# Additive Manufacturing for TSO Applications

Cindy Ashforth, Senior Technical Specialist for Composites

Office of Senior Technical Experts, AIR-20

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STEP SENIOR TECHNICAL EXPERTS PROGRAM
ADVANCING SAFETY THROUGH SCIENCE

# Outline

- What Makes AM Special
- Regulatory Requirements
- Quality System Requirements
- Material and Process Control
- Other Affected Subjects
  - Structural Substantiation
  - Flammability
  - ICAs
- Information Request
- Summary

# Additive Manufacturing (AM) – What's the Big Deal?

- AM is a type of advanced manufacturing
  - Other examples include composites or friction stir welding
- In advanced manufacturing, **the part manufacturer is also the material manufacturer** and is responsible for characterizing and controlling the final material
- The process that is used to transform feedstock material to a finished material greatly affects the final properties that will be achieved
  - Not just strength but also flammability, for example
  - Manyfold increase in sources of variability for your final part
- The first and most important consideration for all advanced manufacturing methods is adequate material and process definition and control
  - If you cannot manufacture a part repeatably (within some known tolerance) then do not expect to be able to certify it
  - Requires close coordination and input between design, materials engineers, and manufacturing

**binder jetting,** *n*—an additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials.

**directed energy deposition,** *n*—an additive manufacturing process in which focused thermal energy is used to fuse materials by melting as they are being deposited.

Discussion—"Focused thermal energy" means that an energy source (e.g., laser, electron beam, or plasma arc) is focused to melt the materials being deposited.

**material extrusion,** *n*—an additive manufacturing process in which material is selectively dispensed through a nozzle or orifice.

**material jetting,** *n*—an additive manufacturing process in which droplets of build material are selectively deposited.

Discussion—Example materials include photopolymer and wax.

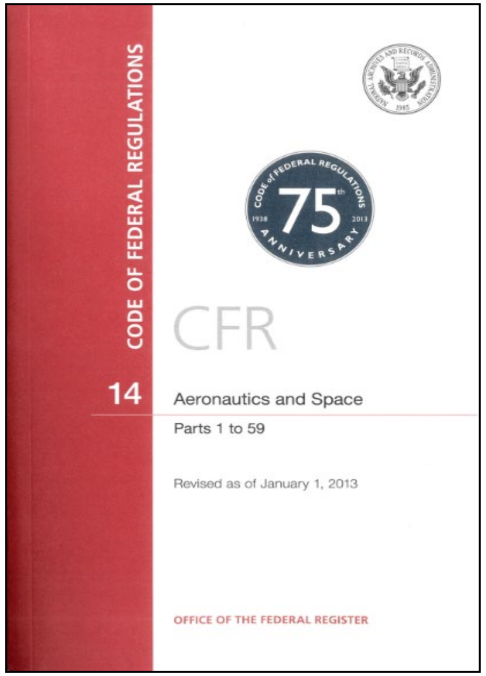
**powder bed fusion,** *n*—an additive manufacturing process in which thermal energy selectively fuses regions of a powder bed.

**sheet lamination,** *n*—an additive manufacturing process in which sheets of material are bonded to form an object.

**vat photopolymerization,** *n*—an additive manufacturing process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization.

Ref: ASTM F2792 − 12a Standard Terminology for Additive Manufacturing Technologies

# Type Design Requirements




**Key Takeaway**: *Material and Process Definition, <u>including specifications</u>, are part of the Design and must be approved as such (same as any drawing)*

## Some requirements for material and process control apply to all products, at all levels of criticality

- Title 14 Code of Federal Regulations (14 CFR) part 21 “Certification Procedures for Products and Parts” Reference [eCFR :: Title 14 of the CFR -- Aeronautics and Space]

**§ 21.31 Type design.**

The type design consists of - *(in part)*

(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;

*(.......)*

# Regulatory Requirements

Additionally, there are specific regulations for different products, but the regulations for material and process control are similar across the products

## 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
§ 33.15 Materials
§ 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
§ 33.15 Materials
§ 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"

# TSO Requirements

- A number of TSO MPS have wording like this
  - Very similar to the wording in 14 CFR 2x.603 and 2x.605

**MATERIAL AND WORKMANSHIP**

All materials used in the structure shall be of a quality which experience or tests have demonstrated to be suitable and dependable for use and shall conform to specifications which will ensure their having the strength and other properties assumed in the design. All workmanship shall be consistent with high-grade aircraft manufacturing practice.

Fabrication methods

The methods of fabrication employed in the construction shall be such as to produce consistently sound structures. When a fabrication process requires close control to attain this objective, the process shall be one for which the suitability and dependability have been established on the basis of experience or tests.

- In addition, part 21 has very specific requirements for TSOA holders
  - Parts produced using advanced manufacturing techniques are more process-intensive and subject to more variability, requiring close control to ensure compliance with the requirements over the production run and life of the part

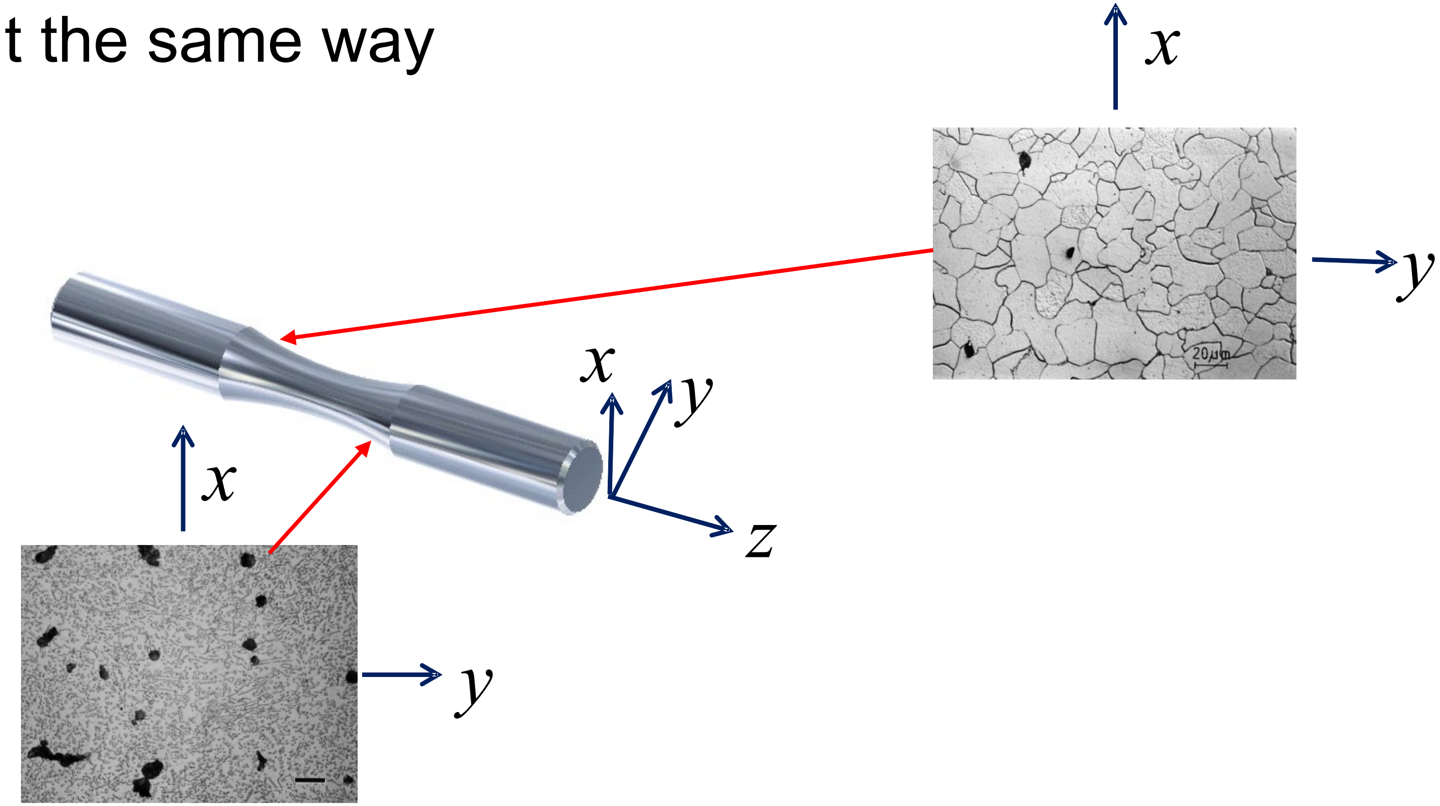
**§ 21.616 Responsibility of holder.**
Each holder of a TSO authorization must—

…

(c) Ensure that each manufactured article conforms to its approved design, is in a condition for safe operation, and meets the applicable TSO;

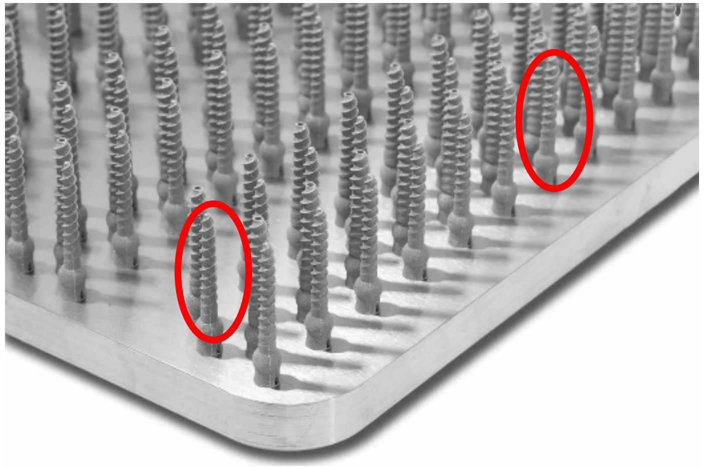
# What do we mean by “Consistent Manufacturing”?

- Variations within a part may be acceptable
  - Parts may have different microstructure along the part build direction
  - Must be consistently built the same way



# What do we mean by “Consistent Manufacturing”?

- Variations within the build space
  - Currently finding that parts at one end of the build space are not always the same as those at the other end
  - This may be acceptable if they are a repeatable pattern (e.g., Part 1 is always the strongest and Part 10 is always the weakest)



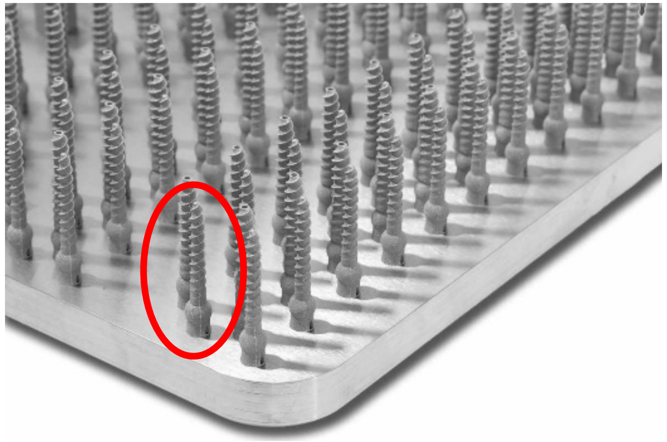
**Are these parts the “same”?**

# What do we mean by “Consistent Manufacturing”?

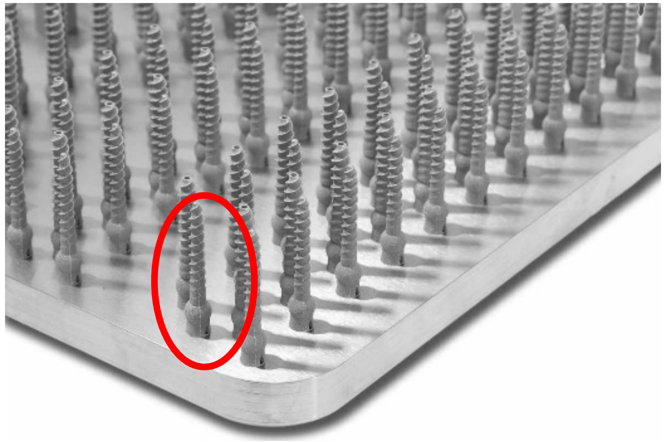
- Variations between builds
  - Are parts produced in different build runs the same?

Always some variation around the mean, however…

  - If the process has significant differences in final properties that appear inconsistently (e.g., sometimes Part 1 is strongest and Part 10 is weakest, and sometimes vice-versa), that indicates “randomness” that may not be acceptable



**Are these parts the “same”?**

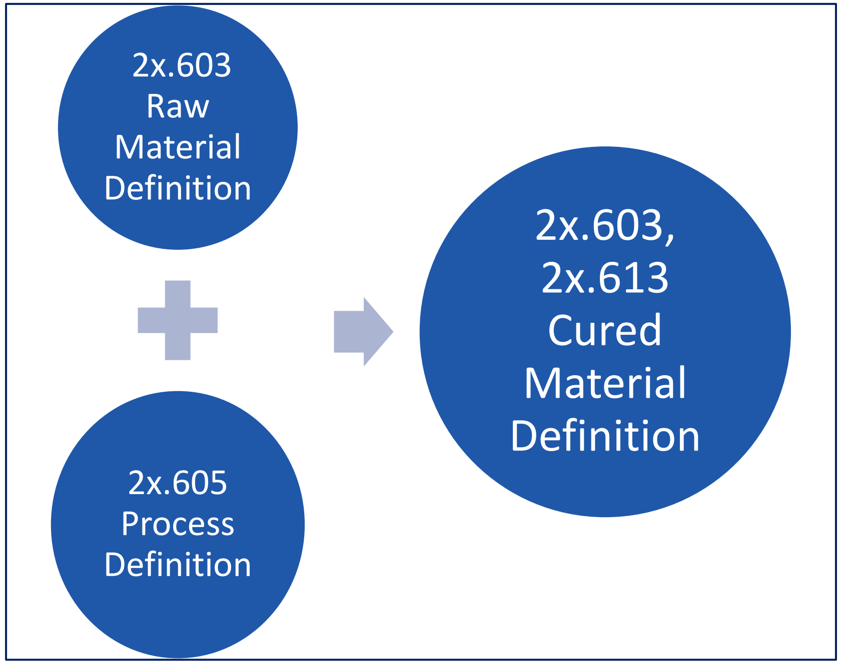


# Material and Process Control

- Type design may include, but is not limited to, the tooling, processes, process controls, calibration specifications, material specifications, and inspection requirements leading up to the final part
- The type design must control the key process parameters (Kpp) that will govern final part performance (e.g., strength or flammability) shown to comply with the airworthiness standards
- Material and process definition is typically in material specifications, process specifications, and process control documents (PCD), although other documentation formats are acceptable as long as all necessary information is captured
- The level of detail and control needed for material and process documentation may vary depending on the specific application
  - The degree of rigor can be commensurate to the criticality of the application

# Material and Process Control

- Three items to define and control
  1. Raw or Feedstock Material
     - May require additional controls for support materials
  2. The process to convert feedstock materials into the consolidated material and post-print process steps (e.g., stress relief, HIP, other heat treat)
  3. Final Part Material
     - Ensure required chemical, physical and mechanical properties are achieved
     - Tied to the process specification used to create the part




- Sources of information
  - Standards Development Organizations such as ASTM F42 Committee, SAE AMS AM Committee, American Welding Association, etc., have published feedstock material specifications, process specification guidelines, finished material specifications, design guides, test methods, equipment qualification guides, etc.
  - Industry consortiums and handbooks AIA AM Working Group, MMPDS Volume 2 (metallic materials), and CMH-17 AM Coordination Committee (non-metallic materials)
  - FAA Order 8110.4C, EASA Cert Memo CM-S-008 Issue 3, FAA-EASA Working Groups

# Material Specifications

- Material specifications should define the requirements of incoming materials, whether virgin or reused, to ensure consistency over time
- Material specifications also define the final material produced with the advanced manufacturing technique
- The specification(s) should define: shipping, storage, handling requirements, chemical, physical, and mechanical material characteristics before and after processing, as well as test methods and quality assurance requirements
  - Inspection of AM parts is uniquely challenging due to their inherent surface roughness (if not machined) and complicated geometries, including interior cavities
- Additive manufacturing feedstock reuse techniques may be defined and controlled under a material or process specification or similar document
- Published specifications may be used, if demonstrated to be applicable
- Compliance with 14 CFR 2x.613 often coincides with 14 CFR 2x.603 as statistical values are used as pass/fail criteria in the material specification

## AIA Recommendations

A typical part material specification would be specific to an alloy, additive process, and thermal treatments. A typical part material specification consists of controls around the following:

Feedstock material specification.

Material fusion process specification.

Chemistry – typically based on the limits established by the feedstock specification with considerations for constituents that might change in concentration as a result of fusion.

Thermal treatment – thermal treatments required to meet mechanical properties

Metallography – typically would control general microstructure and grain size

**Anomaly types and limits**

Mechanical properties – at a minimum, room temperature tensile properties

Reference: The Aerospace Industries Association (AIA) Additive Manufacturing Working Group “Recommended Guidance for Certification of AM Component” (February 2020)

# Process Specification Expectations

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

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 order is being revised to reference Certification Branch instead of ACO

# Process Specifications

- **Per AIA, a process specification would be additive process-specific and material-agnostic. The process specification and supporting PCD are generally in five categories:**
  1. Infrastructure
  2. Machine Qualification Plans
  3. Feedstock Control Plan
  4. Part Production Plans
  5. Post-process Plans

(The following are examples of Process Control Documents)

- Infrastructure
  - Facility Control Plan
  - Operator Training and Qualification Plan
  - Work Instruction Plan
  - Software Configuration Control Plan
- Machine Qualification Plans
  - Key Process Variable (KPV) Plan
  - Machine Configuration Plan
  - Preventative Maintenance Plan
  - Machine Calibration Plan
  - Machine Requalification Plan
- Feedstock Control Plan
  - Feedstock Lot Control Plan
  - Feedstock Handling Plan
  - Powder Feedstock Re-use Plan
  - Machine and Material Alloy Change Contamination Avoidance Plan
- Part Production Plans
  - Engineering Requirements Plan
  - Manufacturing Part Definition Plan
  - Machine Parameters Plan
  - Build Interruption Plan
  - Quality Control Plan
  - In-Process Monitoring Inspection Plan
  - Record Keeping Plan
- Post-Process Plans
  - Powder Removal Plan
  - Stress Relief Plan
  - Hot Isostatic Press (HIP) Plan
  - Heat Treatment Plan
  - Build Plate Removal Plan
  - Support Removal Plan
  - Surface Enhancement Plan

Reference: The Aerospace Industries Association (AIA) Additive Manufacturing Working Group "Recommended Guidance for Certification of AM Component" (February 2020)

# Quality System Effects

- Per 14 CFR 21.137(d), the PAH must evaluate the advanced manufacturing process specification and determine if a change to their quality system is needed and per § 21.620, the PAH must notify the FAA when a quality system change affects inspection, conformity, or airworthiness
  - Introducing AM often affects multiple items from the approved quality system

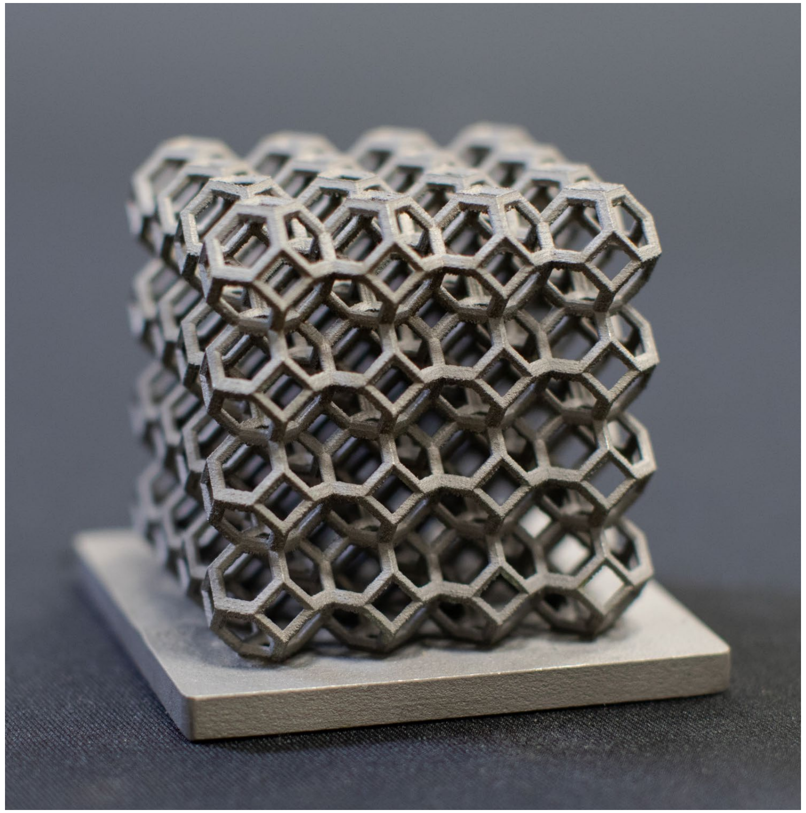
- Design data control
- Document control
- Supplier control
- Manufacturing process control
- Inspection and testing
- Inspection, measuring, and test equipment control
- Inspection and test status
- Nonconforming product and article control
- Corrective and preventive actions
- Handling and storage
- Control of quality records
- Internal audits
- In-service feedback
- Quality escapes
- Issuing authorized release documents (if applicable)

# Quality System Effects

- **Supplier Control**
  - Procuring feedstock materials is different than wrought products – generally requires more than a certificate of conformance
  - May repeat supplier testing upon receipt to ensure that the product can be processed at your facility with your equipment and meet requirements (can propose to reduce sampling over time)
- **Manufacturing Process Control**
  - AM equipment calibration is challenging. Aviation standards involve a process of IQ/OQ/PQ (initial qualification, operator qualification, product qualification)
  - AM equipment has some inconsistency S/N to S/N
  - Operator training requirements
- **Inspection and Testing**
  - Unique test standards for AM
  - Inspection is very challenging due to as-built rough surface, hidden features, and complex geometries
- **Handling and storage**
  - Most feedstock materials require environmental controls with inert gas or humidity control, drying cycles, etc.,
  - Many powder products in particular require special storage as they can be flammable

# Other Requirements

- Only after M&P is under control should you consider demonstrating compliance to the remaining TSO MPS requirements
- While neither regulations nor the MPS change because you are introducing an AM part, the means of compliance often will
- Subjects that are often affected include
  - Structural Substantiation
  - Flammability
  - Instructions for Continued Airworthiness



# Other Requirements

- **Structural Substantiation**

  Consider that the structural behavior of parts produced with AM may not be the same as those produced with traditional manufacturing methods. For example, the parts may exhibit anisotropic and/or inhomogeneous properties as a function of part geometry and other factors or develop and propagate damage in different manners during cyclic loading. It is expected that these factors will be evaluated when showing compliance to requirements for static strength and fatigue and damage tolerance. Additionally, the number and type of flaws and anomalies in AM parts are often quite different from those found in traditional manufacturing, which may necessitate an investigation into the effects of those flaws and anomalies and use of additional safety factors or inclusion of intentional flaws and anomalies in static and dynamic test articles. These factors can make determining the structural failure loads, modes, and locations difficult. Bulk material properties derived from coupons may not be representative of actual part microstructure, defect distribution, or overall structural behavior. Additional work is required to correlate coupon data to part performance.

- **Flammability**

  The applicant should consider that an AM part may have different characteristics, such as increased porosity and voids, decreased material density, or increased surface roughness, compared to parts produced with the same material in traditional forms using customary manufacturing technologies, possibly resulting in different flammability behavior. Complex geometries such as additively manufactured lattice structures are another consideration that can affect flammability performance, as are changes in polymer dye colors or print direction. A certificate of compliance or other data from constituent material suppliers is typically insufficient to assure compliance for materials processed with advanced manufacturing techniques.

- **Instructions for Continued Airworthiness**

  When required, the applicant or DAH will generate maintenance instructions or ICA for parts produced with AM. Due to the manufacturing process or material change, inspection technologies, thresholds, and intervals may differ. Best industry practice is to uniquely identify parts produced with AM to support future maintenance activities, including corrective actions. Also consider the challenges to inspect and repair AM components.

# Information Request

- When certifying AM articles, check the product issues list
  - While not required for a TSOA, issue papers are often used for certifying AM parts, particularly in critical applications
- In addition to issue papers, the FAA has been issuing Applicant-Specific Guidance Memos (ASGM)
  - These documents are unique for each applicant
- The ASGM is used to help gain an understanding of
  - The project part function
  - Critical applied technology (e.g. material, process, finishing processes, inspection)
  - Certification basis
  - Method of compliance approach to process control and validation
- The ASGM is not a final or exhaustive checklist for certification of AM parts
- The Applicant's answers to the ASGM will help determine
  - The extent of Technical Policy Branch involvement
  - Whether an Issue Paper is needed for the project

# Information Request

- ASGM Process:

  <u>Projects for Product Certification</u>
  - The Project Certification Office transmits the ASGM questionnaires to the applicant
  - The applicant's response to the ASGM questionnaires is evaluated by the Project Certification Office
  - The need for policy staff involvement depends on specific levels of criticality

  <u>Projects for TSO approvals</u>
  - The ASGM process becomes applicable on projects that install TSO articles using AM technology
  - TSO article installers may need support from TSOA holders when providing response to the ASGM
- TSOA applicants should
  - Coordinate AM use in TSO articles with their project certification branch
  - Communicate AM use information to TSO installers
  - Prepare to support installers in providing the ASGM response

# Information Request

The type of information requested includes:

1. Identification of each part or assembly intended to be installed on a product that is manufactured using AM processes. The identification for each part includes:
    a. Description and images or drawings that provide an overall understanding of the location of the AM parts and how they attach, interface, and function.
    b. Material(s) and the associated material specification(s) used in the manufacture of the parts.
    c. The specific AM process the applicant proposes to use (e.g., laser powder bed fusion, material extrusion, binder jetting, electron beam directed energy deposition-wire) and the associated additive process specification used for each part.
    d. Identification of whether the part is classified as an airframe, mechanical system, cabin safety item, propulsion, engine, propeller, or other part as applicable.
    e. A list of the applicable regulatory requirement(s) for each part based on its classification as airframe, mechanical system, cabin safety, propulsion, engine, propeller, or other. For each regulatory requirement, identify the intended method of compliance (e.g., test, analysis) for each part.
    f. Risk classification according to severity of the part's failure consequence to safety of the product, crew, and passengers as applicable.*

2. Present an inspection plan that proposes how part(s) will be inspected and tested over their production run. The inspection plan should describe in sufficient detail to allow the FAA to assess the applicant's approach toward ensuring the additive manufactured part:
    1. Is manufactured consistently within type design.
    2. Description of the validation process for the determining the capability of each NDI process.
    3. Is produced within manufacturing defect limits.
    4. Has the strength and other properties assumed in the design data and required by regulations.

3. Identify the need to develop design values or to perform fatigue tolerance evaluations per 25.571 to support compliance by analysis as applicable. AM processes used in the production of parts above a certain criticality level, including but not limited to those requiring design values or a fatigue tolerance evaluation may require an Issue Paper to agree on the specific method of compliance.

4. Identify the proposed use of consensus standards.

*ASTM F3572-22 provides risk classification of AM parts for aerospace applications

# Information Request

The type of information requested includes (continued):

5. For each part, the failure of which could adversely affect safety, present a high level plan for FAA evaluation. The plan should describe:
   a. How the applicant will demonstrate to the FAA they have established the basis of experience or testing, per 25.603, needed to ensure parts produced using AM processes including the consideration of acceptable manufacturing anomalies, have the strength, suitability, durability, and other properties assumed in the design data.
   b. Definition and description of the manufacturing induced anomalies that can be introduced by the AM process.
   c. How the acceptance limits for detectable and non-detectable manufacturing anomalies will be determined and incorporated into the design data.
   d. The machine and process qualification plans, including the use of recurring qualification builds to ensure process control.
   e. The key process variables (KPV), their effect on the fabricated article, and how they will be controlled.
   f. How the additive manufacturing process will be validated to ensure that, due to KPV process drift or other causes (e.g., foreign object or build environment contamination), parts will be fabricated that meet strength and other properties assumed in the design requirements (e.g., dimensional, material acceptance standards, microstructure, and anomaly limits).
   g. Design practices, design constraints or other criteria used to define the applicant proposed approach to certification and any clarifying rationale. Examples include conservative knockdown factors, process limitations, geometrical features, working stress limits, or strain cutoffs.
   h. How the limits for feedstock reuse will be established. The high level plan should describe the expected effects from reuse on the feedstock, how the reuse cycle will be defined and controlled, and how any effects from reuse on the strength and other properties assumed for the type design will be determined and controlled. With regard to expected effects on feedstock, the plan should identify possible trends affecting the feedstock that should be quantified relevant to the material or alloy being used. These effects may include, but are not limited to, size, shape, chemistry and properties such as flowability. When effects on feedstock are identified, the plan should consider how components made using reused material, as well as the material itself, will be inspected and tested.

# Summary

- The way a part is manufactured, including the materials that are used (feedstock) and produced (printed), are part of the type design and cannot be changed without FAA approval
- Implementing AM often results in a change to the quality manual that is communicated and coordinated with the FAA
- Methods and means of compliance to requirements may change due to implementing AM
- It is important to coordinate the use of AM with the TSO installer and be prepared to support installation certification, including answering requests from the ASGM

# Questions?

Request More Information

**Cindy Ashforth**
Senior Technical Specialist for Composites
cindy.ashforth@faa.gov

**Dr. Tom Broderick**
Chief Scientific and Technical Advisor for Advanced Manufacturing and Materials
Thomas.F.Broderick@faa.gov

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