenced by the process specification is also type design

Scenario 1:

- Process specification equipment list says “**AM Equipment Make, Model, Calibrated**”
- In this case, the quality system is responsible to ensure the equipment is calibrated and may use any methods it deems appropriate
- Changes to the calibration process, if it affects the quality system, requires FAA production approval

Scenario 2:

- Process specification equipment list says “**AM Equipment Make, Model, Calibrated per Process XYZ**”
- In this case, the calibration process is part of type design and must be followed exactly
- The quality organization does not have any freedom in how it calibrates the equipment
- Changes to the calibration process requires FAA design approval
- If it affects the quality system, it also requires FAA production approval



Relationship Between Design and Production

- When specialists review process specifications, they are supposed to notice things like this – whether calibration is part of type design or not – and evaluate accordingly
 - Perhaps the less stringent calibration, which is controlled as part of the quality system (and therefore can be changed without engineering review), is only acceptable for non-critical parts
 - Or perhaps it's acceptable for structural parts if the manufacturer implements NDT and tests one part/build
 - It's not about one element of process definition and control – consider the big picture



Summary

- Material and process specifications are part of a product's type design
 - Initial approval and changes are reviewed and approved the same as drawings
- The type design must be adequate to ensure the part has all the properties necessary to comply with the regulations
 - Specifications must ensure strength and other required properties
 - Measured properties should ensure consistent measured and inferred properties
- Process specifications include step-by-step instructions
 - Do not use ambiguous terms like “as required,” “if necessary,” or “room temperature”
- There is a relationship between type design and production controls
 - Type design can offer significant or limited latitude in production details
 - Whatever is allowed by design must be substantiated during certification

Remember Material and Process Control is only the beginning – other regulations may require unique MOC for AM parts





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